



Effects of a nursing care program focused on basic self-care in older acute medical in-patients: a randomized controlled trial

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Abstract

Background: Acute illness and hospitalization are often associated with decreased independence in basic activities of daily living. The aim of this study was to test the hypothesis that a nursing care program focused on basic self-care (N_BSC) improves functional outcomes in older patients admitted to an acute medical unit.

Methods: This was a 2-group randomized controlled trial with repeated measures: 182 older patients admitted to an acute medical unit were randomly allocated to the usual care group (n=91) and intervention group (n=91). The intervention consisted of nursing care centered on basic self-care that includes promotion of daily walking and all daytime meals seated, out of bed. The main outcome was changes in the number of independent basic activities of daily living (BADL) from 2 weeks before admission (baseline) to discharge.

Results: There was significant effect of the N_BSC on the outcomes. Changes from baseline to discharge in the number of independent BADL differ significantly between the intervention and usual care group. Intervention group patients were discharged with a superior functional status than usual care group. On discharge they were able to perform independently 2.93 BADL, whereas usual care patients performed independently 1.90 BADL (P < .001).

Conclusions: N_BSC for hospitalized older adults was feasible and program participants were discharged with better functional status than a clinically similar comparison group. N_BSC could be readily adapted for use in other hospitals and warrants further evaluation as a potential new tool for improving outcomes for hospitalized older patients.

Keywords: basic activities of daily living, functional decline, hospitalization, nursing, older people

Introduction

There is cumulative evidence in the literature indicating that older people hospitalization leads to functional decline, morbidity, and mortality that is not related directly to the cause of hospitalization.¹

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In older patients, acute illness with subsequent hospitalization leads, in a large number of cases, to a decline in the ability to perform basic activities of daily living (BADL) independently.^{2–5} Previous studies report that 18% to 63% of older patients are more dependent at hospital discharge than their preillness baseline.^{5–9}

Functional changes around the time of hospitalization follow complex trajectories of decline and improvement. Several studies report significant functional decline at the time of hospitalization, rates from 34% to 78%,^{5–8,10,11} whereas the rate of hospital decline was low.^{5,7,8,11} This suggests that in older patients, gains in functional improvement are more likely to be achieved by promoting early functional recovery.

Although most of the functional decline occurs before hospitalization in response to the acute illness, the role played by nursing care in the functional trajectories around hospitalization is unclear. In hospital low-mobility and suboptimal continence care account for functional decline and are modifiable risk factors for which nurses should focus their efforts.^{1,9,12}

In recent years, several attempts to study the impact of interventions that decreases the immobility of older patients hospitalized for acute illness have been made, but the results have not been conclusive.^{13–19} A recent randomized clinical trial shows that an exercise intervention provided significant benefits over usual care; at discharge, significant differences between the exercise intervention and the control groups were noted for functional independence and cognitive and quality of life level.²⁰ Another program that included a mobility program utilizing patient-and-staff education with a specific mobility goal (900 steps/days) was effective in reducing hospital-associated functional decline.²¹

The aim of this study was to test the hypothesis that a nursing care program focused on basic self-care (N_BSC) improves functional outcomes in older patients admitted to an acute medical unit.

Methods

Design

This study was a 2-group randomized controlled trial conducted in an acute 580-bedded teaching hospital in Portugal and was designed to be compliant with the recommendations of the Consolidated Standards of Reporting Trials statement.²² Detailed study protocol was described in an earlier publication.²³

The study was conducted in a single unit. Randomization took place in a time-dependent manner to avoid contamination: the possible effect of subjects in the usual care group seeing subjects in the intervention group performing additional activities to the usual hospital care and the clinical staff itself could involuntarily intervene in the usual care group. Therefore, it was decided that after the beginning of each phase, the usual care group and the intervention group would close when the 91st patient was discharged.

Patients consecutively admitted for the first 22 weeks were assigned to the usual care group. After these 22 weeks, there was a 14-week break and in the following weeks (weeks 37–50) the admitted patients were assigned to the intervention group. During the break, all nurses and nursing assistants received training on the tasks to the intervention program and changes were made to the service structure (these changes were made with low-cost materials available in the hospital and therefore did not require extra funding).

