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The effectiveness of Function Focused Care among patients acutely admitted to hospital: A stepped wedge cluster trial

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ABSTRACT

Background: During acute hospital admission, patients often experience loss of functional status. A low level of physical activity is associated with higher levels of loss of functional status. Stimulating physical activity to maintain functional status is considered essential nursing care. Function Focused Care is a promising approach stimulating physical activity. In a previous study, Function Focused Care in Hospital was deemed feasible.
Objective: To determine the effectiveness of Function Focused Care in Hospital compared with usual care on the functional status of hospitalized stroke and geriatric patients.
Design: A multicenter stepped wedge cluster trial.
Methods: A neurological and a geriatric ward of an academic hospital and a general hospital in the Netherlands participated in this study; each was considered a cluster in the trial. The primary outcome was patients' functional status over time, measured with the Barthel Index and Elderly Mobility Scale. Secondary outcomes were the patients' length of stay, fear of falling, self-efficacy, motivation, resilience, and outcome expectations for functional and exercise activities. Data was collected at hospital admission (baseline), day of discharge, and three and six months after discharge via patient files and questionnaires and analyzed with generalized linear mixed models.
Results: In total, we included 892 patients, of which 427 received Function Focused Care in Hospital and 465 received usual care. Although we did not find significant differences in the Barthel Index and Elderly Mobility Scale at discharge or follow-up, we found a significant decrease in the mean length of stay (−3.3 days, 95 % CI −5.3 to −1.1) in favor of the Function Focused Care in Hospital group. In addition, in the Function Focused Care in Hospital group, a larger proportion of patients were discharged to home compared to the control group (38.2 % vs. 29.0 %, p = 0.017), who were discharged more often to a care facility.
Conclusion: The length of hospital stay was substantially decreased, and discharge to home was more common in the group receiving Function Focused Care in Hospital with equal levels of independence in Activities of Daily Living and mobility in both groups upon discharge. Although significant differences in the Barthel Index and Elderly Mobility Scale were not found, we observed that neurological and geriatric patients were discharged significantly earlier compared to the control group.
Registration: https://onderzoekmetmensen.nl/en/trial/24287 (date of first recruitment: 05-02-2016).
Tweetable abstract: Patients receiving Function Focused Care in Hospital were discharged from the hospital 3.3 days earlier and discharged home more often than the group of patients receiving care as usual. @umcutrecht @hogeschoolutrecht.

What is already known

- Hospital admission is associated with physical inactivity; therefore, patients admitted to the hospital are at risk for loss of functional status.

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- During hospital admission, nursing interventions can be effective in improving patient outcomes, such as independence in Activities of Daily Living and mobility.

What this paper adds

- This study shows similar levels of dependence in activities of daily living and mobility at discharge, 3 and 6 months after discharge, between the Function Focused Care and usual care groups.
- This study shows that the group of patients receiving Function Focused Care in Hospital was discharged from the hospital 3.3 days earlier and discharged home more often than the group of patients receiving care as usual.
- When considering functional status in a patient population admitted to a hospital, length of stay and discharge destination must be considered as functional status contributes to determining the moment and destination of discharge.

1. Introduction

The worldwide aging population, in combination with the positive consequence of the medical and societal improvement in health care over the past decades, results in a growing number of older and chronically ill persons with comorbidity and multimorbidity (Hoogendijk et al., 2016; Marengoni et al., 2011). Since normal aging and chronic diseases are associated with a decline in functional status (Hoogendijk et al., 2016; Marengoni et al., 2011), this demographic trend will lead to increasing demands on health care, not the least on nursing care. Simultaneously, we face a severe shortage of other healthcare professionals in the coming years (de Vries et al., 2023; WHO, 2016). These developments emphasize the importance of proactively preventing physical activity and loss of functional status, especially in older people.

Independently performing activities of daily living is one of the most critical health outcomes for older people as well as for individuals with chronic illness or disability (Basic et al., 2017; Tappenden et al., 2012; Karppinen et al., 2016). It enables persons to live as independently and participate in society (Bierman, 2001; Karppinen et al., 2016). In general, the main goal for patients admitted to the hospital is to recover to their functional status before hospital admission (Krishnamurthi et al., 2013; van der Kluit et al., 2019). Unfortunately, hospital admission is associated with poor health outcomes after admission (Buurman et al., 2011). Hospitalized patients often have a low level of physical activity (Brown et al., 2009; Fini et al., 2017; Pedersen et al., 2013), and 30–60 % of older patients show loss of functional status during or after hospitalization (Hoogerduijn et al., 2014; Smith et al., 2020; Zisberg et al., 2015), often accompanied by a loss of independence in activities of daily living (Buurman and de Rooij, 2015; Loyd et al., 2020; Floegel et al., 2018). Physical activity is crucial in regaining independence in activities of daily living because of its positive effect on maintaining and restoring patients' functional status (Karppinen et al., 2016; Bierman, 2001), and it should start as soon as possible after hospital admission and discharge, regardless of the discharge destination.

Nurses play a crucial role in patients' recovery to their prior functional status (Englebright et al., 2014; Kitson et al., 2013; Kirkevold, 2010). Therefore, assisting patients to reach or maintain their best condition is the main focus of nursing care (Englebright et al., 2014; Kitson et al., 2013; van Hell-Cromwijk et al., 2021). In their daily care, nurses assist patients with their activities of daily living and mobility, which are essential nursing care activities (Kitson et al., 2010; Zwakhalen et al., 2018). However, the care provided in daily nursing practice generally focuses on task completion, such as a doctor's visit, measuring vital signs, wound care, and medication rounds (Kitson et al., 2010; Resnick et al., 2012). Nurses tend to prioritize completing these tasks more than focusing on optimizing underlying physical capability by actively engaging patients in daily care. This quickly leads to the loss of the remaining activity of daily living abilities and facilitates the loss of functional status, causing further dependency. Furthermore, this focus is evoked by the intrinsic tendency of nurses to care for their patients, especially when the patient is in a vulnerable condition (Resnick et al., 2012). Therefore, there is an urgent need for a transformation in the nurses' care approach toward preventing, maintaining, or improving patients' functional status (Loyd et al., 2020).

