The effect of systematic functional assessment and immediate rehabilitation on physical performance in acutely admitted older adults with reduced functional performance
a randomised clinical trial

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TITLE: The effect of systematic functional assessment and immediate rehabilitation on physical performance in acutely admitted older adults with reduced functional performance: A randomized clinical trial

ABSTRACT

Aims

We hypothesised that a systematic functional assessment in a short stay unit at an emergency department (ED) and/or immediate rehabilitation after discharge will result in sustained or improved physical performance in comparison to a regimen in which neither of these interventions is offered.

Methods

A two-way factorial randomized clinical trial was completed in an ED and the primary sector. We enrolled 336 nonsurgical patients of 65 years or older, scoring eight or less in the 30-s chair stand test. The interventions were: 1) Usual assessment; 2) Usual rehabilitation; 3) A systematic functional assessment performed within 48 h of admission, in order to identify those with loss of functional mobility, or at risk thereof; and 4) Immediate rehabilitation initiated within five days after discharge. The primary outcome was the 30-s chair stand test three weeks after admission. Secondary outcome measures were Barthel, EQ-5D-3L, and length of stay (LOS).

Results

An intention-to-treat analysis showed no significant difference in the 30-s chair stand test score nor when analysed by groups or by intervention. The changes were approximately 1% when compared to the reference.

No significant differences were found in the secondary outcomes. A per-protocol analysis showed that 99% had received assessment as assigned; however, the extent of mobilisation

during hospitalisation was not disclosed. Of the patients, 485 were received the post-discharge rehabilitation they were assigned to.

Conclusion

Systematic functional assessment and immediate rehabilitation led to no significant differences in physical performance. The study was weakened by the incomplete implementation of mobilisation during hospitalisation and low adherence to protocol on immediate rehabilitation.

Keywords: 30-s chair stand test; functional assessment; rehabilitation; older adults; acute admission

IMPLICATIONS FOR REHABILITATION

- A systematic functional assessment within the first 48 h of hospital admission is suitable for the identification of older adults in need of post-discharge rehabilitation when compared to usual assessment.
- To sustain physical performance in older adults *during acute hospitalisation*, further research focusing on mobilisation or physical activation is needed in older adults with a loss of functional mobility, or at risk thereof.
- Further research focusing on physical activation during transition is needed to ameliorate tiredness and inactivity in older adults *after acute hospitalisation.*

Introduction

For older adults, hospitalisation presents a risk of functional decline, after even a few days of physical inactivity or bed rest—in particular for those with reduced physical reserve capacity [1,2,3]

Older adults make up a large part of patients admitted to short stay units in Danish emergency departments (ED). The short stay units focus on providing short term care (48–72 hours) and thereafter patients are either transferred to another hospital department or discharged.

In the short stay unit, functional assessments are carried out by nurses primarily based on self-reported information on activities of daily living (ADL) [4,5].

Self-reported information provides important information on habitual functional status. However, 12%-48% discrepancy between self-reported and tested ability poses a challenge to the validity of this information [6]. Moreover, using only self-reported information also provides a late identification of older adults with reduced physical reserve capacity, as reduced physical capacity usually is followed by reduced physical performance and functional decline [7]. Furthermore, studies have shown an incomplete documentation of older adults' need for help with ADL [8,9].

At the time of admission to a short stay unit, the low physical performance measures might be temporary and caused by the reason for hospitalisation, or it could be permanent due to reduced reserve capacity [10]. Still, in acutely admitted older adults, physical performance measures have demonstrated the ability to predict length of stay (LOS) and mobility limitation 30 d after hospitalisation, and the physical performance measures have shown to be associated to need for help with ADL [11,12,13].

In the Danish short stay units, physical therapy is usually limited to chest physiotherapy or provision of gait aids [14]. For the geriatric patient, this implies that in-hospital mobilisation and physical rehabilitation is only initiated upon transfer to another department. This could be a problem as early rehabilitation has shown to be an important element in the successful geriatric concept [15], where mobilisation and exercise during hospitalisation have demonstrated an effect on functional ability [16,17].

The effect is even larger when supplemented with a follow-up after discharge to primary sector [17]. Thus, coherence in rehabilitation is important - especially, when older adults after an acute admission experience low physical activity, and two weeks with reduced walking activity means a significant loss of muscle mass [18,19,20].

We believe that a systematic functional assessment of older medical patients at admission is capable of identifying those with a loss of functional mobility, or at risk thereof. It provides information on physical and functional issues, and forms the basis for early mobilization, recommendations on mobilisation and assessments of the need for post-discharge rehabilitation.

Post-discharge rehabilitation initiated immediately is expected to support older adults' physical activity and thus maintain their physical performance**.** The combined effect of an early systematic functional assessment in the short stay unit of ED and an immediate onset of rehabilitation is expected to affect older adults' physical performance more than either would on its own. The effect of this combination has not previously been studied.

We hypothesised that a systematic functional assessment in a short stay unit and/or immediate rehabilitation would result in sustained or improved physical performance, in comparison to a regimen in which neither of these interventions is offered.

Materials and methods

Design

A two-way factorial randomized clinical trial with equal distribution was conducted in a short stay unit in a Danish emergency department. Patients were recruited from April 2015 to August 2016; follow-up data were collected in the patients' homes from May 2015 to October 2016.

A study protocol was published prior to the study [21]. While alterations have been made in the exclusion criteria and secondary outcomes after the release, the most important change was the adjustment in sample size before the beginning of recruitment. This adjustment was made to integrate the results of a prospective cohort pilot study of 78 older adults who were acutely admitted to the short stay unit.