Participants

Participants included older patients consecutively admitted to medical ward that exist in the hospital. Patients were eligible for inclusion if they had an acute medical condition, were aged 65 or older, were able to ambulate, with or without personal/ technical assistance, and were able to communicate. Patients were excluded if they had a length of stay <72 hours, were in the hospital for >4 days until they were admitted to the unit, required intensive care unit admission (eg, polyvalent intensive care or coronary care), had any factor precluding performance of physical activity (eg, terminal illness, unstable cardiovascular disease, or other medical condition and severe dementia), deceased during hospitalization, or were readmitted having previously participated in the study.

Patients were assessed within 24 hours of admission. Functional status was evaluated by a trained nurse at 3 times: at admission patients or their surrogates were asked about their functional status 2 weeks before hospital admission (self-report), at the time of admission by observational assessment, and also on the discharge day (nurse evaluation). The functional status was evaluated based on Katz index, which categorizes 5 BADL (bathing, dressing, eating, transferring, and toileting) as dependent (0) or independent (1), with a global score that ranges from 0 (maximum dependence) to 5 (maximum independence).^{24,25} For each BADL, patients were considered independent if the activity was performed without personal assistance (amendment in comparison with the initial protocol where it was envisaged that the functional status will be assessed through the Katz Index plus the Nursing Patient Classification Systems data).²³

Usual care group versus intervention group

The usual care group received usual hospital care while the intervention group received the N_BSC. Usual care included daily medical assessment, 24 hours nurse assistance, and allied health services on referral from medical, nursing, or other allied health staff.

N_BSC was designed by a nurse and was inspired by the Eat Walk Engage model²⁶ and Function-Focused Care philosophy.²⁷ N_BSC imply promotion of daily walking, plus privileging trips to the toilet by walking (with support devices or with people support) and all daytime meals seated (out of bed). To implement N_BSC, it was necessary to optimize the physical structure of the service, reorganize the nursing care, and coach nurses and nursing assistants.

During the 14-week break, after the closing of the usual care group and before the start of the intervention group, the interventions in the service structure were performed. Those interventions were discussed and implemented by the nursing team: a 30 meter blue line was designed in the central corridor, this path accompanies a handrail that allows patients support while walking; four 10-meter ambulation pathways with clearly defined distance markers were drawn in the 4 service wards; some hospital furniture was arranged in a different way to eliminate obstacles in the passage areas; a room that had no defined function was transformed into a social and dining room, with capacity for 10 people at the table and 4 people sitting on a sofa, in this room was installed a television, a domino and magazines and current newspapers were made available. At the same time, the hospital's repair service built 2 hand-held carts to carry portable oxygen cylinder; these hand-held carts enabled patients who need continuous oxygen not to be avoid from walking during day.

In the same way, during the 14-week break, nurses were educated on N_BSC. After the training it was agreed that nurses would ensure that patients are sitting out ready to eat, provide encouragement and assistance to eat/walk or toilet use; engage family, encouraging the involvement in promoting tasks related to self-care, provide walk destination, and minimize clinical activity during meal times. Daily walk would consist of walking as far as possible with or without assistance (amendment in comparison with the initial protocol where it was envisaged that walk training will consist of walking as far as possible with or without assistance for 20 minutes).²³

The nursing team reorganized their daily routines to focus nursing care on promoting independence in self-care. Adherence to the new nursing care program was checked in a daily record. To maintain adherence to the new nursing care program, the potential benefits of accomplishing this program were explained to the clinical staff before and during the intervention period. Regular interdisciplinary education sessions to support dissemination of evidence were done.

Outcome measures

The main outcome was change in the number of independent BADL from 2 weeks before admission (baseline) to discharge; changes were classified as declined or not declined. Other outcome includes change in the number of independent BADL from admission to discharge.

Differences in scores for BADL between baseline and admission, between admission and discharge, and between baseline and discharge were used to define preadmission, inhospital, and overall functional decline. **Sample size determination.** Sample size determination was performed to achieved a power >80%, a level of significance of 0.05, and to detect a \geq 20% increase in the proportion of patients having a functional improvement at discharge. Based on the results of a pilot study,²⁸ it was expected that the usual care group would improve from ~0 to 20% and as it was defined that a clinically relevant change was a \geq 20% increase, the sample size determination were performed to achieved at least \geq 40% in the intervention group. The calculation of the sample size determined that 91 patients were required in each group.

