

**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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1

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

5 **ABSTRACT**

6 **Aims**

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

11 **Methods**

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

20 **Results**

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

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

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

## 28 **Conclusion**

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

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

## 35 **IMPLICATIONS FOR REHABILITATION**

36

- 37 • A systematic functional assessment within the first 48 h of hospital admission is  
38 suitable for the identification of older adults in need of post-discharge rehabilitation  
39 when compared to usual assessment.
- 40
- 41 • To sustain physical performance in older adults *during acute hospitalisation*, further  
42 research focusing on mobilisation or physical activation is needed in older adults with  
43 a loss of functional mobility, or at risk thereof.
- 44
- 45 • Further research focusing on physical activation during transition is needed to  
46 ameliorate tiredness and inactivity in older adults *after acute hospitalisation*.

47

## 48 **Introduction**

49 For older adults, hospitalisation presents a risk of functional decline, after even a few days of  
50 physical inactivity or bed rest—in particular for those with reduced physical reserve capacity  
51 [1,2,3]

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

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

57 Self-reported information provides important information on habitual functional status.

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

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

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

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

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

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

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

## 93 **Materials and methods**

### 94 **Design**

95 A two-way factorial randomized clinical trial with equal distribution was conducted in a short  
96 stay unit in a Danish emergency department. Patients were recruited from April 2015 to  
97 August 2016; follow-up data were collected in the patients' homes from May 2015 to October  
98 2016.

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

104 The reporting complies with the Consolidation Standards of Reporting Trials (CONSORT)  
105 [22] and the Templates for Intervention Description and Replication (TIDieR) [23]. The study  
106 was approved by the Regional Scientific Ethical Committees of Southern Denmark (Project  
107 ID: S-20130168) and registered with the Danish Data Protection Agency (2008-58-0035) and  
108 ClinicalTrials.gov. Identifier: NCT02062541 (02/12/2014).

### 109 **Setting**

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

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

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

### 125 **Participants**

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

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

### 136 **Outcome measures**

137 The primary outcome measure was a 30s-CST score three weeks after admission. By counting  
138 the number of stands completed in 30 seconds with hands crossed against the chest, this test  
139 provides a valid measure of physical performance and a proxy measure for lower body  
140 strength [24], which is associated with the ability to perform activities of daily living  
141 [26,27,28]. The 30s-CST has demonstrated good inter-rater reliability in acutely admitted  
142 older adults [29].

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

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

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

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

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

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

### 162 **Trial procedures**

163 Patients were recruited and enrolled by one of the two project physiotherapists within the first  
164 48 h of admission. All patients gave their written consent to participate. Baseline data were  
165 then collected by a project physiotherapist, who also initiated the systematic functional  
166 assessment and immediate rehabilitation.

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

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

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



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

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

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

## 192 **Intervention**

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

199

		Assessment	
		Usual assessment	Systematic functional assessment
Rehabilitation	Usual rehabilitation	Group I	Group III
	Immediate rehabilitation	Group II	Group IV

200

201 Figure 1. The four groups to which patients were randomised

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

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

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

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

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

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

#### 228 **Power calculation**

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

**240 Statistical methods**

241 Baseline data for the intervention group and the control group were compared to assess the  
242 homogeneity of the randomized groups. Fisher's exact test was used for categorical variables.

243 One-way analysis of variance (ANOVA) was used for normally distributed continuous  
244 variables; the Kruskal–Wallis test was employed for non-normally distributed data.

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

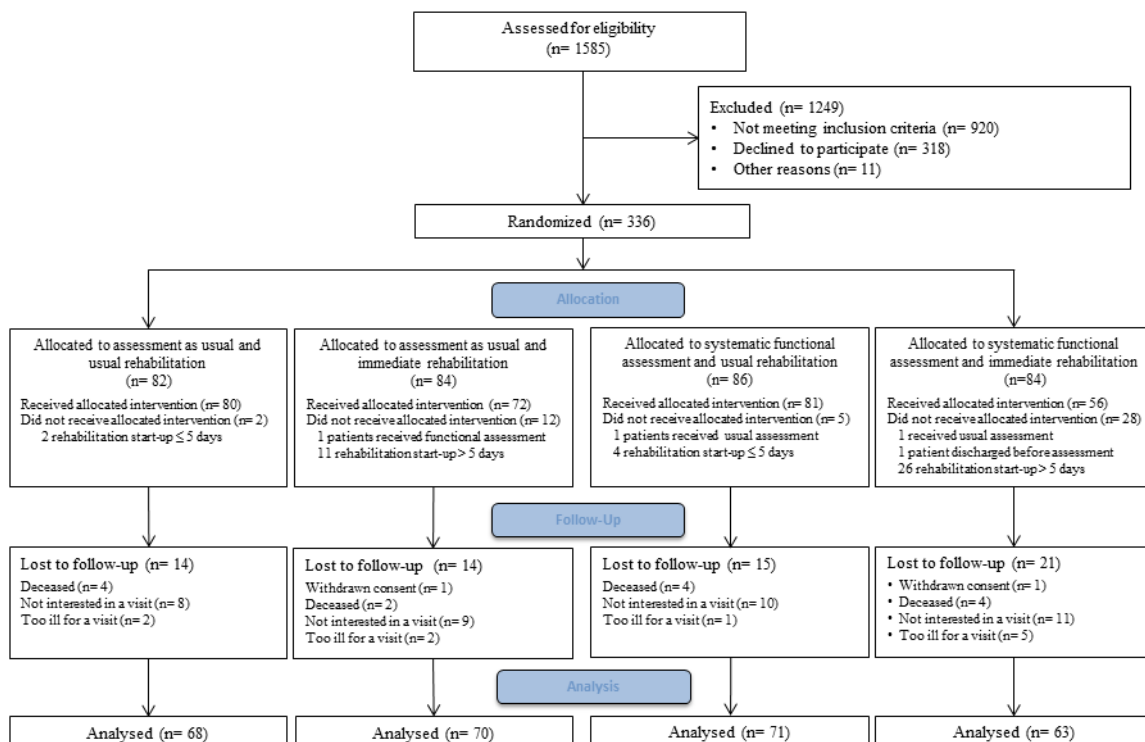
251 Due to the  $2 \times 2$  design, a test for interaction was performed, and since no significant  
252 interactions were found, the four groups were collapsed into two: Assessment and  
253 Rehabilitation.