The reporting complies with the Consolidation Standards of Reporting Trials (CONSORT) [22] and the Templates for Intervention Description and Replication (TIDieR) [23]. The study was approved by the Regional Scientific Ethical Committees of Southern Denmark (Project ID: S-20130168) and registered with the Danish Data Protection Agency (2008-58-0035) and ClinicalTrials.gov. Identifier: NCT02062541 (02/12/2014).

Setting

All enrolled patients were referred to a short stay unit at a medium-sized regional hospital covering a population of 300.000 citizens. Common complaints in the short stay unit include infection, thromboembolic disease, musculoskeletal disease, and cardiovascular disease, but not obvious signs of stroke or ST-elevation myocardial infarction. The cooperation on post-discharge rehabilitation in primary sector comprised three municipalities, all of them with a mixed urban and rural population.

The Danish health system operates in two parallel systems – primary and secondary health care - and each system has its own budget, jurisdiction and criteria for patient selection. The responsibility for rehabilitation is shared by the secondary sector and the primary sector. The primary sector is in responsible for the rehabilitation before and after admission and the secondary sector during hospitalisation. This organization leaves a gap as in primary sector, the decision on older adults' rehabilitation needs is based on their functioning whereas the secondary sector request that post-discharge rehabilitation has to relate to the cause of hospitalisation.

All rehabilitation services are free of charge, irrespective of the patient's income or insurance.

Participants

Patients of 65 years of age or older residing in one of the three municipalities who presented with nonsurgical diagnoses during weekdays were tested for eligibility. The inclusion criteria were ability to perform eight or fewer repetitions in the 30-s Chair-Stand Test (30s-CST) [24],

which is considered a validated cut-off point for identifying community-dwelling older adults at risk of loss of functional mobility [25] moreover, for acutely admitted older adults a 30s-CST score ≤ 8 indicates a risk for need for help in ADL [10]. Further inclusion criteria were patient orientation to time and place; ability to speak and understand Danish; and, in order to avoid enrolling patients too ill for mobilisation and physical activity, ability to sit on an ordinary chair within the first 48 hours of admission. Patients with terminal illness, inability to walk at baseline, or prohibited from physical activity for medical reasons were excluded.

Outcome measures

The primary outcome measure was a 30s-CST score three weeks after admission. By counting the number of stands completed in 30 seconds with hands crossed against the chest, this test provides a valid measure of physical performance and a proxy measure for lower body strength [24], which is associated with the ability to perform activities of daily living [26,27,28]. The 30s-CST has demonstrated good inter-rater reliability in acutely admitted older adults [29].

The secondary outcomes were the Barthel Index, the EQ-5D-3L and LOS. The Barthel index provides a valid and reliable measure of activities of daily living performance for geriatric patients. The activities assessed are feeding, transfers, grooming, toilet use, bathing, mobility, stair climbing, dressing, bowels, and bladder [30].

The EQ-5D-3L is a standardized, non-disease-specific instrument which measures the health-related quality of life on five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [31].

Data on LOS were obtained from the hospital patient administration system.

Adherence to protocol for the systematic functional assessment was checked against the total score of the de Morton Mobility Index (DEMMI) [32]. This was possible because the index was not ordinarily used in the short stay unit.

Adherence to the protocol for immediate rehabilitation was tested by checking the date of the first rehabilitation visit by municipal staff.

Baseline data included, besides demographic information (on age, gender, living arrangement, and education), the use of gait aids, self-rated health, number of drugs, the destination following the short stay unit (discharge or transferal), presenting complaints, the Orientation–Memory–Concentration test (OMC) [33], the body mass index (BMI), whether the patient received services at home before hospital admission, and whether he or she was participating in primary sector rehabilitation at time of admission.

Trial procedures

Patients were recruited and enrolled by one of the two project physiotherapists within the first 48 h of admission. All patients gave their written consent to participate. Baseline data were then collected by a project physiotherapist, who also initiated the systematic functional assessment and immediate rehabilitation.

For the 30s-CST, inter-rater reliability between the two project physiotherapists was tested in a pilot study of 21 randomly selected patients admitted to the short stay unit; the calculated intraclass correlation (ICC) for acceptable reliability was 0.98 (95% CI: 0.96;0.99).

Randomisation was performed by opening sequentially numbered opaque envelopes. A secretary with no patient contact undertook this job. The envelopes had been prepared in advance using a balanced internet based randomisation list using 4, 8, and 12 blocks, stratified for each municipality [34].

Blinding of the physiotherapist performing the systematic functional assessment, or of the patients, was not possible. In order to keep post-discharge rehabilitation unaffected by the assignment to immediate rehabilitation, the primary sector staff who received information on the randomisation was asked to conceal this information from the physiotherapist or occupational therapist providing the post-discharge rehabilitation. To ensure that the follow-

up data were unaffected by previous measurements, the assistants responsible for collecting follow-up data had no access to patient information collected at baseline and were asked not to elicit it from the participants. In the analysis, the randomized groups were concealed until intention-to-treat and per-protocol analyses had been completed.

Follow-up data were collected no sooner than three weeks after admission by a group of assistants (nursing assistants, physiotherapists, and occupational therapists). Delays were unavoidable in cases where the patient was still admitted or ill at the time, but data were collected at the hospital or as soon as possible after discharge. For patients lost to follow-up, one of the following was recorded: Deceased, Not interested in visiting, Too ill to visit, or No contact possible.

To ensure consistent data collection despite changes in staffing, all assistants were instructed by a project physiotherapist; furthermore, in order to standardize data collection, the assistants and the project physiotherapist all met twice during the data collection period.

Intervention

Patients were randomized into one of four groups: (1) usual assessment and usual rehabilitation (*Group I*)*;* (2) usual assessment and immediate rehabilitation (*Group II*); (3) systematic functional assessment and usual rehabilitation (*Group III*); and (4) systematic functional assessment and immediate rehabilitation (*Group IV*) (Figure 1). The four interventions are briefly described below; further information is provided in the supplementary material.