Randomization and blinding. As previously mentioned, randomization was made in a time-dependent manner to avoid the confounding variable of participants in the usual care group seeing subjects in the intervention group performing additional basic self-care activities to usual hospital care and to avoid the confounding variable of staff intervention. Given the design of the study, participants were blind; they did not know that they were being part of a study. With this methodology we intended to avoid Hawthorne effect.

Data analysis

Differences in measures of patient outcomes between the intervention and usual care groups were evaluated. For qualitative variables frequencies were calculated and for continuous variables statistics of central tendency and dispersion such as means, standard error, and median were analyzed. Significant mean differences between groups were assessed by parametric tests (T tests). A linear mixed model (random intercept and slope model) was used to evaluate the BADL changes over time.

Proportions were compared using Chi-square test. Logistic regression was used to analyze the association between N_BSC and BADL changes, and the results are expressed in terms of odds ratios (ORs), crude, and adjusted for sex, age group, reason for admission, and hospitalization in the last 12 months. The level of statistical significance was set at 0.05. Data were analyzed with SPSS package 24.0 and R software.

Ethical consideration. Board and Hospital Ethics Committee approvals were obtained in 2016 (DEFI 2016.037). As the study used only routinely collected administrative and clinical data from the institutional record, this permission was granted without requesting a written informed consent from patients. The study was registered at ClinicalTrials.gov (Identifier NCT03106064).

All measurements (at admission and discharge) were performed in the same setting and by the same investigators. The study was performed between May 2017 and April 2018, following the ethical guidelines of the Declaration of Helsinki, last modified in 2013.

Results

Between May 2017 and April 2018, 589 patients were screened for study inclusion (Fig. 1). After the start of each phase, the usual care group and the intervention group closed when the 91st patient was discharged.

Characteristics of subjects

There were no significant differences between patients included in the intervention group and in usual care group, except for the reason of admission (Table 1). In addition, there were no differences in the mean number of independent BADL at baseline and admission between both groups (Table 2).

Functional trajectories of patients before and during hospitalization

Usual care group. In the usual care group, the BADL function of 36.3% of the 91 patients did not decline between baseline and discharge (Fig. 2). This include the 22.0% of patients with stable function throughout their course (no decline before or during hospitalization) and the 14.3% of patients who declined between baseline and admission but recovered to their baseline level of function between admission and discharge. About 64% of patients declined in BADL function between baseline and discharge (independent in fewer BADLs at discharge than baseline). This include the 59.4% of patients who declined between baseline and admission and failed to recover to their baseline function between admission and failed to recover to their baseline function between admission and discharge, and the 4.4% of patients who declined between baseline and additional decline between admission and discharge.

Therefore, most patients (78.0%) had unstable BADL function consisting of decline in BADL function before admission that persisted or progressed during hospitalization (41.8%), or some recovery compared to admission during hospitalization, but not at baseline (22.0%). Of the 63.7% discharged patients who had worse BADL function compared to the baseline, the decline in activities of daily living was attributable to the decline in activities of daily living that occurred before admission. Summarizing, in the usual care group, preadmission, in-hospital, and overall functional decline occurred in 78.0%, 4.4%, and 63.7% of the patients, respectively.

Intervention group. In the intervention group, contrasting with usual care group, the BADL function of 62.6% of the 91 patients did not decline between baseline and discharge (Fig. 3). This include the 24.2% of patients with stable function throughout their course (no decline before or during hospitalization) and the 38.5% of patients who declined between baseline and admission but recovered to their baseline level of function between admission and discharge. About 37% of patients declined in BADL function between baseline and discharge (independent in fewer BADLs at discharge than baseline). In the intervention group, preadmission, in-hospital, and overall functional decline occurred in 74.7%, 2.2%, and 37.4% of the patients, respectively. In-hospital functional improvement for baseline level occurred in 35 patients (compared with the usual care group in-hospital functional improvement more than doubled).

A spaghetti plot showing the BADL evolution (grey lines) for each of the 2 groups (usual care/intervention) is presented in Figure 4. The black lines in this figure represent a smooth spline of all observation points.