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

**258 Results**

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

265 to them. This left 336 patients for randomisation, which was reduced to 334 when two  
 266 patients withdrew their consent. An analysis of patients assessed for eligibility compared to  
 267 the non-assessed patients showed no significant differences in age or gender. An examination  
 268 of patients assessed at follow-up and patients not assessed at follow-up (n = 62) showed no  
 269 significant differences in baseline data, physical performance measures, or LOS.  
 270 The follow-up was conducted a median of 23 (IQR 21–29) days after admission. There were  
 271 no significant differences in time from admission to follow-up between the groups (I–IV).



272  
 273 Figure 2. Flowchart of inclusion process

274  
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280 The baseline data for the included patients are shown in Table 1. A total of 147 (54%) patients  
281 had received services at home within the last six months before hospitalisation. When tested  
282 for comparability, the differences between for all four groups were found acceptable for all  
283 variables ( $p > 0.05$ ).

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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) <sup>a</sup>		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%)	
Self-rated health	Not going out	n (%)	14 (5%)	4 (6%)	3 (4%)	4 (6%)	3 (5%)	
			Less good/bad	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) <sup>b</sup>		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 <sup>b</sup>	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%)	
OMC <sup>c</sup>	median (IQR)		(n= 250)	(n= 60)	(n= 64)	(n= 69)	(n= 57)	
			22 (20–26)	22 (20–24)	24 (20–26)	23 (19–26)	22 (18–26)	
BMI <sup>d</sup>	median (IQR)		(n= 137)	(n= 35)	(n= 32)	(n= 36)	(n= 34)	
			26 (23–29)	27 (21–31)	27 (23–33)	25 (23–28)	26 (23–29)	
30s-CST <sup>e</sup>	median (IQR)		(n= 272)	(n= 68)	(n= 70)	(n= 71)	(n= 63)	
			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)	
Barthel <sup>f</sup>	median (IQR)		(n= 268)	(n= 67)	(n= 68)	(n= 71)	(n= 62)	
			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

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

307 **Primary outcome**

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

319 **Table 2 Primary outcome by group and intervention**30s-CST<sup>a</sup>, by group

At baseline median (IQR) <sup>b</sup>	At follow-up median (IQR)	Intention to treat	IRR <sup>c</sup>	95% CI <sup>d</sup>	<i>P</i> -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

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

320



321 **Secondary outcomes**

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

327 **Table 3 Secondary outcomes by randomised group**

Barthel (standardized)		Intention-to-treat	Coef.	95% CI <sup>b</sup>	<i>p</i> -value
At baseline median (IQR) <sup>a1</sup>	At follow-up median (IQR)				
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		Intention-to-treat	Coef.	95% CI <sup>b</sup>	<i>p</i> -value
At baseline median (IQR) <sup>a1</sup>	At follow-up median (IQR)				
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		Intention-to-treat	IRR <sup>c</sup>	95% CI	<i>p</i> -value
At baseline median (IQR)	At follow-up median (IQR)				
4 (2–7)	4 (2–7)	Assessment as usual and usual rehabilitation (group I) (n= 68)		Reference	
4 (2–7)	4 (2–7)	Assessment as usual and immediate rehabilitation (group II) (n= 70)	1.1	0.8;1.4	0.48
3 (1–6)	4 (2–7)	Systematic functional assessment and usual rehabilitation (group III) (n= 71)	1.0	0.8;1.3	0.91
4 (1–6)	4 (2–7)	Systematic functional assessment and immediate rehabilitation (group IV) (n= 63)	0.93	0.7;1.2	0.59

<sup>a</sup> Interquartile range (IQR) <sup>b</sup> Confidence interval (CI) <sup>c</sup> Incidence rate ratio (IRR)