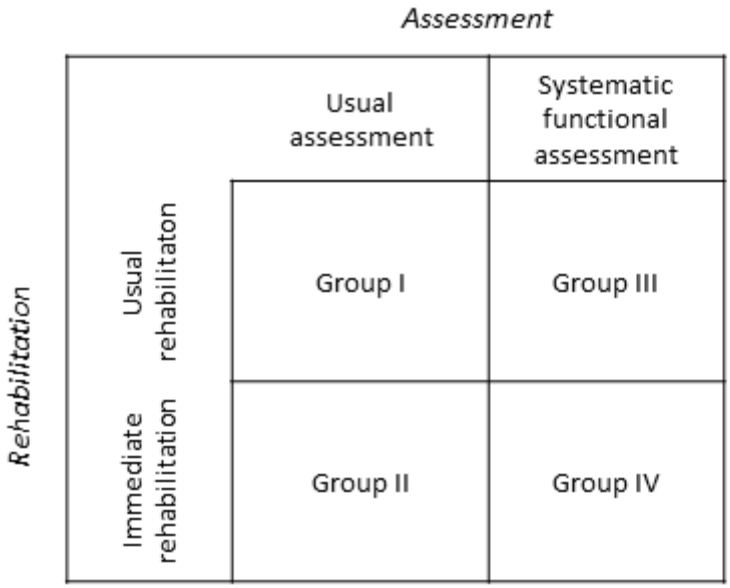

Figure 1. The four groups to which patients were randomised

Usual assessment *(Groups I and II):* The usual assessment was carried out by nurses during the short-term hospitalisation. If a need for rehabilitation was identified, a referral to post-discharge rehabilitation was drafted by a physician or a nurse; the need ought to relate to the actual reason for hospitalisation. If physical therapy was prescribed, it was undertaken the day after admission and administered by a physiotherapist with no knowledge of the systematic functional assessment.

Usual rehabilitation (*Groups I and III*): The usual procedure was followed-up on referral to post-discharge rehabilitation. This was possible as the primary sector had no knowledge of patients randomized to usual rehabilitation. The Danish legislation prescribes that usual rehabilitation must be initiated within 14 days of primary sectors receipt of the referral [35].

Systematic functional assessment (*Groups III and IV*): The assessment, which was based on a biopsychosocial model of functioning, was performed within 48 h of admission, by one of several trained physiotherapists. In practice, it was undertaken the day after admission. With a view to the importance of a physical performance measure and early mobilization, a de Morton Mobility Index (DEMMI) based evaluation of physical performance was performed.

The DEMMI assesses mobility and balance across the spectrum from bed-bound to independently mobile [32,36].

If physical therapy was requested, this was carried out by the same physiotherapist performing the systematic functional assessment. When relevant, a referral for post-discharge rehabilitation was sent to the primary sector. Afterward, usual procedures were followed.

Immediate rehabilitation (*Groups II and IV*): An agreement had been made: if patients were assigned immediate rehabilitation, the post-discharge rehabilitation would be initiated as soon as possible: preferably within five days. The referral on post-discharge rehabilitation was sent to the primary sector staff, who also received information on patients assigned to immediate rehabilitation. Except for the task being passed on to the first available physiotherapist or occupational therapist, ordinary procedures were followed after receiving the referral.

Power calculation

The power calculation was based on a pilot cohort study with 30 days follow-up after admission. We found a 30s-CST mean change of 3.9 repetitions and a standard deviation (SD) of 4. It was assumed that a systematic functional assessment followed by immediate rehabilitation would improve the patient's ability to sustain physical performance, for this reason a two tail calculation was used; it allowed the control group to experience a physical decline due to inactivity. We aimed at a change higher than the Minimal Detectable Change (MDC_{90}), which is defined as two sit to stands in the 30s-CST [37]. The power calculation indicated that, to achieve power and α significance levels of 0.8 and 0.05, respectively, 64 patients would be required in each of the four groups. The vulnerability of this group was expected to result in a 30% dropout rate, thus requiring a total of 336 patients, with 84 patients in each group.

Statistical methods

Baseline data for the intervention group and the control group were compared to assess the homogeneity of the randomized groups. Fisher's exact test was used for categorical variables. One-way analysis of variance (ANOVA) was used for normally distributed continuous variables; the Kruskal–Wallis test was employed for non-normally distributed data.

The analyses were conducted following the intention-to-treat principle. The 30s-CST and LOS were analysed using a negative binominal regression model; a linear regression model was used for the secondary outcome measures. The baseline measurement was applied as a covariate; the analyses were furthermore performed both with and without age and gender as covariates. Data were missing on one item in the Barthel sum score; an imputation by standardization was therefore performed based on the remaining nine items.

Due to the 2 × 2 design, a test for interaction was performed, and since no significant interactions were found, the four groups were collapsed into two: Assessment and Rehabilitation.

Based on poor adherence to the protocol for immediate rehabilitation, a secondary per-protocol analysis was performed. This was followed by ancillary analyses: a descriptive analysis and an analysis of association between the 30s-CST and LOS. All analysis was performed using STATA version 15 (Stata Statistical Software, College Station, TX) [38].

Results

Overall, 2981 patients were admitted to the emergency department during the recruitment period; 1585 were assessed for eligibility within 48 hours of admission (a flowchart of inclusion appears in Figure 2). The two largest groups of patients who failed to meet the inclusion criteria were those with a 30s-CST > 8 (35%) and those lacking orientation in time and place (30%). The main reasons offered by patients for refusal to participate (25%) were: feeling tired, already had too many visits (home care, etc.), or that the study had no relevance

to them. This left 336 patients for randomisation, which was reduced to 334 when two patients withdrew their consent. An analysis of patients assessed for eligibility compared to the non-assessed patients showed no significant differences in age or gender. An examination of patients assessed at follow-up and patients not assessed at follow-up (n = 62) showed no significant differences in baseline data, physical performance measures, or LOS.