Considering Figure 4, we verify that the values of BADL scores at baseline and at admission are similar in both groups and that the increase in the mean values of the of BADL scores from baseline to discharge differs according to the patients group, showing a possible association between intervention and functional status.

Usual care group and intervention group were similar in their capacity for BADL at baseline (P=.787) and at hospital admission (P=.337) (Table 2). Changes from baseline to discharge in the number of independent BADL differ significantly between the intervention and usual care group. Intervention

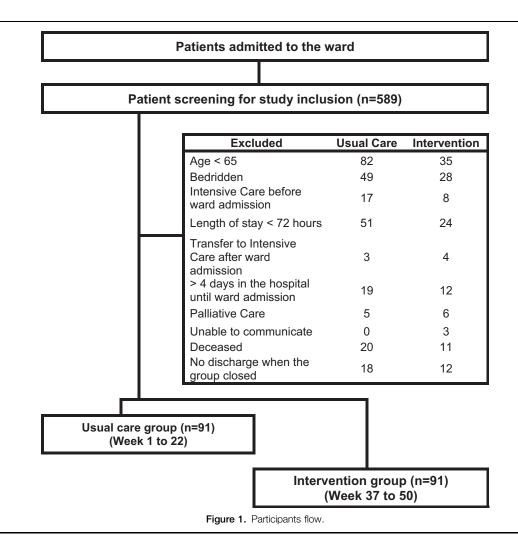


Table 1

Characteristics	of	182	study	patients
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Variable	Usual care (n=91)	Intervention (n = 91)	Р
Age (mean – SD)	79,44–7.9	81,19-8.3	.148 [*]
Age (median)	81	82	
Age – n (%)			.749†
65–74	27 (29.7)	23 (25.3)	
75–84	35 (38.5)	35 (38.5)	
≥85	29 (31.9)	33 (36.3)	
Sex – n (%)			.455†
Men	48 (52.7)	54 (59.3)	
Women	43 (47.3)	37 (40.7)	
Length of stay in days (mean - SD)	11.1 (12.0)	9.6 (6.8)	.310 [*]
Independent BADL (baseline) - n (%)			.151 [‡]
0	5 (5.5)	2 (2.2)	
1	12 (13.2)	14 (15.4)	
2 3	6 (6.6)	7 (7.7)	
3	11 (12.1)	20 (22.0)	
4	12 (13.2)	4 (4.4)	
5	45 (49.5)	44 (48.4)	
Hospitalized in past year – n (%)	32 (35.2)	38 (41.8)	.446
Reason for admission – n (%)			.026†
Respiratory	40 (44.0)	52 (57.1)	
Circulatory	19 (20.9)	23 (25.3)	
Other	32 (35.2)	16 (17.6)	

Baseline refers to 2 weeks before admission to the hospital.

BADL = basic activities of daily living.

T-test.

[†] Chi-square test.

* Fisher exact test.

group patients were discharged with a superior functional status than usual care group. On discharge they were able to perform independently 2.9 BADL, whereas usual care patients performed independently 1.9 BADL (P < .001). Results of the Linear Mixed Model are shown in Table 3: the statistical significant interaction (P < .001 - MomentDischarge*Group I) found, confirms that the improvement in the BADL score from baseline to discharge is significantly higher in the intervention group. Although not significant, a difference of 1.5 days was observed in the length of stay between the groups (P = .310) (Table 1).

Relation between nursing care program focused on basic self-care and changes in basic activities of daily living function: bivariate analysis.

Functional decline before admission was similar between the 2 groups (P=.727) (Table 4). Usual care was associated with

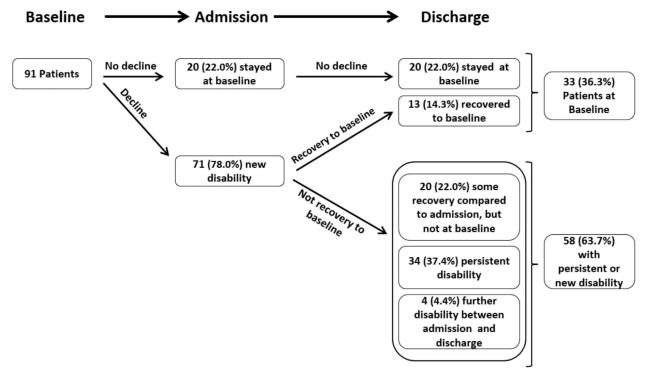
Table 2

Usual Care versus Nursing care program focused on basic self-care (N_BSC)

