The impact of Function Focused Care in Hospital (FFCiH) on geriatric and stroke patients.

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The study hypothesis is that FFCiH will maintain or improve functional status and physical activity in hospitalized stroke and geriatric patients compared to usual care.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24287

Bron
NTR

Aandoening

- Geriatric patients
- stroke patients
- hospitalization
- basic nursing care
- functional status
- physical activity
- activities of daily living (ADL)

Ondersteuning

Primaire sponsor: University Medical Center, Utrecht, the Netherlands
Overige ondersteuning: ZonMw: The Netherlands Organisation for Health Research and Development.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Bathing & Dressing: measured by the Barthel-Index (BI) supplemented with the total number of body parts the patient washed and dressed himself.
2. Mobility: measured by the Elderly Mobility Scale (EMS). In case of a maximum score of the EMS (patient performs all tasks without any problem), the EMS will be followed by the 2-minute walk test.

Toelichting onderzoek

Achtergrond van het onderzoek

Normal aging, chronic and acute diseases such as a stroke cause functional decline whereby the person needs basic nursing care structurally or temporarily. Additionally, hospitalization itself often leads to deterioration in physical functioning in patients. Early activity, beginning as soon as possible after hospital admission, has been shown to benefit physical functioning in geriatric and stroke patients. However, the literature also shows that hospitalized adults are physically inactive and spend most of the time in bed. As a result, functional decline occurs. This is proven to be an important predictor for a prolonged length of hospital stay, loss of independence, high costs and increasing mortality. Considering the nature of their care, nurses can play an important role to prevent further disability and optimize the functional status of their patients. However, nurses tend to meet their patients' needs by task completion rather than by stimulating active engagement in daily activities.

Function Focused Care in Hospital (FFCiH) is an approach that stimulates nurses to encourage a patient to take a more active part in the activities of daily living and to increase patients' time spent in physical activity to attain and maintain their highest level of function. FFC has been developed in nursing homes in the USA and evaluated in several care settings, especially in long-term settings in elderly patients. Although results of these studies provided support for the safety and efficacy of the FFC-approach in those settings, there is little research to evaluate the effectiveness of FFC in hospitalized patients.

The Medical Research Council has been used to adapt the FFC approach to the Dutch Hospital Setting. In phase I the FFC approach was translated and developed in collaboration with future users, eight nurses working in two different hospitals in the Netherlands. In phase II a pilot study was conducted to test the practicability of the data collection and the feasibility of the FFCiH. This pilot showed that FFCiH is adaptable to the Dutch hospital care and gave relevant information regarding challenges for implementation of this intervention.

A multicenter stepped wedge cluster trial is currently running comparing FFCiH with care as usual in 4 different wards (two neurological and two geriatric) of two hospitals in the Netherlands, in which approximately 800 hospitalized geriatric and stroke patients will participate. In the first four months, none of the wards will receive the intervention. Then, FFCiH will be implemented sequentially in all participating wards every four months. Nurses will be trained in delivering the intervention by two-hour training sessions and bed-side teaching. So, all wards will shift from care as usual (control period) to the intervention (intervention period). Outcomes will be compared within and across wards. During the 4 months implementation period (transition) no patient outcomes will be measured.

Alongside, a process evaluation will be conducted to facilitate interpretation of outcome effects and to gain insight into the experiences of nurses and patients with regard to benefits, burden, stimulating factors and barriers.

Doel van het onderzoek

The study hypothesis is that FFCiH will maintain or improve functional status and physical activity in hospitalized stroke and geriatric patients compared to usual care.

Onderzoeksopzet

Timepoints Primary Outcomes (patients):

baseline at hospital admission, day 7 after hospital admission, the day of discharge, 3 and 6 months after discharge.

Timepoints Secondary outcomes (patients):

baseline at hospital admission, day of discharge, 3 and 6 months after discharge

Timepoints Secondary outcomes (nurses)

baseline (before implementation of FFCiH), 3 and six months after implementation of FFCiH.

Onderzoeksproduct en/of interventie

In the intervention group, trained nurses will stimulate patients in active engagement in daily activities instead of taking over those activities with the aim that patients maintain or restore their physical functioning. Examples of FFCiH include walking with the patient to the toilet instead of giving him a urinal in bed or using verbal cues during bathing. Key elements of the FFCiH approach are goal setting in collaboration with the patients and motivational techniques.

Patients in the control group will receive care as usual

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- stroke (onset < 1 week) patients admitted to the neurological ward

- geriatric patients admitted to the geriatric ward

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- a life-threatening situation or in a terminal phase on admission;

- Dutch language barrier regardless of cognitive or communicative impairments;

- Already participated once in the FFCiH study

- Hospitalization duration of < 48 hours

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	05-02-2016
Aantal proefpersonen:	800
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-01-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6780
NTR-old	NTR6964
Ander register	ZonMw / Medical Research Ethics Committee : 520002003 / 15/517

Resultaten