The follow-up was conducted a median of 23 (IQR 21–29) days after admission. There were no significant differences in time from admission to follow-up between the groups (I–IV).

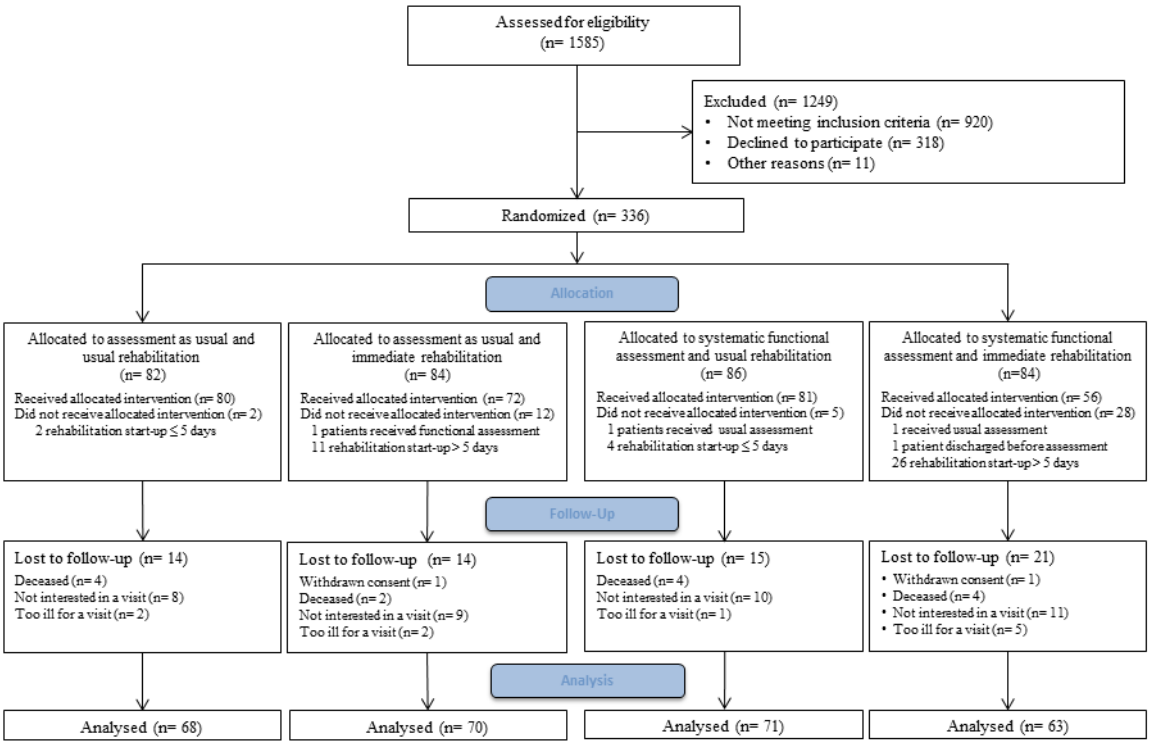

Figure 2. Flowchart of inclusion process

The baseline data for the included patients are shown in Table 1. A total of 147 (54%) patients had received services at home within the last six months before hospitalisation. When tested for comparability, the differences between for all four groups were found acceptable for all variables ($p > 0.05$).