Recent scoping and systematic reviews concerning care regarding activity of daily living, mobility, and physical activity have provided insight into interventions, barriers, and facilitators. The systematic review, which included nine interventions to optimize patients' functional status during daily nursing care, concluded that multicomponent interventions were the most promising, but further research should evaluate these interventions using research methods aiming to produce rigorous evidence (Verstraten et al., 2020). Another systematic review exploring interventions to reduce dependence on bathing concluded that there was a lack of well-designed studies evaluating interventions (Golding-Day et al., 2017). In a scoping review identifying barriers and facilitators to physical activity in patients during hospital stay, the authors identified as an essential barrier the many factors influencing hospitalized patients' physical activity and recommended implementing multifaceted interventions (Geelen et al., 2021). These reviews underscore the complexity of improving physical activity and the necessity for multifaceted interventions tailored to individual needs (Geelen et al., 2021; Golding-Day et al., 2017; Verstraten et al., 2020). Interventions with such a multidisciplinary approach are, for example, 'reablement' (Golding-Day et al., 2017) and 'Function Focused Care' (Boltz et al., 2014, 2021; Resnick et al., 2013); these interventions focus on physical activity and function and changing the care philosophy from doing for toward doing with.

Function Focused Care is an approach that engages patients in physical activity and has been proven to be effective (Lee et al., 2019; Boltz et al., 2015, 2023). Function Focused Care is defined as "…a philosophy of nursing care that focuses on evaluating the older adult's underlying capability concerning function and physical activity and helping him or her optimize and maintain functional abilities and increase time spent in physical activity…" (Resnick et al., 2012). The main objective of this approach is to optimize and maintain function and increase the time patients spend in physical activity (Galik et al., 2013; Resnick et al., 2012). Active patient engagement in all daily care activities is encouraged and tailored to each patient (Galik et al., 2013, Resnick et al., 2012).

Function Focused Care is tested in various care settings for older adults, including nursing homes, assisted living or residential care, and acute care settings (Boltz et al., 2014; Galik et al., 2021; Resnick et al., 2013). Previous research in acute care in the U.S. has shown promising results regarding functional status and mobility in older hospitalized patients (Resnick et al., 2016; Boltz et al., 2023, 2021). Unequivocal generalization of these findings to the Dutch hospital setting is impossible because of the significant differences in healthcare systems in the U.S. and the Netherlands. For example, American hospitals have varying mobilization policies, with patient-to-nurse staffing ratios typically lower than those in Dutch hospitals (Lorgunpai et al., 2020, Aiken et al., 2012). Therefore, further evaluation of Function Focused Care in the Dutch hospital setting is needed.

Based on the Medical Research Council (MRC) framework of complex intervention, Function Focused Care is considered a complex intervention (Craig et al., 2008). Function Focused Care has several interacting components within the intervention and targets different groups and organizational levels. There is also variability in outcomes and a need for flexibility in tailoring the intervention to its setting (Craig et al., 2008). A previous study evaluating the feasibility of Function Focused Care adapted to the Dutch hospital setting assessing the feasibility demonstrated that Function Focused Care in Hospital is feasible while emphasizing the importance of team involvement, nursing leadership, and the involvement of patients and their families (Kok

et al., 2021). As a next step in evaluating Function Focused Care in Hospital, the effectiveness should be studied. The current study aims to evaluate the effectiveness of Function Focused Care in Hospital on the functional status of stroke and geriatric patients admitted to hospital compared to usual care. We expect that Function Focused Care in Hospital positively affects the functional status during a hospital admission.

2. Methods

2.1. Trial design

We conducted a multicenter stepped wedge cluster trial over 24 months between February 2016 and September 2018. In this design, all participating clusters start in the control condition, and one by one the clusters move via a transition period into the intervention condition. In our study, this design enabled 1) a sequential introduction of Function Focused Care in Hospital on the different participating wards, thereby overcoming logistical constraints; 2) each ward switched from control to intervention condition, participation in the study was, therefore, more appealing; and 3) enabled us to study the implementation and intervention effects per cluster (Mdege et al., 2011; Hemming et al., 2015).

Our study consisted of six periods of four months each, and in this design, we used wedges (w1–w6). In the first wedge (w1), all wards delivered care as usual, the control condition. The first ward moved to the transition period in w2 and started with Function Focused Care in Hospital, the intervention condition in w3; for the second ward, these steps were in w3 and w4, respectively, followed by the third ward in w4 and w5, and the last ward in w5 and w6, respectively. The study ended in w6, where all wards delivered care according to Function Focused Care in Hospital (Table 1). In the transition period, Function Focused Care in Hospital was implemented in the wards (see Section 2.5 Implementation).

Allocation was based on clusters, i.e., ward level rather than individual patients, because of the nature of the application of Function Focused Care in Hospital and the risk of introducing bias when nurses apply Function Focused Care in Hospital to one patient and not to another. The four wards in this study differed in size, i.e., two larger and two smaller wards. Therefore, we pre-planned the crossover of clusters to ensure that the larger wards were not the first or the last ones to switch from the control to the intervention period to prevent a drop in efficiency of the stepped wedge design due to an imbalance in absolute numbers between usual care and Function Focused Care in Hospital. As a result, no randomization method could be used.

2.2. Setting and participants

In the hospital setting, we considered neurological and geriatric wards to be eligible for participation because they mainly admit patients with an acute event that is accompanied by a high risk of loss of functional status (Brown et al., 2009; Fini et al., 2017; Pedersen et al., 2013) and thus likely to benefit from the implementation of the Function Focused Care in Hospital approach (Kok et al., 2021). In the neurological and geriatric wards of an academic and general hospital in the middle of the Netherlands, four wards agreed to participate in this study. Patients of these wards were included if they were aged ≥18 years and admitted with a recent (onset ≤1 week) stroke (neurological wards) or who were treated by the geriatrician (geriatric wards). Patients were included regardless of their ability to communicate adequately due to cognitive decline or aphasia to include a representative sample of the patient group. Patients were excluded if they were expected to stay in the hospital <48 h, if they had a life-threatening condition or were in a terminal phase, if patients did not master the Dutch language, or if they had been previously enrolled in the study.

We obtained informed consent from the patients or their legal representatives in case of communicative impairment due to verbal or cognitive impairments. To determine the patients' ability to communicate adequately, we explained the purpose of this assessment and obtained verbal permission before proceeding with the shortened Frenchay Aphasia Screening Test (short-FAST) and the Mini-Mental State Examination (MMSE) (Arevalo-Rodriguez et al., 2015; Enderby et al., 1987).

We, therefore, used the combination of the Mini-Mental State Examination and the shortened Frenchay Aphasia Screening Test to assess overall adequacy of communication. The Mini-Mental State Examination was used to assess the cognitive impairments and shortened Frenchay Aphasia Screening Test to assess verbal impairments. The shortened Frenchay Aphasia Screening Test, which consists of four items covering comprehension and expression, scores from 0 to 20, with higher scores indicating better language function (Enderby et al., 1987). The Mini-Mental State Examination, consisting of 24 items that assess orientation, memory, concentration, language, and praxis, scores from 0 to 30, with higher scores indicating better cognitive functioning (Folstein et al., 1975).