	Usual care (n=91)	Intervention (n=91)	P [*]
BADL at baseline, mean (SD) (range 0–5)	3.6 (1.7)	3.5 (1.6)	.787
BADL at admission, mean (SD) (range 0-5)	1.4 (1.8)	1.6 (2.1)	.337
BADL at discharge, mean (SD) (range 0-5)	1.9 (1.9)	2.9 (1.9)	<.001

BADL = basic activities of daily living.

T test.





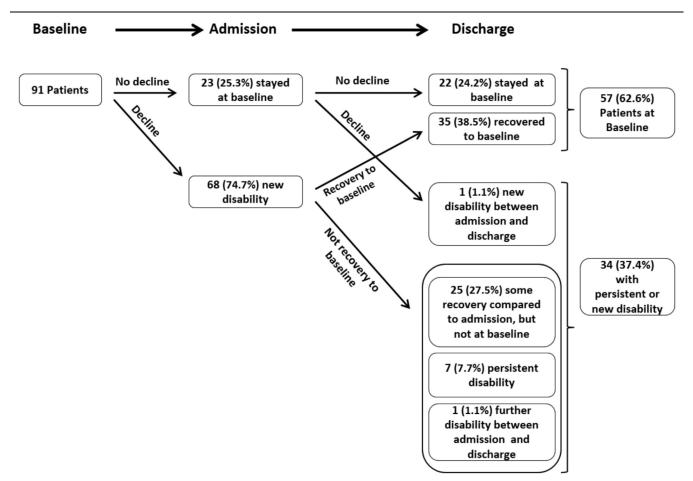
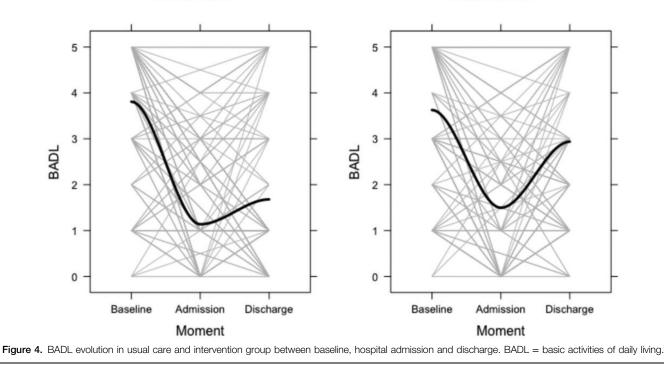


Figure 3. Intervention group: functional trajectories of patients between baseline (2 weeks before admission), hospital admission, and discharge.

Usual care

Intervention



functional worsening between baseline and discharge. Patients in the usual care group are those with a higher overall decline (P=.001) and are the ones who fail most to recover to baseline during hospitalization (P < .001). About 37% of patients in the intervention group declined in BADL function between baseline and discharge, whereas >63% of patients in the usual care group declined (P=.001).

Relation between nursing care program focused on basic self-care and changes in basic activities of daily living function: multivariable analysis.

Logistic regression was used to analyze the association between N_BSC intervention and BADL change and the result are expressed in terms of OR (Table 5). After adjusting for sex, age group, reason for admission and hospitalization in the last 12 months, patients who received usual care presented poorer

Table 3

Parameter	estimates	for	linear	mixed	model	fitted	to	basic
activities of	f daily living	, val	ues (lor	ngitudin	al outco	ome)		

	Coefficient (se)	Р
Fixed effects		
Intercept	3.626 (0.173)	<.001
Moment (admission)	-2.219 (0.171)	<.001
Moment (discharge)	-1.725 (0.147)	<.001
Groupl (intervention)	-0.066 (0.244)	.787
MomentAdmission*Groupl	0.340 (0.242)	.159
MomentDischarge [*] Groupl	1.088 (0.208)	<.001
Random effects	Standard deviation	
Intercept	1.546	
Moment (admission)	1.423	
Moment (discharge)	1.156	
Residual	0.565	