305 Table 1 Baseline characteristics at admission

			Patients received allocated intervention	Admission characteristics by randomized group			
				Group I*	Group II*	Group III*	Group IV*
			(n= 272)	(n= 68)	(n= 70)	(n= 71)	(n= 63)
Age (years)		median (IQR)[a]	78 (72–85)	78 (71–84)	77 (72–84)	76 (73–84)	80 (72–86)
Gender: female		n (%)	167 (61%)	39 (57%)	39 (56%)	43 (61%)	46 (73%)
Living arrangement	Alone	n (%)	150 (55%)	39 (57%)	38 (54%)	41 (58%)	32 (51%)
	Cohabiting		119 (44%)	29 (43%)	31 (45%)	29 (41%)	30 (48%)
	Nursing home		3 (1%)	0 (0%)	1 (1%)	1 (1%)	1 (2%)
Education	No vocational education	n (%)	84 (31%)	22 (32%)	18 (26%)	22 (31%)	22 (35%)
	Vocational/short-term training		132 (49%)	36 (53%)	34 (48%)	31 (44%)	31 (49%)
	Medium/long/other		56 (20%)	10 (15%)	18 (26%)	18 (25%)	10 (16%)
Gait aids: indoor	Yes	n (%)	96 (35%)	24 (35%)	26 (37%)	23 (32%)	23 (37%)
Gait aids: outdoor	Yes	n (%)	145 (53%)	40 (59%)	34 (49%)	35 (49%)	36 (57%)
	Not going out		14 (5%)	4 (6%)	3 (4%)	4 (6%)	3 (5%)
Self-rated health	Less good/bad	n (%)	104 (38%)	33 (49%)	27 (39%)	25 (35%)	19 (30%)
	Good		115 (42%)	21(31%)	29 (41%)	32 (45%)	33 (52%)
	Excellent/very good		53 (20%)	14 (20%)	14 (20%)	14 (20%)	11 (18%)
Number of drugs		median (IQR)	10 (7–13)	10 (7–14)	10 (6–13)	9 (7–13)	10 (7–13)
Length of stay		median (IQR)[b]	4 (2–6)	4 (2–7)	4 (2–7)	3 (1–6)	4 (1–6)
Discharged from ED to home		n (%)	105 (39%)	24 (35%)	22 (31%)	31 (44%)	28 (44%)
Transferred from ED to another department		n (%)	167 (61%)	44 (65%)	48 (69%)	40 (56%)	35 (56%)
Participation in rehabilitation at admission		n (%)	32 (12%)	12 (18%)	8 (11%)	5 (7%)	7 (11%)
Presenting complaints[b]		n (%)	(n= 225)	(n= 56)	(n= 58)	(n= 60)	(n= 51)
	Respiratory disorder		61 (27%)	13 (22%)	12 (21%)	19 (31%)	17 (33%)
	Nonspecific illness		44 (20%)	9 (16%)	15 (25%)	12 (20%)	8 (15%)
	Fever		36 (16%)	9 (16%)	12 (21%)	7 (11%)	8 (15%)
	Emergency track		11 (5%)	4 (7%)	0 (0%)	4 (7%)	3 (6%)
	Chest pain		11 (5%)	4 (7%)	3 (5%)	1 (2%)	3 (6%)
	Impaired or loss consciousness		15 (7%)	2 (4%)	4 (7%)	4 (7%)	5 (11%)
	Abdominal pain		9 (4%)	2 (4%)	4 (7%)	3 (5%)	0 (0%)
	Others		38 (16%)	13 (24%)	8 (14%)	10 (17%)	7 (14%)
			(n= 250)	(n= 60)	(n= 64)	(n= 69)	(n= 57)
OMC[c]		median (IQR)	22 (20–26)	22 (20–24)	24 (20–26)	23 (19–26)	22 (18–26)
			(n= 137)	(n= 35)	(n= 32)	(n= 36)	(n= 34)
BMI[d]		median (IQR)	26 (23–29)	27 (21–31)	27 (23–33)	25 (23–28)	26 (23–29)
			(n= 272)	(n= 68)	(n= 70)	(n= 71)	(n= 63)
30s-CST[e]		median (IQR)	3 (0–6)	3 (0–6)	3 (0–5)	4 (0–7)	3 (0–6)
EQ-5D-3L		median (IQR)	0.7 (0.6–0.8)	0.7 (0.5–0.8)	0.7 (0.6–0.8)	0.7 (0.6–0.8)	0.7 (0.6–0.8)
			(n= 268)	(n= 67)	(n= 68)	(n= 71)	(n= 62)
Barthel[f]		median (IQR)	18 (16–20)	17 (15–19)	18 (16–20)	18 (16–20)	18 (16–19)

*Group I: Assessment as usual and usual rehabilitation; II: Assessment as usual and immediate rehabilitation; III: Systematic functional assessment and usual rehabilitation; IV: Systematic functional assessment and immediate rehabilitation

[a]Interquartile range (IQR) [b]Acute diagnoses were extracted from a central database (these depend on doctor's report) [c]Orientation-Memory-Concentration test (OMC)(0–28) [d] Body Mass Index (BMI) [e]30-s Chair- Stand Test (30s-CST) [f]Barthel (0–20)

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Primary outcome

Although all four randomisation groups improved their physical performance from baseline to follow-up, as measured by the 30s-CST; the analysis showed no significant differences in physical performance between the four randomisation groups a median of 23 d after admission (Table 2). No significant differences were identified by including age and gender covariates: the incidence rates were between 0.92 and 1.0. A test of interaction revealed no statistically significant differences; for this reason, patients assigned to the usual assessment were compared to patients assigned to the systematic functional assessment; similarly for the usual rehabilitation and immediate rehabilitation. Still, no significant difference in 30s-CST scores was found (Table 2). Whether the analysis was performed by group or by intervention, with or without age and gender as covariates, the changes remained at 1% when compared to the reference.

Table 2 Primary outcome by group and intervention

30s-CST[a], by group					
At baseline median (IQR)[b]	At follow-up median (IQR)	Intention to treat	IRR[c]	95% CI[d]	*p*-value
3 (0–6)	7 (0–11)	Assessment as usual and usual rehabilitation (group I) (n= 68)		Reference	
3 (0–5)	6 (2–9)	Assessment as usual and immediate rehabilitation (group II) (n= 70)	0.99	0.7;1.3	0.93
4 (0–7)	7 (0–10)	Systematic functional assessment and usual rehabilitation (group III) (n= 71)	1.0	0.8;1.3	0.99
3 (0–6)	6 (3–10)	Systematic functional assessment and immediate rehabilitation (group IV) (n= 63)	0.99	0.7;1.3	0.95
		Interaction assessment and rehabilitation			1.0
30s-CST, by intervention					
		Intention to treat			
3 (0–6)	7 (0–10)	Usual assessment (n= 138)		Reference	
3 (0–7)	6 (2–10)	Systematic functional assessment (n= 134)	1.0	0.8;1.2	0.98
3 (0–7)	7 (0–10)	Usual rehabilitation (n= 139)		Reference	
3 (0–6)	6 (3–9)	Immediate rehabilitation (n= 133)	1.0	0.8;1.2	0.91

[a]30-sChair-Stand Test (30s-CST), [b] Interquartile range (IQR), [c] Incidence rate ratio (IRR), [d] Confidence interval(CI)

Secondary outcomes

As shown in Table 3, neither of the secondary outcome measures showed any significant differences between the four randomisation groups or when analysed by intervention. These results were obtained regardless of whether age and gender were included as covariates. For each prediction variable, a trivial beta coefficient or incidence rate ratio was found, as well as an identical improvement per group from baseline to follow-up.

