Hospital at Home care for elderly patients with cognitive impairment presenting on the emergency department with acute somatic illness and an indication for hospital admission: a randomized feasibility trial

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The aim of the study is to assess the feasibility of conducting a definitive trial in terms of recruitment, use and acceptability of H@H, quality of care and the advantages and disadvantages of H@H in comparison to usual hospital care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON43141

Source
ToetsingOnline

Brief title
Hospital@Home

Condition

- Bacterial infectious disorders
- Cognitive and attention disorders and disturbances
- Age related factors

Synonym
delirium, Dementia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Deltaplan Dementie/ZonMw

Intervention

Keyword: Cognitive impairment, Elderly, Hospital level care, Hospitalization

Outcome measures

Primary outcome

The main study parameters are the participation rate of the H@H trial among patients 65 years and older with cognitive impairment at the ED and the reasons for non-participation.

Secondary outcome

Furthermore the different steps in the H@H care process will be timed and evaluated and if the quality of H@H care differs from usual hospital care will be studied. In addition we investigate advantages and disadvantages of H@H care and usual hospital care with regards to: time spent at home, number of transfers needed, number of health care professionals involved, (medical) equipment needed, functional status (ADL), health status, (health related) quality of life and costs.

Study description

Background summary

Most of the older persons with cognitive impairment live at home with assistance of informal care and specialized home care. An acute hospital

admission is a stressful life event for these patients and is often complicated by hospital-related complications such as falls, delirium, malnutrition and functional decline. The hospitalization of these patients is often followed by nursing home admission and most of them never return to their own home again. In order to decrease the risk on hospital-related complications and nursing home admission, Hospital at Home (H@H) offers a new care trajectory which provides hospital care in a patients* own home. The general aim of H@H is to avoid hospital-related complications and nursing home admission in elderly patients with cognitive impairment.

Study objective

The aim of the study is to assess the feasibility of conducting a definitive trial in terms of recruitment, use and acceptability of H@H, quality of care and the advantages and disadvantages of H@H in comparison to usual hospital care.

Study design

Randomized controlled feasibility trial

Intervention

When hospital admission is indicated after a visit to the emergency department, eligible patients with informed consent will be randomized to receive hospital care in their own home (H@H-care) or usual hospital care, with a randomization ratio of 4:1 to H@H care. The intervention is hospital level care delivered to the patients* own home including: visits of heath care professionals, diagnostics (laboratory tests, blood cultures) and treatment (iv medication, fluids), all provided according to current Dutch treatment guidelines. Measurements will be at inclusion, during admission, at discharge and at 3 and 6 months follow-up.

Study burden and risks

The questionnaires will take participants a maximum of 20-40 minutes at a time to complete and do not contain burdensome questions. Participants will be contacted by telephone at 3 and 6 months to avoid distress of an extra hospital visit. Caregivers and medical professionals will be asked to complete a questionnaire at discharge of the patient. The expected burden of being allocated to the intervention arm (H@H) could involve psychological stress by unfamiliarity with the H@H care, although patients are selected based on their agreement to receive hospital level care at home. Occurrence of disease-related complications which need additional care in H@H will result in a delay in the time-to-intervention, to forestall this; strict inclusion- and exclusion criteria are applied. The expected burden of being allocated to the control arm

(usual hospital care) could involve psychological stress by disappointment of not being able to go home. In a study population of elderly patients with cognitive impairment, there is a possibility of participants being (temporarily) incapacitated. In case of participants being incapacitated, the legal representative will be closely involved in informing on the study and sign informed consent. Cognitive impaired patients are more prone to the risks of an acute hospital admission and have higher in-hospital mortality and most likely they will benefit most from care in their own homes and the expected decrease in hospital related complications. The additional risk and burden of the intervention are proved negligible in previous trials.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

> Age >= 65yr > Established dementia, delirium or other cause of cognitive impairment present Previously diagnosed or; Confirmed with the IQCODE-sf (family) or in a patient by the 4AT-test31 and/or Short Blessed Test on the ED > Presentation with a defined acute illness > Felt to require hospital admission by attending ED physician, but not expected to require emergency interventions MEWS <= 2 / VIEWS < 7 > Living in hospital catchment area > Ambulatory ability 24hrs prior to ED presentation > Informal caregiver present, able to understand and perform instructions > Appropriate home circumstances (running water, adequate heating, safety)

Exclusion criteria

- Need for medium or intensive care, based on MEWS-score and clinician judgment > Cut-off value emergency scores: MEWS >=3 / VIEWS >7 - Need for surgical assessment - Hospitalized within 7 days preceding ED presentation - Nursing home residents or awaiting a nursing home place on an active waiting list (excluding so called sleeping waiting list candidates) - Suspected acute coronary syndrome or cardiac arrythmia - Dialysis dependent patients - Expected terminal events or in need of palliative care due to oncological illness - Acute illness requiring hospital admission independent of the target diagnosis of presentation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2018
Enrollment:	143
Type:	Actual

Ethics review

Approved WMO Date:	18-04-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL60371.042.16