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**331 Adherence to protocol and per-protocol analysis**

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

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

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

349 Analysis of secondary outcomes demonstrated no significant differences.

**350 Ancillary analyses**

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

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

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

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

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376 Table 4. Ancillary analyses

		Referrals (n=82)* <sup>1</sup>		Discharged home or transferred (n=272)* <sup>1</sup>	
		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) <sup>a1</sup>	81 (73–86)	79 (73–86)	77 (71–84)	80 (72–85)
Living arrangement	n (%)				
Alone		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)* <sup>2</sup>
No home service within the last six months	n (%)	10 (38%)	21 (38%)	44 (42%)	80 (48%)
Participants in rehabilitation at admission	n (%)	0	0	14 (13%)	18 (11%)
30s-CST <sup>b</sup>	at admission median (IQR)	0 (0–3)	0 (0–5)	5 (0–7)	0 (0–6)* <sup>2</sup>
	at follow-up	4 (0–7)	5 (0–8)	7 (3–10)	6 (0–9)* <sup>3</sup>
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%)* <sup>2</sup>		
Referrals outside the short stay unit	n (%)	22 (85%)	15 (27%)* <sup>2</sup>		
Referrals	n (%)			22 (21%)	23 (14%)* <sup>2</sup>
		(n=21)	(n=51)	(n=98)	(n=152)
OMC <sup>c</sup>	median (IQR)	22 (19–26)	22 (18–24)	24 (20–26)	22 (18–24)* <sup>2</sup>
		(n=26)	(n=55)	(n=104)	(n=164)
Barthel	at admission median (IQR)	16 (12–18)	17 (15–19)	18 (16–20)	18 (16–19)* <sup>4</sup>
		(n=26)	(n=56)	(n=105)	(n=167)
	at follow-up	18 (14–19)	18 (17–20)	19 (17–20)	19 (17–20)

<sup>a</sup>Interquartile range (IQR) <sup>b</sup>30-sChair-Stand Test (30s-CST) <sup>c</sup>Orientation-Memory-Concentration test (OMC) (0–28)

\*<sup>1</sup>P-values are only specified if there is a significant difference. \*<sup>2</sup>p<0.00 \*<sup>3</sup>p=0.03 \*<sup>4</sup>p=0.04

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378 **Discussion**

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

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

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

### 388 **Systematic functional assessment**

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

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

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

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

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

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

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

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

### 431 **Immediate rehabilitation**

432 The adherence to protocol on immediate rehabilitation was poor, and for this reason the study  
433 was unable to demonstrate any effect of immediate rehabilitation on physical performance.

434 An interim analysis or procedural integrity check performed at an earlier stage may have  
435 revealed the lack of adherence.

436 Several factors may lie behind the difficulties with protocol adherence: 1) the older adults’  
437 frailty and lack of energy; 2) the force of work habits—the regulations stipulate that post-  
438 discharge rehabilitation be initiated within 14 d; 3) heavy workloads and a lack of financial  
439 resources in the municipalities; 4) different perspectives in the secondary and primary sectors  
440 [41]. Further research is needed to explore this.

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

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

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

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

### 458 **Strengths and limitations**

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

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

### 475 **Conclusion**

476 We hypothesised that a systematic functional assessment and immediate rehabilitation would  
477 lead to sustained or improved physical performance. However, we found no significant  
478 difference in physical performance, as measured by the 30s-CST or the Barthel.

479 Implementation of mobilisation or physical activity during and after an acute hospitalisation  
480 remains important; however implementation of interventions in existing structures is a



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

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489

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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)

637 [59], a biopsychosocial framework focusing on the impact of the patient's health condition,  
638 in which disability is consistently seen as a result of the interactions between functioning and  
639 contextual factors [60]. In the systematic functional assessment, we focused on body  
640 functions and activities, thus giving priority to study, inactivity, and rehabilitation needs.  
641 Within the first 48 h of admission, the systematic functional assessment was performed by  
642 one of the nine project physiotherapists, all of whom were familiar with the ICF framework.  
643 Both sexes were represented in the group; three of the physiotherapists had more than ten  
644 years of experience, two had between five and ten years, while five had qualified less than  
645 five years previously. A checklist was developed to ensure consistency in assessment  
646 throughout the study period. The systematic functional assessment was based on information  
647 obtained from medical records and self-reports of mobility and activities of daily living.  
648 Combining this with the observation of mobility and balance in the De Morton Mobility Index  
649 (DEMMI) at admission, we were able to base the assessment on information on morbidity,  
650 comorbidity, number of admissions within the last six months, falls, balance–walking  
651 problems, use of walking aids, habitual mobility, and need for activities of daily living help;  
652 as well as changes in mobility and activities of daily living capability within the last six  
653 months, participation in and motivation for training. If needed, gait aids were provided for  
654 early mobilisation, since the de Morton Mobility Index (DEMMI) includes items on getting  
655 out of bed, moving from sitting to standing position, and walking a distance of 50 meters. The  
656 information on mobility and balance provided a secure basis for the mobility during  
657 hospitalisation.

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

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

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

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