Table 3 Secondary outcomes by randomised group

Barthel (standardized)					
At baseline median (IQR)[a1]	At follow-up median (IQR)	Intention-to-treat	Coef.	95% CI[b]	*p*-value
17 (15–19)	18 (17–20)	Assessment as usual and usual rehabilitation (group I) (n= 68)		Reference	
18 (16–20)	19 (16–20)	Assessment as usual and immediate rehabilitation (group II) (n= 70)	0.09	-0.7; 0.8	0.81
18 (16–20)	19 (18–20)	Systematic functional assessment and usual rehabilitation (group III) (n= 71)	0.37	-0.4; 1.1	0.32
18 (16–19)	19 (17–20)	Systematic functional assessment and immediate rehabilitation (group IV) (n= 63)	0.37	-0.3; 1.0	0.28
EQ-5D-3L					
0.7 (0.5–0.8)	0.7 (0.5–0.8)	Assessment as usual and usual rehabilitation (group I) (n= 68)		Reference	
0.7 (0.6–0.8)	0.7 (0.5–0.8)	Assessment as usual and immediate rehabilitation (group II) (n= 70)	0.01	-0.07; 0.08	0.90
0.7 (0.6–0.8)	0.7 (0.5–0.8)	Systematic functional assessment and usual rehabilitation (group III) (n= 71)	0.04	-0.03; 0.1	0.27
0.7 (0.6–0.8)	0.7 (0.4–0.8)	Systematic functional assessment and immediate rehabilitation (group IV) (n= 63)	-0.02	-0.1; 0.1	0.58
Length of stay median (IQR)			IRR[c]	95% CI	*p*-value
4 (2–7)		Assessment as usual and usual rehabilitation (group I) (n= 68)		Reference	
4 (2–7)		Assessment as usual and immediate rehabilitation (group II) (n= 70)	1.1	0.8;1.4	0.48
3 (1 –6)		Systematic functional assessment and usual rehabilitation (group III) (n= 71)	1.0	0.8;1.3	0.91
4 (1–6)		Systematic functional assessment and immediate rehabilitation (group IV) (n= 63)	0.93	0.7;1.2	0.59

[a] Interquartile range (IQR) [b]Confidence interval (CI) [c]Incidence rate ratio (IRR)

Adherence to protocol and per-protocol analysis

DEMMI based scrutiny of the implementation of the systematic functional assessment in the short stay unit demonstrated adherence to protocol, given that 269 (99%) were treated according to the protocol for their assigned group. No data were collected on the degree of mobilisation in the short stay unit or any subsequent department. Regarding usual assessment, for 64 (46%) patients physical therapy was prescribed during the short-term admission, leaving 54% of the patients without contact with a physiotherapist.

The hospital sent 82 referrals to the municipalities, 37 (45%) of which concerned patients randomized to the usual rehabilitation and 45 (55%) concerned patients randomized to immediate rehabilitation. Scrutiny of the municipal response to patients allocated to immediate rehabilitation demonstrated that only 39 (48%) of the patients had received the post-discharge rehabilitation they were assigned to. Immediate rehabilitation was defined as rehabilitation initiated within five days after receipt of the referral. The average delay from the receipt of referral to initiation of post-discharge rehabilitation was 12 d (SD 7.1). The corresponding figure for immediate rehabilitation was 11 days (SD 7.6), with 13 days for usual rehabilitation (SD 6.3).

A per-protocol analysis demonstrated no significant differences between the four groups; the same result was obtained when comparing the rehabilitation and the assessment interventions. Analysis of secondary outcomes demonstrated no significant differences.

Ancillary analyses

A comparison of the usual assessment against systematic functional assessment identified no significant differences regarding baseline data and follow-up data, except for the number of referrals (Table 4).

An examination of the data on referred patients showed that 31 (38%) had had no contact with the primary sector within the last six months; of those, 15 (48%) were discharged from the short stay unit.

The 30s-CST score at time of admission was demonstrated to be significantly associated with LOS; the decrease in the incident rate of LOS was approximately 1% for every extra repetition of the 30s-CST, holding age and gender constant.

Moreover, as Table 4 demonstrates, patients discharged from the short stay unit and patients transferred to another department showed significant differences in 30s-CST scores at time of hospital admission. Similar results were found at follow-up.

Table 4. Ancillary analyses

			Referrals (n=82)*[1]		Discharged home or transferred (n=272)*[1]	
			Usual assessment (n=26)	Systematic functional assessment (n=56)	Discharged home from the short stay unit (n=105)	Transferred to other units (n=167)
Age years		median (IQR)[a1]	81 (73–86)	79 (73–86)	77 (71–84)	80 (72–85)
Living arrangement	Alone	n (%)	15 (58%)	31 (55%)	57 (54%)	93 (56%)
	Cohabitation		11 (42%)	24 (43%)	47 (45%)	72 (43%)
	Nursing home			1 (2%)	1 (1%)	2 (1%)
Education	No education	n (%)	12 (46%)	20 (36%)	32 (30%)	52 (32%)
	Vocational/short training		9 (35%)	30 (54%)	48 (46%)	84 (50%)
	Medium/long/Other		5 (19%)	6 (11%)	25 (24%)	31 (19%)
Gait aids: indoor	Yes	n (%)	11 (42%)	21 (38%)	34 (32%)	62 (37%)
Gait aids: outdoor	Yes	n (%)	18 (69%)	35 (63%)	59 (56%)	100 (60%)
Self-rated health	Less good/bad	n (%)	14 (54%)	24 (43%)	42 (40%)	62 (37%)
	Good		8 (31%)	23 (41%)	43 (41%)	72 (43%)
	Excellent / very good		4 (15%)	9 (16%)	20 (19%)	33 (20%)
Number of drugs		median (IQR)	10 (6–13)	10 (7–13)	10 (7–13)	9 (7–13)
Length of stay		median (IQR)	7 (4–9)	4 (2–7)	1 (1–2)	6 (4–7)*[2]
No home service within the last six months		n (%)	10 (38%)	21 (38%)	44 (42%)	80 (48%)
Participants in rehabilitation at admission n (%)		n (%)	0	0	14 (13%)	18 (11%)
30s-CST[b]	at admission	median (IQR)	0 (0–3)	0 (0–5)	5 (0–7)	0 (0–6)*[2]
	at follow-up		4 (0–7)	5 (0–8)	7 (3–10)	6 (0–9)*[3]
EQ-5D-3L	at admission	median (IQR)	0.6 (0.5–0.7)	0.7 (0.6–0.7)	0.7 (0.6–0.8)	0.7 (0.5–0.8)
	at follow-up		0.6 (0.5–0.7)	0.7 (0.6–0.8)	0.7 (0.5–0.8)	0.7 (0.5–0.8)
Referrals in the short stay unit		n (%)	4 (15%)	41 (73%)*[2]		
Referrals outside the short stay unit		n (%)	22 (85%)	15 (27%)*[2]		
Referrals		n (%)	(n=21)	(n=51)	22 (21%) (n=98)	23 (14%)*[2] (n=152)
OMC[c]		median (IQR)	22 (19–26) (n=26)	22 (18–24) (n=55)	24 (20–26) (n=104)	22 (18–24)*[2] (n=164)
Barthel	at admission	median (IQR)	16 (12–18) (n=26)	17 (15–19) (n=56)	18 (16–20) (n=105)	18 (16–19)*[4] (n=167)
	at follow-up		18 (14–19)	18 (17–20)	19 (17–20)	19 (17–20)

