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Effects of a nursing care program on functional outcomes in older acute medical in-patients: protocol for a randomized controlled trial

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Abstract

Background: Hospitalization often leads to long periods of bed rest and inactivity which is associated with an increase in length of hospital stay, loss of capacity for basic self-care and discharge into a nursing home.

Objective: This trial aims to verify if a nursing care program centered on basic self-care and predefined physical activity, improves functional outcomes in older hospitalized patients.

Methods: This is a 2-group randomized controlled trial with repeated measures: 182 older acute medical patients will be blindly randomly allocated to the control group (n = 91) or intervention group (n = 91). The intervention will consist of nursing care intervention centered on basic self-care that includes a twice daily walking training, plus privileging pre-established trips to the toilet by walking and all daytime meals seated, off the bed. The main outcome was changes in the number of independent activities of daily living from 2 weeks before admission (baseline) to discharge. Trial registration: ClinicalTrials.gov (Identifier NCT03106064).

Results: This intervention has the potential to change the outcomes of the older patient in the acute setting.

Conclusion: The loss of independence in self-care is determinant in future health care needs. If our hypothesis is correct and demonstrate that this nursing care program centered on basic self-care for older acute medical patients improves functional outcomes, a change in the paradigmatic organization of hospital care may be justifiable.

Keywords: activities of daily living, elderly, functional outcomes, nursing care program, self-care

Introduction

Hospitalization can, opposing to what people imagine, change the prognosis of older patients negatively by changing their life from independent to dependent.[1–4] The iatrogenic aspects of hospitalization, such as bed rest, are a burden for older patients resulting in an acceleration of problems related to aging and a loss of independence in basic self-care. That is why hospitalization is significantly associated with negative outcomes such as increased length of stay, increased risk of falls, and loss of capacity for self-care or activities of daily living, discharge into a nursing home, readmissions, and consequent mortality.[4–8] These negative effects, such as decreased functional capacity and ability to perform daily life activities, occur even in short hospital stays (a few days). Functional decline at discharge when compared to the condition before admission to hospital is experienced by 30% to 60% of the older hospitalized patients and this decline is not related to the severity of the illness that led to hospitalization.[2,5,9–11]

The primary focus of hospital care is treating acute and exacerbation of chronic illnesses. An intervention that preserves independence and physical function is not often part of the treatment.[12] Older people need effective health care focused not only on the prevention and treatment of diseases but also on active interventions to prevent or delay functional decline. Because of their aptitude to observe, support, and guide patients and their 24 hours patient supervision, nurses play a key role in strategies to prevent functional decline in older patients. An adequate planning of nursing care that includes interventions to promote and maintain mobility, in the logic of self-care, can be a valuable contribution in the prevention of functional decline and in the reconstruction of independence in self-care after a generative event of dependence.[1,13] The scheduling of exercise routines, activities to prevent sensory deprivation, and early hospital discharge are interventions that may help to prevent functional decline.[14] A multidisciplinary intervention that includes exercise may increase the proportion of patients

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discharged to home and reduce length and cost of hospital stay for acutely hospitalized older medical patients.[15] Programs centered in basic self-care to older hospitalized patients can reduce the number of falls, the incidence of pressure ulcers, the rate of readmissions, and the discharges to a nursing home.[6,16] These programs, in addition to improving patient outcomes, also improve hospital outcomes (eg, reducing treatment costs).[17–19]

There is some conceptual uniformity in measuring functioning of patients in terms of activities of daily living, but simultaneously there is a large variability in measuring activities of daily living functioning of older hospitalized medical patients and a large range of clinical definitions of functional decline.[12,20,21] For example, a decline of a 1 point in 1 study is equivalent to a 2% decrease in activities of daily living functioning, whereas in other studies a decline of 1 point is equal to a 20% decrease in activities of daily living functioning.[20]

The number of studies focusing on individuals abilities to perform activities of daily living, in what we can call basic self-care (eating, dressing, personal hygiene, getting around, using the toilet, walking) is smaller when compared to the significant number of studies focusing on self-care associated with the ability to manage chronic disease (adequate diet, physical exercise, self-monitoring, drug regimen, and interpretation of signs and symptoms of disease worsening).[22,23] Most studies on programs promoting self-care in hospitals was focused on specific populations such as intensive care patients, stroke, or heart disease patients.