Reference category: i) group: usual care group; ii) moment: baseline.

functional outcomes. They remained at significantly higher risk of declining in BADL function between baseline and hospital discharge [P < .001, OR = 4.14, 95% confidence interval (CI): 2.04-8.39] and were more likely to fail to recover to their baseline level of function (P<.001, OR=7.52, 95% CI: 2.89–19.59). Patients aged 75 years or over had significant higher risk of poorer functional outcomes in the functional trajectories studied (Table 6). For example, the oldest patients (age ≥ 85 years) have a significant higher risk of functional decline before hospitalization (P < .001, OR = 7.56, 95% CI: 2.71–21.09), functional decline between baseline and discharge (P < .001, OR = 10.59, 95% CI: 4.08-27.52) and were more likely to fail to recover to their baseline level of function (P < .001, OR = 9.40, 95% CI: 2.75-32.08) relative to patients aged 65 to 74. Interaction between the age group and the N_BSC intervention was tested and no statistically significant interactions were found, so the effect of the intervention on the outcome measures was not affected by the

Table 4

Relation between nursing care program focused on basic self-care
and functional decline: bivariate analysis

	Usual care (n=91)	Intervention (n = 91)	
Outcome		%	Р
Decline before admission	78.0	74.7	.727
Decline between baseline and discharge	63.7	37.4	.001
Failure to recover to baseline during hospitalization in patients who declined before admission (usual care, $n=71$; intervention, $n=68$)	81.7	48.5	<.001

*Chi-square test.

Table 5

	Unadjusted or	lds ratio (95% confidence	interval)	Adjusted odds ratio [*] (95% confidence interval)			
Outcome	Intervention	Usual care	Р	Intervention	Usual care	Р	
Decline before hospitalization $(n = 182)$	1.0	1.20 (0.65–2.38)	.601	1.0	1.42 (0.67–3.00)	.359	
Decline between baseline and discharge ($n = 182$)	1.0	2.95 (1.61–5.38)	<.001	1.0	4.14 (2.04–8.39)	<.001	
Failure to recover during hospitalization in patients who declined before hospitalization (n = 138)	1.0	4.60 (2.13–9.92)	<.001	1.0	7.52 (2.89–19.59)	<.001	

* Adjusted for sex, age group, reason for admission, and hospitalization in the last 12 months.

patients' age. In relation to sex, the males have a significant higher risk of overall functional decline (P=.035, OR=2.12; 95% CI: 1.05–4.27), but no significant differences were found in the risk of functional decline before hospitalization and failure to recover during hospitalization.

Discussion

A small number of randomized controlled trials have evaluated the effects of mobility intervention on functional outcomes in acutely hospitalized older adults.^{20,29} Even if in-hospital exercise interventions may reduce length of stay or hospital costs, consistent evidence is lacking to support the benefits of such interventions in the functional capacity of acutely ill older patients. In this respect, our study shows that a nursing care program focused on basic self-care (N_BSC) provides a significant benefit comparing to usual care and can help to reverse the functional decline associated with acute hospitalization in older adults. The hypothesis that older adults who received N_BSC will improve functional status was supported; the intervention group was discharged with higher functional status than the usual care group (P < .001) These findings were significant even after adjusting for potential confounders such as sex, age, prehospitalization, and reason for admission. Overall, the number of patients experiencing a decline in BADL between baseline and discharge was reduced by 40% in the intervention group compared with the usual care group.

Available evidence on the implementation of mobility promotion programs in older patients hospitalized for acute illness is contradictory, but there is no increased risk for this population. A recent randomized controlled trial showed no significant benefit of an in-hospital mobility program consisting of ambulation up to twice daily and behavioral strategy to encourage mobility in older patients after acute hospitalization.²⁹ In opposition Martinez-Velilla et al,²⁰ in other randomized clinical trial shows that an exercise intervention provided significant benefits over usual care; at discharge, significant differences between the exercise intervention and the control groups were noted for functional independence as well as cognitive and quality of life level.

Asplund et al,¹³ in a randomized trial found that a geriatric approach with greater emphasis on early mobilization in an acute geriatrics-based ward shortened the length of hospital stay and may have reduced the need for long-term institutional living; this occurred despite patients in an acute geriatric ward not having better medical or functional outcome than older acute patients treated in general medical wards. In this study, the opposite was found, despite the length of stay was lower in the intervention group this difference was not significant (P=.310); however, the patients in N_BSC were discharged with better functional status than patients in usual care group (P<.001).