[a]Interquartile range (IQR) [b]30-sChair-Stand Test (30s-CST) [c]Orientation-Memory-Concentration test (OMC) (0–28)
*[1]P-values are only specified if there is a significant difference. *[2]p<0.00 *[3]p=0.03 *[4]p=0.04

Discussion

This study was based on the assumption that older patients would benefit from the introduction of systematic functional assessment within 48 hours, either alone or in combination with immediate rehabilitation. However, when the older adults with reduced physical performance (30s-CST ≤ 8) were followed up 23 d after admission, we were unable

to detect any significant improvement in physical performance as a result of the new interventions.

The interventions are complex and we would probably have achieved a different result if the interventions had been developed as complex interventions and evaluated as such with a specific view to whether the intervention had been implemented.

Systematic functional assessment

We had assumed that systematic functional assessment would at least sustain physical performance in older adults with reduced physical performance at hospital admission. We likewise expected that we would be able to identify patients with reduced physical performance, provide early mobilisation and by recommendations stimulate to mobility.

A previous study of 15–20 min mobility training sessions with elderly geriatric hospital patients demonstrated a significant difference in follow-up mobility after one month [39]. The intervention was assisted mobility training and walking twice a day, combined with a behavioral intervention strategy to encourage the patients to spend more time out of bed [39]. Besides the encouragement, the major difference from our study was that responsibility for mobilisation was delegated to one person, whereas our study involved the entire nursing staff of the busy short stay unit.

A previous study on multidisciplinary collaboration has indicated that, despite the best intentions among staff, in a ward with heavy workloads and no clear assignment of responsibility, recommendations result in poor implementation [40]. Such factors may have weakened the implementation of mobilization. Another limitation is that no data on mobility were collected, and for this reason any improvement in mobilisation during the hospital stay was not transparent.

With regard to the transferred patients, the health professionals in the receiving departments were optimistic that the existence of a systematic functional assessment would have a

beneficial effect, since its recommendations would stimulate speedier continuation after the relocation [14]. However, our study may have been weakened by the fact that the staff was not effectively alerted to the existence of the assessment and that continuity in mobilisation was unknown, since no data were collected on mobility level.

Based on the above-mentioned studies, poor implementation of the systematic functional assessment explains the nonsignificant result. Nevertheless, the study has demonstrated that it is possible to implement a systematic functional assessment within the first 48 h in a short stay unit. Ancillary analysis has furthermore shown that a systematic functional assessment, based on a biopsychosocial model identify a significantly higher number of patients in need of referral to post-discharge rehabilitation than the usual assessment. The nonsignificant differences in results between the usual regimen and the systematic function assessment found for other baseline variables lead us to believe that the rise in referrals is based on the real need for rehabilitation, rather than on increased attention.

The relevance of a systematic functional assessment is corroborated by the fact that almost half of the older adults who were referred to rehabilitation upon discharge from the short stay unit to home had received no home services before admission. It can thus be assumed that their needs were unknown to the primary sector.

The study demonstrated that physical performance in older adults discharged from a short stay unit was significantly different at time of admission and at time of follow-up when compared to older adults transferred to another department. Moreover, we found that fifty percent of the older adults who were discharged from the short stay unit or transferred to another ward achieved a 30s-CST score ≤ 8 at follow-up, which indicates a loss of functional mobility, or a risk of such loss.

Immediate rehabilitation

The adherence to protocol on immediate rehabilitation was poor, and for this reason the study was unable to demonstrate any effect of immediate rehabilitation on physical performance. An interim analysis or procedural integrity check performed at an earlier stage may have revealed the lack of adherence.

Several factors may lie behind the difficulties with protocol adherence: 1) the older adults' frailty and lack of energy; 2) the force of work habits—the regulations stipulate that post-discharge rehabilitation be initiated within 14 d; 3) heavy workloads and a lack of financial resources in the municipalities; 4) different perspectives in the secondary and primary sectors [41]. Further research is needed to explore this.

We expected immediate rehabilitation to support older adults' physical activity, thus it is a limitation that no data had been collected to assess whether it implied increased physical activity. Moreover, it would have been appropriate if additional information on rehabilitation had been collected, e.g. frequency and content of physical activity.