Patients were considered able to communicate adequately if they scored above 17 on the shortened Frenchay Aphasia Screening Test for those aged ≤60 years, a score of above 16 for patients 61–70 years, and above 15 for those aged ≥71 years (Enderby et al., 1987; de Man-van Ginkel et al., 2012), as well as a Mini-Mental State Examination score of ≥18 (Folstein et al., 1975; Joling and van Hout, 2009). Patients scoring below cutoff on at least one of these scales were considered unable to communicate adequately.

Table 1
Stepped wedge cluster trial – design and inclusion per period.

	2016		2017			2018	
Period	**1**	**2**	**3**	**4**	**5**	**6**	
	Feb – May	**Jun – Sept**	**Oct – Jan**	**Feb – May**	**Jun – Sept**	**Oct – Jan**	
University hospital - geriatric ward	43		44	40	34	45	
General hospital - neurological ward	42	38		43	38	48	
General hospital - geriatric ward	55	54	49		43	55	
University hospital neurological ward	44	46	45	49		37	
Total per period	184	138	138	132	115	185	893
Total care as usual (control)							427
Total Function Focused Care in Hospital (intervention)							465
Legend: Control period = yellow, Transition period = white, Intervention period = blue							

2.3. Intervention

In the intervention condition, all patients received care using the Function Focused Care in Hospital approach. Function Focused Care in Hospital is the version of Function Focused Care that has been translated into the Dutch hospital setting. A detailed description using the Template for Intervention Description and Replication (TIDieR) was published earlier (Kok et al., 2021). Function Focused Care in Hospital, like FFC, primarily concerns a) patients and nurses, b) patients' families and the multidisciplinary team, c) wards' environment, and d) the policy and culture of the ward. Furthermore, Function Focused Care in Hospital comprises four components: 1) Environmental and Policy Assessment: This component evaluates the suitability of policies, cultural norms, and the overall ward environment. 2) Education: In this component, nurses are educated and trained to educate patients, inform the patient's family, and engage the multidisciplinary team. Its main impact is on patients, nurses, patients' families, and the multidisciplinary team. 3) Goal Setting with the Patient: This component is directed toward patients and nurses, emphasizing collaborative goal setting based on the patient's physical and psychological capabilities and preferences. There were two types of goals: a long-term goal to work toward and a short-term goal for the day. 4) Ongoing Motivation and Mentoring: The final component pertains to nurses who, in close collaboration with the multidisciplinary team, receive motivation training and learn strategies to motivate patients and their families while boosting their self-confidence. Its intended recipients are patients, nurses, patients' families, and the multidisciplinary team.

2.4. Control - usual care

In the control condition, all patients received care as usual. In Dutch hospitals, usual care is focused on the recovery of the patients. It is provided by a multidisciplinary team of physicians, nurses, nurse assistants, physiotherapists, and other healthcare professionals. Goal setting and activity plans are part of the nursing care policy. However, this is not applied as a matter of course.

Moreover, if applied, the patient is hardly ever involved in setting goals. In addition, there is no policy for family participation in the nursing care policy. As a result, family participation is primarily determined by the personal preferences of the individual patients or nurses.

2.5. Implementation

During the four-month transition period, before moving to the intervention condition, Function Focused Care in Hospital on the ward was implemented by providing all the nurses with sufficient training and time to practice Function Focused Care in Hospital. During this period, the researcher (CV) introduced the nurses and informed them about applying the four components of Function Focused Care in Hospital in daily nursing care. We conducted a two-hour training session for all nursing staff, focusing on the benefits of physical activity for patients. Also, the patient's families and multidisciplinary team members received written materials providing information about Function Focused Care in Hospital. A detailed description of the intervention and its implementation was published earlier in a feasibility study (Kok et al., 2021).

The transition period was not considered part of the control or intervention condition; hence, no patient data was collected.

2.6. Procedures of data collection

Trained research assistants or a researcher not involved in the data analyses (CV) collected the data. Primary and secondary outcomes were measured at hospital admission (baseline) and three follow-up time points: day of discharge (t0), three months (t1), and six months (t2) after discharge. Patient characteristics were obtained from the patient's medical files or questionnaires administered by the research assistants.

All data were collected via electronic patient files, performance-based measurements, and questionnaires. All research assistants were trained extensively in the inclusion and the data-collection procedures and had access to the protocol in which these procedures were described to ensure uniform data collection over wards and time. In addition, the researcher had regular training meetings with the research assistants and was available when they needed to discuss any questions.

2.6.1. Blinding

Due to the education on ward level during the transition period, it was impossible to blind nurses of the participating wards to the ward's condition per wedge. Patients were not aware of the wards' condition during their participation. Nevertheless, complete blinding was not possible since it was not guaranteed that nurses or other healthcare providers might discuss the introduction of Function Focused Care in Hospital with patients, for example, regarding goal-setting with the patient, one of the core elements. The research assistants who collected data were not acquainted with the content of the intervention. However, due to the stepped wedge design of the study, they could not be completely blinded to the ward's condition. Moreover, nurses from the wards sometimes discussed the ward's condition with them (for example, asking something about Function Focused Care in Hospital). Also, the researcher who conducted the data analysis was not blinded.

2.6.2. Primary outcomes measurements

We determined the primary outcome functional status with the Barthel Index (BI) for independence in activities of daily living and the Elderly Mobility Scale (EMS) for mobility. The Barthel Index consists of 10 items, scored on a scale of 0–3, with a maximum score of 20 (de Haan et al., 1993; Collin et al., 1988). A higher score indicated a higher level of independence in activities of daily living. We obtained the Barthel Index by interviewing the patient or, in case of communicative impairment, the nurse caring for the patient at the moment of data collection. The Elderly Mobility Scale consists of seven mobility tasks patients are asked to perform (Prosser and Canby, 1997). The Elderly Mobility Scale had a maximum score of 20, representing independent mobility. When patients scored 20 points on the Elderly Mobility Scale, we measured the walking distance within 2 min. We obtained the Elderly Mobility Scale performance-based; we adapted the verbal instructions of the items in case of communicative impairment.

2.6.3. Secondary outcomes measurements

In addition, length of stay and determinants associated with patients' intention or willingness to engage in physical activity: fear of falling, self-efficacy and outcome expectations for functional and exercise activities, motivation, and resilience were measured as secondary outcomes since these determinants are known to be associated which patients' intention or willingness to engage in physical activity (Resnick et al., 2012). The length of stay was measured in days and determined by the difference between the admission and discharge dates. We measured the fear of falling with the Short Falls Efficacy Scale-International (Short FES-I). Scores vary from 7 to 28, with 28 representing a maximum concern to fall (Kempen et al., 2008). We used the Self-Efficacy and Outcome Expectations Scales for Restorative Care to measure self-efficacy and Outcome expectations for Functional and Exercise activities (Resnick et al., 2008). This scale consists of four subscales: self-efficacy for activities in daily living (score range 10–50), outcome expectations for daily living (score range 3–15), self-efficacy for physical activity (score range 9–45), and outcome expectations for physical activity (score range 9–45). A higher score represents higher self-efficacy or higher outcome expectations. We measured the patients' motivation with the Apathy Evaluation Scale (Clarke et al., 2007). A higher score (range 7–28) represents a higher motivation. Resilience was measured by the Psychical Resilience Scale, with a score

between 0 and 15 (Resnick et al., 2011). The higher the score, the more resilience the patients showed.

