The Hospital Elder Life Program (HELP) a multicomponent targeted intervention to prevent delirium in hospitalized older patients. A study on efficacy and cost-effectiveness in Dutch health care.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Deliria (incl confusion)
Study type	Interventional

Summary

ID

NL-OMON37868

Source
ToetsingOnline

Brief title
(Cost-)effectiveness study on HELP, a delirium prevention program.

Condition

- Deliria (incl confusion)

Synonym
acute confusion, loss of orientation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw Doelmatigheid

Intervention

Keyword: Cost-effectiveness, Delirium, Prevention, Volunteers

Outcome measures

Primary outcome

The primary outcome of the study is the incidence of delirium. Secondary outcomes include delirium duration (number of days) and severity, length of stay, care consumption up to three months after admission, experienced quality of the care process by patients, family, professionals and trained volunteers.

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Study description

Background summary

In 2005 the Dutch Health Care Inspectorate (IGZ) indicated that in the Netherlands annually 40.000 to 160.000 hospitalized patients of 70 years and over suffer from a delirium. From January 2010 delirium incidence in hospitalized older adults is a quality of care indicator for the Dutch Health Care Inspectorate (IGZ). Previous research in the USA showed that as a result of implementation of Hospital Elder Life Program (HELP) the incidence of delirium can be reduced, as well as its duration and severity. The HELP program is expected to be cost-saving and improve patient outcomes.

Study objective

This research project aims at quantification of the efficacy and (cost-) effectiveness of the Hospital Elder Life Programme (HELP) in the Dutch health care situation. Furthermore, this project will describe and understand the experiences of patients, family, professionals and trained volunteers.

Study design

A multiple baseline (also known as a stepped-wedge design) will be used to evaluate the (cost-) effectiveness of the introduction of HELP within the Dutch health care system. In addition a study with a qualitative design based on the grounded theory (27; 28) will be carried out.

Intervention

HELP has four unique components:
1. The program provides standardized protocols targeted toward six delirium risk factors.
2. A multidisciplinary geriatric team, with a central role for the Nurse Practitioner Elderly Care.
3. Trained volunteers to provide personal, supportive attention to vulnerable older patients.
4. Personalized interventions that match their changing needs throughout the course of hospitalization.

Study burden and risks

The incidence of delirium in the included patients will be diagnosed with the Confusion Assessment Method. After inclusion, nurses will rate their observations of patients regarding symptoms of delirium at the end of each shift with the Delirium Observation Screening scale. In patients diagnosed with delirium according to the CAM, delirium severity will be assessed daily with the Delirium Rating Scale by the nurse-practitioner. Health related quality of life (general quality of life, functional well being and emotional wellbeing) will be measured with the EQ-5D (consisting of the EQ-5D descriptive system and the EQ VAS) at admission, discharge and after discharge.
No risks are expected for the participating patients. They will receive extra attention from the volunteers and from the geriatric team.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Patients are at least 70 years of age
-Have no delirium at the time of admission, and are considered at risk for delirium at admission as determined by the VMS criteria (www.vmsveiligheid.nl)
According to these criteria at least on of the following three questions has to be answered positive to include a patient with an increased risk of delirium:
- Dou you have memory problems?
- During the past 24-hours did you need assistance for your daily self-care?
- Were you confused during earlier hospital admissions or illnesses?

Exclusion criteria

-Older patients in life threatening situations or with a terminal illness at admission.
-Patients with an expected hospital stay of 24 hours or less.
-Patients who are legally incapable of participating or with precluded verbal communication.
-In case of a language barrier.
-Patients with profound aphasia.
-Patients with intubation or respiratory isolation

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2012
Enrollment:	1080
Type:	Actual

Ethics review

Approved WMO

Date:	27-09-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL40239.041.12