The external validity of this study is challenged by the incomplete implementation and low adherence to the protocol and for this reason it prevents us from making clinical recommendations based on our work.

However, we do wish to offer some proposals for future studies: The different results for discharged patients, compared with the transferred patients, indicate the two populations differ significantly, which makes it difficult to demonstrate an effect. We therefore recommend that future clinical studies take the heterogeneity of the older adults discharged or transferred into account. The small between-group variance may stem from the poor implementation of systematic functional assessment and immediate rehabilitation and for this reason the intervention groups and the control groups had several similarities. The relevance of a systematic functional assessment of acutely admitted older adults remains; the same

applies for coherence in rehabilitation across sectors. Therefore, we advise that future studies are developed and evaluated as complex interventions.

Strengths and limitations

We consider it a strength of this study that our population was recruited from three different municipalities (primary sector) and that the systematic functional assessment was performed by several physiotherapists, as this minimizes the influence of individual behavior and values. However, besides the already mentioned limitations, the inability to blind the patients and physiotherapists implied a risk of bias in performance and detection, although we believe we have minimized the risk by collecting the baseline data before randomisation, and ensuring that the assistants who collected the follow-up data had no knowledge of the previous data. Although our sample size was calculated on the basis of a two-group design, it was applied to a design with four groups. In any case, a calculation for four groups and a minimal difference of two sit to stands would have required 324 patients, allowing for a 30% dropout—less than the 336 enrolled in our study.

The high number of participants who declined participation because they felt burdened by multiple service visits may have led to an underrepresentation of those requiring help with basic activities of daily living. Similarly, recruiting only on weekdays might have left out some of the frailest older adults, who are admitted during the weekend when their general practitioner is unavailable.

Conclusion

We hypothesised that a systematic functional assessment and immediate rehabilitation would lead to sustained or improved physical performance. However, we found no significant difference in physical performance, as measured by the 30s-CST or the Barthel. Implementation of mobilisation or physical activity during and after an acute hospitalisation remains important; however implementation of interventions in existing structures is a

challenge and for this reason, such intervention should be developed and evaluated as complex interventions.

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612

613 **SUPPLEMENTARY MATERIAL**

614 **Usual assessment** *(Groups I and II):* The usual assessments were performed by nurses in the
615 short stay unit. The theoretical foundation for the assessment was the biomedical model. The
616 assessments were based on self-reported information on the need for help with ADL, and no
617 physical performance measures were used.
618 The theoretical foundation for the assessment of need for post-discharge rehabilitation was
619 based on the biomedical model's linear relationship between diagnosis and rehabilitation
620 needs.
621 **Usual rehabilitation** (*Groups I and III*)*:* The usual procedure was followed upon receiving
622 the referral on post-discharge rehabilitation. The assignment was passed on to a
623 physiotherapist or occupational therapist, who was responsible for drawing up an individual
624 rehabilitation plan that would take into account the older adult's preferences and other
625 contextual factors, such as other rehabilitation services being offered. The primary sector
626 determines the elements of post-discharge rehabilitation, which may involve planned or
627 structured physical exercise, self-training and physical activity – including chores and
628 walking. The latter is implemented as collaboration between home care and the therapist.
629 The primary sector also determines the number of sessions, the duration and the intensity of
630 the activities or exercises.
631 **Systematic functional assessment** *(Groups III and IV):* The systematic functional
632 assessment was designed in collaboration between the first author and experienced
633 physiotherapists from the short stay unit and the geriatric unit. Recent literature on older
634 adults, along with the knowledge obtained in our study of the short stay unit, were likewise
635 integrated into the work [9]. The theoretical concept underlying the systematic functional
636 assessment was the International Classification of Functioning, Disability, and Health (ICF)

[59], a biopsychosocial framework focusing on the impact of the patient's health condition, in which disability is consistently seen as a result of the interactions between functioning and contextual factors [60]. In the systematic functional assessment, we focused on body functions and activities, thus giving priority to study, inactivity, and rehabilitation needs. Within the first 48 h of admission, the systematic functional assessment was performed by one of the nine project physiotherapists, all of whom were familiar with the ICF framework. Both sexes were represented in the group; three of the physiotherapists had more than ten years of experience, two had between five and ten years, while five had qualified less than five years previously. A checklist was developed to ensure consistency in assessment throughout the study period. The systematic functional assessment was based on information obtained from medical records and self-reports of mobility and activities of daily living. Combining this with the observation of mobility and balance in the De Morton Mobility Index (DEMMI) at admission, we were able to base the assessment on information on morbidity, comorbidity, number of admissions within the last six months, falls, balance–walking problems, use of walking aids, habitual mobility, and need for activities of daily living help; as well as changes in mobility and activities of daily living capability within the last six months, participation in and motivation for training. If needed, gait aids were provided for early mobilisation, since the de Morton Mobility Index (DEMMI) includes items on getting out of bed, moving from sitting to standing position, and walking a distance of 50 meters. The information on mobility and balance provided a secure basis for the mobility during hospitalisation.

Immediate rehabilitation (*Groups II and IV*): The intervention was developed in cooperation with municipal rehabilitation centers, represented by the heads of the department and the therapists involved in post-discharge rehabilitation. A steering group with representation from all parties was appointed to monitor the conduct of the study.

The physiotherapist or occupational therapist in charge of rehabilitation was tasked with drawing up individual rehabilitation plans that took the older adult's preferences and contextual factors into account. They also coordinated with other rehabilitation services being offered.

The municipalities' ordinary procedures on physical exercise and activity were followed in this study, except for an agreement that immediate rehabilitation was initiated as soon as possible, preferably within five days. The theoretical background for the intervention was that coherence in rehabilitation had a positive effect on the older adults' physical performance.