Due to the content of the questionnaires, it was impossible to customize the secondary outcome measurements in case of communicative impairments.

2.6.4. Patient characteristics

The following patient characteristics were measured at baseline: age (in years), sex (male/female), ability to communicate adequately (collected with shortened Frenchay Aphasia Screen Test and Mini-Mental State Examination as aforementioned), impaired vision or hearing (yes/no), medical history such as admission reason, comorbidities, and polypharmacy. We also collected the discharge destination to determine if the patient was discharged to a care facility or their home setting (i.e., where they lived before admission).

2.6.5. Sample size

The sample size was calculated for the effect of the intervention on the primary outcome functional status in terms of independence in activities of daily living, as measured by the Barthel Index (Collin et al., 1988). This calculation was based on a clinically relevant effect size of 1 with a standard deviation of 3 (Chippala and Sharma, 2016) and an assumed intra-cluster correlation of 0.01. Therefore, to achieve 80 % power and an alpha of 5 % (two-sided) in each of the 20 periods (i.e., 6 wedges in 4 clusters minus the transition period in each of the 4 clusters) in which patient data was collected, a total of 40 patients per wedge per cluster were needed in both control and intervention condition, thus a total of 800 patients for the whole study. This calculation was performed using Stata, version 13.1 (StataCorp).

An epidemiologist (JR) not involved in the intervention delivery advised on the crossover schedule. After consent was obtained from all wards to participate as a cluster in the study, the crossover date was revealed to each of the four wards simultaneously.

2.7. Statistical analysis

Given the clustered approach of the study, equality between the control and intervention groups at baseline cannot be assumed. Therefore, we tested for differences in baseline characteristics between the control and intervention groups using ANOVA for continuous normally distributed variables, Kruskal test for nonnormal continuous variables, and chi-square test for categorical variables.

We used linear models for the difference in Barthel Index and Elderly Mobility Scale at discharge and length of stay, and to correct for the effect of calendar time, linear mixed models (LMMs) for the difference in Barthel Index and Elderly Mobility Scale at three and six months after discharge. Given the possible confounding effects of covariates, we determined these covariates based on literature and clinical knowledge. For both models, the fixed effects were the type of care (usual care or Function Focused Care in Hospital), period (i.e., the wedge), ward (i.e., cluster), baseline measurement of Barthel Index/Elderly Mobility Scale, and the covariates (ability to communicate adequately, impaired vision or hearing, length of stay (for Barthel Index and Elderly Mobility Scale), and discharge destination (for length of stay)). For model 2, in addition to model 1, we added calendar time in months (continuous) as a fixed effect to the model, the interaction term for the type of care * calendar time, and a random intercept and slope per patient. Based on the final model, we calculated the estimates of the mean difference in outcomes between the control and intervention group and their 95 % confidence intervals. We used two-sided tests for all analyses, and a p-value <0.05 was considered statistically significant.

In the exploratory analyses, we used boxplots and descriptive statistics to investigate the differences in the secondary outcomes, fear of falling, self-efficacy and outcome expectations for functional and exercise activities, motivation, and resilience at discharge. We also used ANOVA for continuous, normally distributed variables, the Kruskal test for nonnormal continuous variables, and the chi-square test for categorical variables.

2.7.1. Imputation

We assessed the nature and structure of the missing data. We evaluated the rate of missing data and the reasons why data is missing. As missing data typically leads to biased effect estimates, we conducted multiple imputations using the mice library (Manly and Wells, 2015; Donders et al., 2006; van Buuren and Groothuis-Oudshoorn, 2011). The primary outcomes and length of stay analyses were conducted in all 50 imputed sets, using restricted maximum likelihood estimation to generate unbiased variance estimates. Subsequently, we pooled the results from each of the 50 imputed datasets using Rubin's rule.

Values of primary and secondary outcomes of patients who died before follow-up were not considered missing and were imputed as zero on all subsequent follow-up measurements, with zero being the 'worst' value to the patient outcomes. Excluding these patients from all analyses could lead to too optimistic results (Biering et al., 2015).

All statistical procedures were performed in RStudio (version 1.3.1093).

2.8. Informed consent and ethics approval

The study received approval from the Medical Ethics Board of the University Medical Centre of Utrecht (protocol number 15/517). The following procedure was followed to obtain individual patients' informed consent for the use of clinical data and additional data collection, as equipoise was not considered for the nature and working mechanisms of the Function Focused Care in Hospital (Freedman, 1987) but for the healthcare providers' application of Function Focused Care in Hospital. First, information about the study was provided to the patient. Second, when the patient verbally agreed to participate, we assessed the patient's ability to communicate adequately with the shortened Frenchay Aphasia Screen Test and the Mini-Mental State Examination. Next, patients were asked for written informed consent. In case of inability to communicate adequately, the patient's relatives were asked for written informed consent. The type of information provided and the consent procedure did not differ between the intervention and control conditions. In case of more hospital admissions than needed in one wedge, we only approached the required number of eligible patients for participation in the study. Since this procedure is prone to selection bias, the following method was applied to prevent it. Based on the random admissions over time by patients, we approached patients based on the admission date and time, following a chronological order. Finally, we monitored the reasons for dropout (e.g., death or withdrawal of consent) to determine differences in baseline characteristics with those with completed data collection.

The study was registered on https://onderzoekmetmensen.nl/en/trial/24287 (date of first recruitment: 05-02-2016). Registration occurred after recruitment commenced, but before the end of the trial. The trial was conducted in accordance with the protocol that was approved for funding and reviewed by the ethics committee prior to first recruitment. The registration reflects this protocol. Documentation is available from the author on request. Journal editors granted an exemption to the usual policy because evidence of adherence to the protocol was provided and prospective registration was not universally accepted as a requirement for publication at the time of commencement.