Older patients with acute medical illness, who frequently have several comorbidities, are usually excluded from exercise intervention trials.[17] Therefore, the purpose of the proposed research is to investigate, through a randomized controlled trial, the effect of a nursing care program centered on basic self-care and predefined physical activity, in dependence of older hospitalized patients.

Methods

Design

This is a 2-group, single-blind randomized controlled trial set in an acute 580-bedded teaching hospital and is designed to be compliant with the recommendations of the Consolidated Standards of Reporting Trials statement.[24] The study flow diagram is shown in Figure 1.

The intervention group will perform the nursing care program focused on basic self-care and predefined physical activity, whereas the control group will receive usual hospital care. As the study will be conducted in the same ward and due to the possible effect of subjects in the control group seeing subjects in the intervention group performing additional activities to normal hospital care and because the clinical staff itself may intervene involuntarily in the control group through increased activity, randomization will take place in a time-dependent manner. Patients admitted for the first 20 weeks will be assigned to the control group. After these 20th weeks there will be a 10-week break and in the next 20 weeks (weeks 30–50) the admitted patients will be assigned to the intervention group. During the 10-week break, all clinical staff will receive training on the tasks to the intervention program.

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

Participants

Participants will include older patients aged 65 years or older recruited from patients admitted into 1 of the 3 medical wards of an acute 580-bedded teaching hospital in Portugal. Because of the length of the study it is possible that a patient will be readmitted after participating in either the control or intervention group. To avoid this confounding effect, a study participant who is readmitted to the hospital during the course of the study will not be included in the analysis a second time.

Recruitment

Patients are eligible for the trial if they fulfill the following inclusion criteria:

- Age: 65 years or older.
- Able to ambulate, with or without personal/technical assistance.
- Able to communicate.

Patients are not eligible if:

- Expected length of stay in the unit <72 hours.
- Days in the hospital until arriving at the medical ward >4 days.
- Transferred from intensive/intermediate care unit.

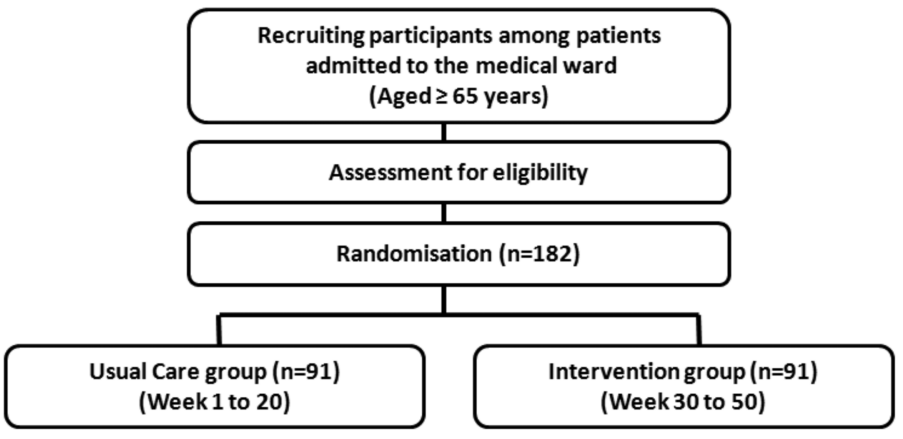

Figure 1. Flow diagram of the study protocol.

- Any factor precluding performance of the physical training program. These factors include but are not limited to the following:
  - Terminal illness.
  - Unstable cardiovascular disease or other medical condition.
  - Severe dementia.

All clinical information will be obtained through patient and/or relatives' interview, direct observation of patients' abilities, and consultation of healthcare records. Standard information including reason for hospitalization, medical history, and history of falls and hospital admissions in the prior year will be collected by the investigators.

Premorbid functioning (2 weeks before admission) will be the baseline measurement in defining change over time and the endpoint will be hospital discharge. The independence level will be assessed through the Katz Index and the Nursing Patient Classification Systems data.

Study procedures

Usual care group (control)

Patients randomly assigned to the control group will receive usual hospital care, which includes physiotherapy when needed.

Intervention group (training)

The intervention consists of a nursing care program application that includes a twice daily walking training, plus privileging pre-established trips to the toilet by walking (with support devices or with support from people) and all daytime meals seated (off the bed). Nurses will ensure that patients are sitting out ready to eat, will provide encouragement and assistance to eat/walk or toilet use; provide walk destination and will minimize clinical activity during meal times. Walk training will consist of walking as far as possible with or without assistance for 20 minutes. All training sessions will be individually monitored with a record of training completed compiled.