It should be noted that a considerable number of patients (>74%) experienced a decline in functional status immediately before admission to the hospital, consistent with existing evidence that points that functional decline actually begins in the hospital preadmission period,^{5–8,10} a finding with important implications for both lay and professional care providers. Patients who experienced a decline in functional status before admission to the hospital can be viewed as particularly vulnerable given that most did not return to baseline function; these results suggest that

Table 6

Relation of age and sex on nursing care program focused on basic self-care and functional decline: multivariable analysis

	Adjusted odds ratio (95% confidence interval)						
		Age [*]	Sex [†]				
Outcome	65-74	75–84	≥85	Women	Men		
Decline before hospitalization $(n = 182)$	1.0	2.94 (1.31–6.60) <i>P</i> =.009	7.56 (2.71–21.09) P<.001	1.0	1.09 (0.58–2.33) <i>P</i> =.827		
Decline between baseline and discharge $(n = 182)$	1.0	5.67 (2.34–13.74) P<.001	10.59 (4.08–27.52) P<.001	1.0	2.12 (1.05–4.27) <i>P</i> =.035		
Failure to recover during hospitalization in patients who declined before hospitalization (n=138)	1.0	7.10 (2.17–23.25) <i>P</i> =.001	9.40 (2.75–32.08) <i>P</i> <.001	1.0	2.31 (0.98–5.46) <i>P</i> =.057		

* Adjusted for sex, reason for admission, and hospitalization in the last 12 months.

⁺ Adjusted for age group, reason for admission, and hospitalization in the last 12 months.

functional trajectories before hospital admission should be taken into account in the organization of care for older people.

Some limitations should be considered when interpreting these results. First, although potential confounders such as sex, age group reason for admission, and hospitalization in the last 12 months were adjusted in the analyses, other potential confounders such as acute illness severity, nutritional status, and the degree of social support could not be adjusted. Adjustment for these other potential confounders could strengthen the association between N_BSC intervention and changes in BADL, and, depending on the results, they could indicate groups or characteristics that could be used as triggers for the organization of nursing care after the patient's admission to the hospital. Second, the measures of BADL function at baseline are based on the reports of patients or surrogates and memory bias might occur. There is, however, evidence of the validity of patients and surrogates reports of BADL function.³⁰ Third, the Katz index stands out for its simplicity and unambiguity, which allowed to mitigate the possible subjectivity of the assessments made by different nurses. Lastly, the study was performed in only 1 ward in on hospital in Portugal, which is not representative of the Portuguese admitted to medical ward whereby it was not possible to generalize the results to other health care units.

Our study, nevertheless, has important strengths. This is the first study performed in Portugal aiming to evaluate the effect of a nursing care program focused on basic self-care on functional outcomes in older hospitalized patients. Most interventions concerning BADL in geriatric patients have been performed in nonacute settings. The intervention we studied, N_BSC, differs from most previous interventions in acutely older hospitalized patients in several ways, including the physical redesign of the unit, the key role of nurses, and the reorganization of daily nursing care; the component which entailed nurses the 7 days of the week to ensure that patients had all daytime meals out of bed and to encourage trips to the bathroom, seem to have been decisive in the results achieved. However, more research is needed to consolidate these findings.

Summarizing, this randomized controlled trial is the first in Portugal evaluating the effects of a nurse-led intervention on basic self-care for hospitalized older adults. Results of this trial indicate that a nursing care program focused on the promotion of basic selfcare is able to improve functional outcomes at discharge.

As conclusion, N_BSC for hospitalized older patients was feasible, low-cost and program participants were more likely to be discharged with better functional status than a clinically similar comparison group. N_BSC could be readily adapted for use in other context and warrants further evaluation as a potential new tool for improving outcomes for acute hospitalized older patients.

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Author contributions

All authors participated in developing the design of the study and contributed to and critically appraised the manuscript. The authors have given final approval of the version to be published and they confirm that there are no other persons who satisfied the criteria for authorship.

Conflicts of interest

The authors declare no conflicts of interest.

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