3. Results

3.1. Study population

Of 2074 eligible patients, 906 met the inclusion criteria and agreed to participate in the study, 803 were excluded for diverse reasons, and 379 random patients were not approached for participation. In the four clusters, we included 892 patients; 465 received usual care, and 427 received Function Focused Care in Hospital. Fig. 1 shows patient

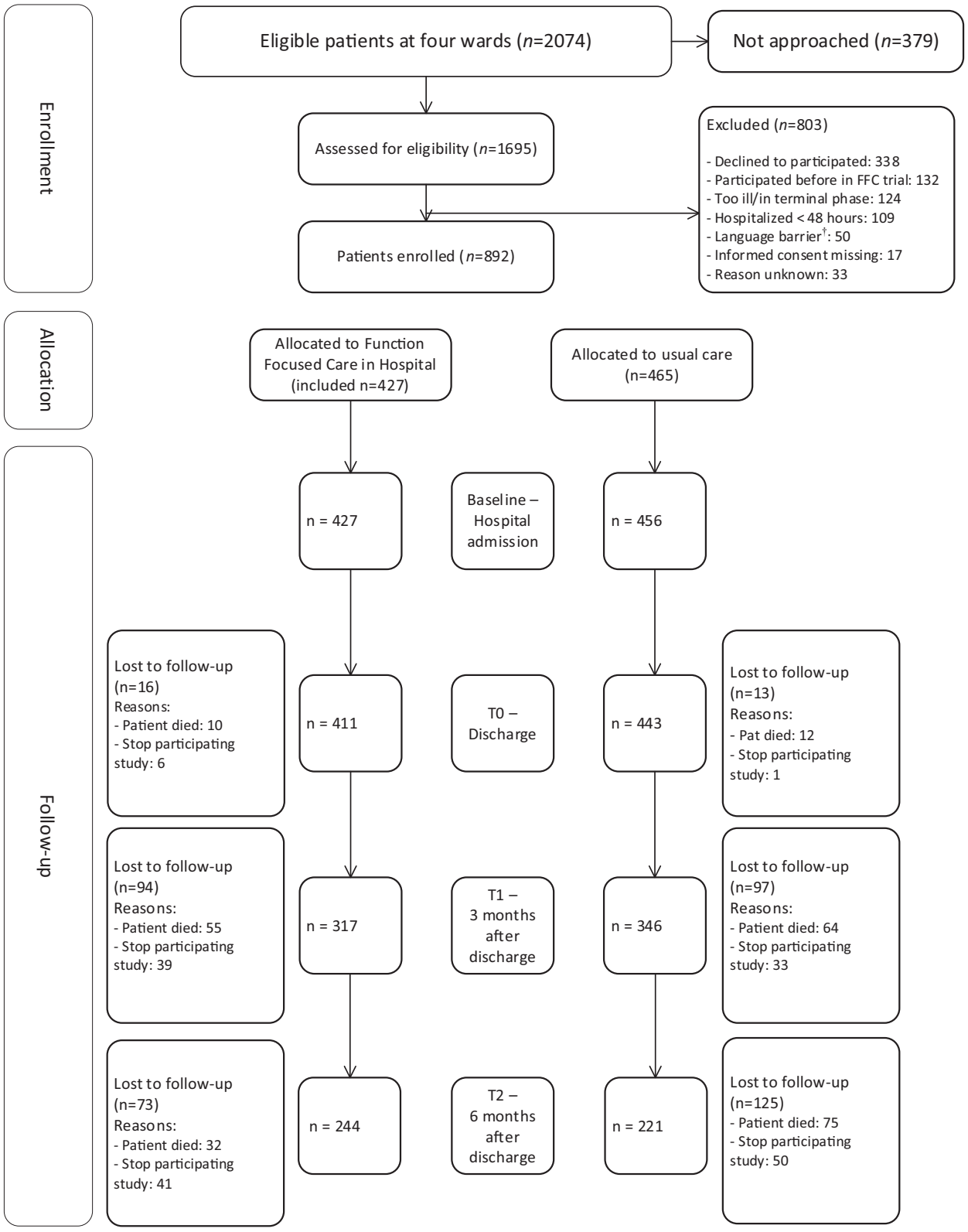

Fig. 1. Flow chart.

recruitment, allocation to usual care or Function Focused Care in Hospital, and loss to follow-up during the study. Of all included patients, we had missing data at baseline for 247 patients, t0 for 132 patients, t1 for 159 patients, and t2 for 126 patients.

The median age was 57 years (IQR 47–63), 54.8 % were female, and 16.7 % lived in an assisted living or nursing home before admission. Of the included patients, 48.2 % were admitted to the geriatric ward, and 51.8 % were admitted to the neurology ward. At baseline, some differences were measured between the intervention and control group; in the intervention group the following measurements were higher: age (Δ median = 5), use of walking aid (Δ % = 15.3), fear of falling (Δ median = 2), outcome expectations

on exercises (Δ median = 3), Activities of Daily Living-independency (Δ median Barthel Index = 2), and mobility (Δ median Elderly Mobility Scale = 2).

Furthermore, at discharge, we found that the group living at home before admission and receiving Function Focused Care in Hospital was more often discharged to home than the group receiving care as usual: 38.2 % vs. 29.0 % p 0.017. The group living at home before admission and receiving usual care was discharged more often to a care facility. All patient characteristics per study arm are presented in Table 2, and the patient characteristics per ward are presented in the supplementary file, Table 1.

3.2. Primary outcomes

The linear model showed no significant differences in independence in activities of daily living (Barthel Index) and mobility (Elderly Mobility Scale) at discharge for the group receiving Function Focused Care in Hospital (intervention condition) compared to the group receiving

Table 2
Patient characteristics and secondary outcome measurements.[a]