Attending of the particular and unexplored characteristics of the proposed intervention, namely the use of the toilet and daytime meals seated, the proposed intervention extends throughout the 24 hours of the day, 7 days a week. Therefore, it is an intervention that requires the alignment of the whole clinical staff in its execution. The duration and quality of the training, planned for weeks 21 to 29, will be crucial to ensure the involvement of the whole team and the success of this study. We will reorganize the daily work of this ward to focus nursing care on promoting independence in self-care. Adherence to the new nursing care program will be checked in a daily register.

To maintain adherence to the new nursing care program, the potential benefits of accomplishing this program will be explained to the clinical staff before and during the intervention period. Regular interdisciplinary education sessions to support dissemination of evidence will be done.

Outcomes

The main outcome is change in the number of independent activities of daily living from 2 weeks before admission (baseline) to discharge; change will be classified as improved, maintained, or declined. Other outcome includes change in the number of independent activities of daily living from admission to discharge.

Patients will be assessed within 24 hours of admission and at discharge. At admission patients will be evaluated on their ability to perform 5 basic activities of daily living (ADL) 2 weeks before admission (self-report) and at the time of admission (nurse evaluation). The 5 ADL were bathing, dressing, toileting, transferring from a bed to a chair, and eating[25]; continence was not included because reports are often unreliable.[20] Baseline data include demographics, comorbidity, medication use, and home circumstances.

For each activity, patients are considered independent if the activity was performed without personal assistance.

In Nursing Patient Classification Systems data items related to basic self-care can be classified as Independent, Partial Aid, or Total Aid. If a patient who at the time of admission was classified as Total Aid and was classified as Partial Aid upon discharge, this patient is considered to have had an improvement in their level of independence during hospitalization. If the reverse is true, for example, transition from Independent to Partial Aid or transition from Partial Aid to Total Aid, this patient is considered to have declined the level of independence.[26]

Sample size determination

We believe that a clinically relevant change is a $\geq$20% increase in the frequency of patients who get at discharge a functional improvement. Based on the results of a pilot study, we expect the control group to improve approximately 0% to 20%; thus, we can detect differences of at least $\geq$40% with a power $>$80% and a level of significance of 0.05 with two groups of 91 subjects.

Randomization and blinding

As previously mentioned, randomization will be made in a time-dependent manner (in 20th weeks blocks) to avoid the confounding variable of participants in the control 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 will be blind; they will not know that they are being part of a study. With this methodology we intend to avoid the Hawthorne effect.

After the first 20 week study block of the control group, during 10 weeks, all clinical staff will be trained to reorganize their daily work to increase patient independence for self-care. This reorganization involves the adoption of a twice daily walking training, privileging trips to the toilet to walk and all daytime meals seated.

Statistical methods

In an initial descriptive analysis, for qualitative variables we will calculate frequencies and for continuous variables we will calculate statistics of central tendency and dispersion such as means, standard error, and median. Normality of continuous variables will be checked graphically and through Kolmogorov–Smirnov and Shapiro–Wilk tests. Significant differences in continuous variables between groups will be assessed by parametric tests (T tests, analysis of variance) or nonparametric tests (Mann–Whitney U, Kruskal–Wallis). Proportions will be compared using chi-square test. Significant changes between admission and discharge in basic self-care dependence will be analyzed using McNemar–Bowker test. The level of statistical significance was set at 0.05. Data will be analyzed with SPSS package 24.0.

Ethical considerations

Board and Hospital Ethics Committee approvals were obtained in 2016 (DEFI 2016.037) was registered at ClinicalTrials.gov (Identifier NCT03106064). Given the study design, which implies a reorganization of nursing care program before the start of intervention group recruitment, informed consent were not required.

Limitations

A possible limitation of this protocol will be the capability to maintain care team adherence to the proposed nursing care program the 24 hours of the day, 7 days a week.

Discussion

Loss of independence in self-care and functional decline is determinant in future health care needs. If our hypothesis is correct and demonstrate that this nursing care program centered on basic self-care for elderly acute medical in-patients improves patient outcomes, a change in the reorganization of hospital care may be justifiable.

Results from the current study will help to better understand the potential of this nursing care program supported in the promotion of physical activity, which depends on the involvement of the whole care team, for improving independence in self-care and will help to clarify the usefulness of Nursing Patient Classification Systems in assessing basic self-care outcomes in elderly acute medical patients.

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Conflicts of interest

The authors declare no conflicts of interest.

Authors' 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.

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