	Overall (n = 892)	Function Focused Care in Hospital (n = 427)	Usual care (n = 465)	p-Value
Patient characteristics				
Baseline (hospital admission)				
Location; (n (%))				<0.001
General hospital – neurological ward	209 (23.4)	129 (30.2)	80 (17.2)	
General hospital – geriatric ward	256 (28.7)	98 (23.0)	158 (34.0)	
University hospital – neurological ward	221 (24.8)	37 (8.7)	184 (39.6)	
University hospital – geriatric ward	206 (23.1)	163 (38.2)	43 (9.2)	
Age (median [IQR])	57.0 [46.8, 63.0]	59.0 [51.0, 64.0]	54.0 [42.0, 62.0]	<0.001
Female sex (n (%))	489 (54.8)	234 (54.8)	255 (54.8)	1.000
Living accommodation before admission (n (%))				0.803
Home	589 (66.0)	287 (67.2)	302 (64.9)	
Care facility	149 (16.7)	74 (17.3)	83 (17.8)	
Use of walking aids (n (%))				<0.001
None	389 (43.6)	154 (36.1)	235 (50.5)	
Cane/crutcher(s)/walker inside and/or outside	405 (45.4)	228 (53.4)	177 (38.1)	
Enable to walk independently/other	55 (6.1)	27 (6.3)	28 (6.0)	
(in)Formal help at home (n (%))	543 (60.8)	311 (72.8)	232 (49.9)	<0.001
Has fallen during the preceding six months (n (%))	357 (40.2)	180 (42.2)	177 (38.1)	0.002
No of comorbidities (median [IQR])	2.0 [1.0, 3.0] (n = 890[a])	2.0 [1.0, 3.0] (n = 426[a])	2.0 [0.0, 3.0] (n = 464[a])	<0.001
Absence of communicational skills (n (%))	437 (49.0)	198 (46.4)	239 (51.4)	0.152
Presence of hearing and/or vision impairment (n (%))	250 (28.0)	106 (24.8)	144 (30.1)	0.056
Presence of depressive symptoms (n (%))	202 (22.6)	100 (23.4)	102 (21.9)	0.075
T0 (discharge)				
Length of stay (median [IQR])	8.0 [5.0, 13.0]	7.00 [5.00, 12.00]	9.00 [5.00, 14.00]	0.001
Presence of depressive symptoms (n (%))	150 (16.8)	85 (19.9)	65 (14.0)	0.313
Discharge destination conditional of living accommodation before admission (n (%))				
Home – home	298 (33.4)	163 (38.2)	135 (29.0)	0.017
Care facility – home	254 (28.5)	104 (24.4)	150 (32.3)	
Care facility – care facility (same as before admission)	106 (11.9)	51 (11.9)	55 (11.8)	
Care facility – care facility (different as before admission)	38 (4.2)	16 (3.7)	22 (4.7)	
Death – home or care facility	24 (2.7)	9 (2.1)	15 (3.2)	
Secondary outcome measurements				
Baseline (hospital admission)				
Barthel Index (median [IQR])	7.0 [3.0, 13.0] (n = 660[a])	8.0 [3.5, 13.0] (n = 294[a])	6.0 [2.0, 12.0] (n = 366[a])	0.009
Elderly Mobility Scale (median [IQR])	7.0 [2.0, 13.0] (n = 592[a])	8.0 [2.0, 14.0] (n = 277[a])	6.0 [1.0, 13.0] (n = 315[a])	0.048
EQ-5D[b] (median [IQR])	6.0 [2.0, 10.0] (n = 246[a])	6.0 [3.0, 10.0] (n = 109[a])	5.0 [2.0, 9.0] (n = 137[a])	0.035
Content with care – CQ index (median [IQR])	5.0 [5.0, 7.0] (n = 249[a])	5.0 [5.0, 8.0] (n = 115[a])	5.0 [5.0, 7.0] (n = 134[a])	0.818
FES-I[c] (median [IQR])	4.0 [0.0, 10.0] (n = 218[a])	5.0 [2.0, 11.0] (n = 103[a])	2.5 [0.0, 9.0] (n = 115[a])	0.021
Aparthy Evaluation Scale (median [IQR])	10.0 [7.0, 12.0] (n = 169[a])	10.0 [7.8, 12.0] (n = 80[a])	10.0 [6.0, 13.0] (n = 89[a])	0.854
Resilience NL (median [IQR])	6.0 [4.0, 7.0] (n = 135[a])	6.0 [4.3, 7.0] (n = 62[a])	5.0 [3.0, 7.0] (n = 73[a])	0.068
SE[d] functional (median [IQR])	26.0 [15.00 31.5] (n = 160[a])	24.0 [15.0, 31.0] (n = 75[a])	27.0 [14.8, 32.0] (n = 85[a])	0.368
OE[e] functional (median [IQR])	8.0 [7.0, 8.0] (n = 152[a])	8.0 [6.0, 8.0] (n = 69[a])	8.0 [7.0, 8.0] (n = 83[a])	0.966
SE[d] exercise (median [IQR])	18.0 [9.5, 25.5] (n = 140[a])	17.0 [8.3, 25.0] (n = 66[a])	21.00 [11.0, 26.0] (n = 74[a])	0.407
OE[e] exercise (median [IQR])	16.0 [10.0, 19.0] (n = 146[a])	18.0 [14.0, 20.0] (n = 66[a])	15.0 [8.0, 18.5] (n = 80[a])	0.023
T0 (discharge)				
EQ-5D[b] (median [IQR])	4.0 [2.0, 7.5] (n = 179[a])	3.5 [1.0, 6.8] (n = 90[a])	4.0 [2.0, 8.0] (n = 89[a])	0.413
Content with care – CQ index (median [IQR])	6.0 [5.0, 8.0] (n = 178[a])	6.0 [5.0, 7.0] (n = 93[a])	6.0 [5.0, 9.0] (n = 85[a])	0.507
FES-I[c] (median [IQR])	3.0 [0.0, 6.5] (n = 167[a])	2.0 [0.0, 6.0] (n = 85[a])	3.0 [0.3, 6.8] (n = 82[a])	0.629
Apathy Evaluation Scale (median [IQR])	10.0 [7.0, 12.0] (n = 147[a])	10.0 [7.0, 12.0] (n = 75[a])	10.0 [7.0, 12.0] (n = 72[a])	0.820
Resilience NL (median [IQR])	8.0 [6.0, 9.0] (n = 112[a])	8.0 [6.0, 9.0] (n = 54[a])	7.5 [6.0, 9.0] (n = 58[a])	0.616
SE[d] functional (median [IQR])	21.0 [16.0, 22.0] (n = 143[a])	22.0 [16.0, 22.0] (n = 75[a])	21.0 [14.8, 22.0] (n = 68[a])	0.529
OE[e] functional (median [IQR])	8.0 [8.0, 8.0] (n = 137[a])	8.0 [8.0, 8.0] (n = 71[a])	8.0 [8.0, 8.0] (n = 66[a])	0.675
SE[d] exercise (median [IQR])	21.0 [10.0, 30.0] (n = 132[a])	18.0 [9.0, 28.0] (n = 69[a])	24.0 [13.0, 30.5] (n = 63[a])	0.149
OE[e] exercise (median [IQR])	18.00 [13.0, 21.0] (n = 138[a])	17.00 [13.0, 21.0] (n = 73[a])	18.0 [13.0, 21.0] (n = 65[a])	0.479

[a] Based on the collected data (not imputed).
[b] EuroQol Five Dimensions Health Questionnaire.
[c] Falls Efficacy Scale International.
[d] Self-efficacy.
[e] Outcome expectations.

Table 3
Mean intervention effects for Barthel Index, Elderly Mobility Scale and length of stay.

	β Δ Function Focused Care in Hospital vs. usual care	95 % CI	p-Value
Discharge			
Barthel Index	−0.602	−2.337 to 1.133	0.496
Elderly Mobility Scale	0.368	−1.587 to 2.322	0.711
Length of stay	−3289	−5.294 to −1.285	0.001
Three and six months after discharge			
Barthel Index	−0.321	−2.026 to 1.383	0.711
Time (in months)	−0.006	−0.028 to 0.175	0.156
Function Focused Care in Hospital * time	0.073	−0.151 to 0.139	0.931
Elderly Mobility Scale	0.295	−1.459 to 2.050	0.741
Time (in months)	0.030	−0.075 to 0.136	0.572
Function Focused Care in Hospital * time	−1.517	−2.518 to −0.517	0.003

care as usual (control condition); Barthel Index: β −0.6, CI 95 % −2.3–1.1, Elderly Mobility Scale: β 0.4, CI 95 % −1.6–2.3 (Table 3). At three and six months after discharge, the linear mixed models for Barthel Index and Elderly Mobility Scale showed no significant differences between the group receiving Function Focused Care in Hospital compared to the group receiving care as usual; Barthel Index: β −0.3, CI 95 % −2.0–1.4, Elderly Mobility Scale: β 0.3, CI 95 % −1.5–2.1 (Table 3).

3.3. Secondary outcomes

Length of stay showed a significant difference in favor of the group Function Focused Care in Hospital (intervention condition). The linear model for length of stay demonstrated a β of −3.3, CI 95 % −5.3 to −1.3, p = 0.001.

For the other secondary outcomes, fear of falling, self-efficacy and outcome expectations for functional and exercise activities, motivation, and resilience at discharge, no significant differences were found in the exploratory analyses (Table 2 and Fig. 2).

4. Discussion

This stepped wedge cluster trial study aimed to determine the effectiveness of Function Focused Care in Hospital compared with usual care on the functional status of hospitalized stroke and geriatric patients. Although no significant differences were found for independence in activities of daily living (Barthel Index) and mobility (Elderly Mobility Scale) between the group receiving Function Focused Care in Hospital and the group receiving usual care at the different time points, our study showed a clear and significant effect in the length of stay of 3.3 days (CI 95 % −5.3 to −1.3) in favor of Function Focused Care in Hospital. Such a reduction of 3.3 days in hospital stay has a large (societal) impact on patients, as hospital admission is burdensome and is associated with many risks, such as further deterioration of physical functioning and poor health outcomes (Buurman et al., 2011; Loyd et al., 2020; Smith et al., 2020).

Our study showed no significant difference in our primary outcome measurements, independence in activities of daily living, and mobility, denoting that patients in the intervention and control condition reached similar functional status levels during their stay in hospital. Remarkable, however, is the 3.3 days shorter length of stay in the intervention condition compared to the control condition. This suggests that patients receiving Function Focused Care in Hospital achieved a similar level of functional status 3.3 days earlier than those receiving usual care. In earlier studies to evaluate Function Focused Care in a hospital setting, no differences were found in functional status at discharge (Boltz et al., 2014, 2021, 2023). In contrast with our study, these studies did not collect length of stay as an outcome measurement. Therefore, no comparison could be made to explain our finding in the length of stay.

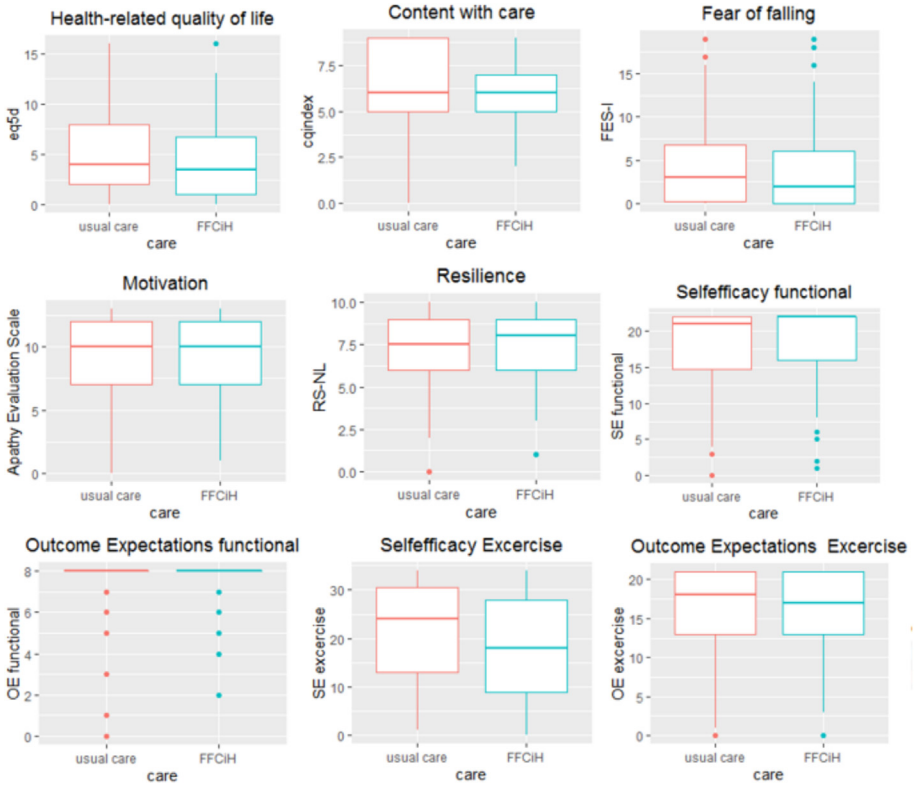

Fig. 2. Boxplot (median & IQR) exploratory analyses secondary outcomes at discharge.

Also contrary to our study are the results of a review on the effects of Function Focused Care in long-term care facilities demonstrating evidence for preventing function loss and improving physical function (Lee et al., 2019). The difference in the setting may explain this contrast in findings, which influenced the study population and the period of exposure to the intervention and time points to measure outcomes. The longer admission period in long-term care facilities enables data collection at fixed points instead of a flexible time point on the day of discharge. Another notable difference is that the longer stay of people in these care facilities allows for more prolonged exposure to the intervention compared to the short stay in the hospital of, on average, 8 days in our study.

The heterogeneous study population might also explain why our study did not significantly affect functional status. We expected (that all subgroups within) our study population would benefit from Function Focused Care in Hospital because they are mainly patients with an acute event that is accompanied by a high risk of loss of functional status (Brown et al., 2009; Floegel et al., 2018; Pedersen et al., 2013). Nevertheless, our study population consists of stroke patients representing all ages over 18 and geriatric patients over 60, and a variety of diseases, especially in the geriatric population. This diverse population might have diluted the overall effect of Function Focused Care in Hospital, as we found some differences between the effects between the included wards. The positive trend of independence in activities of daily living and mobility was more robust in the stroke wards than in the geriatric wards. This suggestion is confirmed by studies evaluating comparable interventions in homogeneous populations that have found positive effects on activities of daily living performance and mobility across these diverse groups (Boltz et al., 2015; Chippala and Sharma, 2016; Brown et al., 2016). Subgroup analyses may provide further insights to statistically test differences between the subgroups, but the number of included patients per ward needed to be bigger to conduct an adequately powered subgroup analysis.

The fact that we found a significant effect on length of stay but not on activities of daily living functioning and mobility may be clarified by clinical practice in determining the time of discharge. The literature describes that the factors determining the discharge time depend, at least partly, on the medical and functional status (Meijer et al., 2005; Dutrieux et al., 2016). We did not find any indication that any other reasons during our study influenced the discharge timing. Hence, the earlier a patient regains a certain level of independence in activities of daily living and mobility, the faster the patient can be discharged. This might explain why we could not detect a difference in functioning in activities of daily living and mobility at discharge, our first outcome measurement, but instead found a difference in length of stay. This might indicate that determining an effect of Function Focused Care in Hospital length of stay might be a more appropriate outcome measure than dependency in activities of daily living and mobility.

Furthermore, in the patients receiving Function Focused Care in Hospital, we found a larger proportion of patients discharged to home than those in the control condition. Functional status is one of the factors that significantly determine a patient's discharge direction: to home, a rehabilitation facility, or a long-term care facility (Meijer et al., 2005; Mees et al., 2016). Consequently, this finding confirmed the positive effect of Function Focused Care in Hospital on functional status. Hence, the reduction in length of stay and a larger proportion discharged to home indicates that the intervention Function Focused Care in Hospital improves stroke and geriatric patients' functional status during a hospital stay.

4.1. Strengths and limitations

A stepped wedge cluster trial design is a pragmatic trial design to evaluate complex interventions in real-life settings (Mdege et al., 2011; Hemming et al., 2015). We included the pre-planned minimum of 42 patients per cluster per wedge, which we considered as a strength. The intense and time-consuming data collection succeeding in the pre-planned inclusion of patients in a stepped wedge trial is not self-evident, as is known from a previous study where data on outcomes routinely collected appeared to be often missing during analysis (Heim et al., 2017). Nevertheless, to complete data collection in our study in all clusters, we needed to focus primarily on completing primary outcome data, accepting missing values on other variables. For the few missing values on primary outcomes, we successfully applied multiple imputations to the primary outcomes and analyzed these outcomes as planned (Enders, 2017), preventing bias that should have been introduced when using only complete cases in the data analysis (Groenwold et al., 2014).

However, the focus on collecting the primary outcomes led to too little data on the secondary outcomes to be able to apply a trustworthiness multiple imputation strategy for that data. Therefore, we adjusted the planned analysis for the secondary outcome measurements and restricted it to exploratory analysis for the discharge measurement. The secondary outcomes were collected to measure how different intervention components could affect the patient and nurses differently. Due to the exploratory analyses, we could not conclude any of the intended effects of the separate components of Function Focused Care in Hospital. This adaption for the secondary outcomes emphasizes the need for a solid study design, taking into account a thorough data collection plan to substantiate the secondary outcomes. We also want to acknowledge the need for a subgroup analysis for the outcome measurements to examine the differences between the patient groups on the different wards.

While our study utilized the Mini-Mental State Examination (MMSE) to assess cognitive function at baseline, it is notable that the use of delirium screening tools was not described in our methodology. This decision was informed by practical considerations, as in Dutch hospital settings delirium observation screening scales (DOSS) are typically administered only when clinically indicated. This approach contrasts with our aim to capture cognitive abilities essential for effective communication. Thus, our choice of the Mini-Mental State Examination aimed to provide a cognitive status to determine the overall adequacy of communication aligned with our study objectives. Also, when informed consent was given, we did not measure cognition again. We emphasize that Function Focused Care in Hospital is an intervention with a personalized approach where nurses adapt the instruction and application of the intervention to the capabilities of the patients, including the communicative capabilities. Patients with a communicative impairment were therefore not excluded from the study, but nurses' communication was adapted to the patient's personalized level.

In this study, design blinding was not possible, which could lead to selection bias. The following actions prevented the risk of selection bias as much as possible by training the researcher who collected the data and selecting patients based on their admission data over their admission reasons. Next, a researcher not involved in the data collection analyzed the data in collaboration with a statistician. Also, a stepped wedge cluster trial is known for its potential for cross-contamination (Hemming et al., 2015). Nurses in the control clusters who learn about and adopt the intervention prematurely can potentially dilute the treatment effect. We prevented this cross-contamination with the transition period between the control and intervention periods. During the transition period, we collected no data and educated nurses about the intervention.

4.2. Implications for research, practice, and education

This study emphasizes the importance of collaboration in nurses' daily practice with patients and families in essential nursing care activities to promote physical activity and prevent function loss. If attention is paid from the start of nurses' vocational and bachelor education, it can become a fundamental attitude toward collaboration, physical activity, and preventing function decline. Further research should investigate the long-term impact of a transitional Function Focused Care approach after hospital admission on patient outcomes. In this study, we found that measurements of differences in the patient's functional status

during a hospital stay were difficult to compare because of the difference in discharge moment. The outcome measurements of functional status should be placed in the context of length of stay and discharge destination. A core outcome set in studies regarding functional status during a hospital admission would help compare studies and interventions such as reablement and Function Focused Care in Hospital with each other.

5. Conclusions

The length of hospital stay was significantly decreased by 3.3 days, and discharge to home was more common in the group receiving Function Focused Care in Hospital with equal levels of independence in activities of daily living and mobility in both groups upon discharge. Although significant differences in the Barthel Index and Elderly Mobility Scale were not found, the earlier discharge and change in discharge destination suggest that Function Focused Care in Hospital helps improve the physical functioning of neurological and geriatric patients earlier during their hospital stay.

Statistician

There are statisticians on the author team: Lisette Vernooij and Johannes B. Reitsma.

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CRediT authorship contribution statement

Selma Kok: Writing – review & editing, Writing – original draft, Visualization, Validation, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation. **Lisette Schoonhoven:** Writing – review & editing, Supervision, Methodology, Funding acquisition. **Lisette M. Vernooij:** Writing – review & editing, Supervision, Software, Methodology, Formal analysis, Conceptualization. **Johannes B. Reitsma:** Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization. **Carolien Verstraten:** Writing – review & editing, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Silke F. Metzelthin:** Writing – review & editing, Methodology, Funding acquisition, Conceptualization. **Nienke Bleijenberg:** Writing – review & editing, Visualization, Supervision. **Janneke M. de Man-van Ginkel:** Writing – review & editing, Visualization, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work the author(s) used Grammarly in order to improve readability and language of the manuscript. After using this tool, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the published article.

Data availability

Due to planned secondary analysis of the data, the data is not publicly available. Data is available on request.

Declaration of Competing Interest

None.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijnurstu.2024.104893.

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