The Hospital Elder Life Program (HELP) een interventie ter voorkoming van acute verwardheid (delier) bij ouderen tijdens een ziekenhuisopname.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24801

Source
NTR

Brief title
HELP

Health condition

acute verwardheid, het delier tijdens ziekenhuisopname

delirium during hospitalization

Sponsors and support

Primary sponsor: UMC Utrecht, Divisie Revalidatie, Verpleegwetenschappen en Sport
Source(s) of monetary or material Support: ZonMw Doelmatigheid

Intervention

Outcome measures

Primary outcome

The primary outcome of the study is the incidence of delirium in the included patients, as diagnosed with the Confusion Assessment Method (CAM).

Secondary outcome

Health related quality of life (general quality of life, functional well being and emotional wellbeing) will be measured with the EQ-5D (37).

The quality of care will be examined by means of focus groups. qualitative interviews with the patienQs and their family members will be conducted. The HELP-volunteers will participate in a focus or supervision/ intervision group.

Cost-effectiveness:

The primary effect parameter of the economic outcome evaluation will be the number of averted cases of delirium. The costs of the program will also be calculated ass well as the costs of care consumption.

Study description

Background summary

Background:

The Hospital Elder Life Program (HELP) has proven (cost)effectiveness in the reduction of delirium incidence in the USA. HELP provides multicomponent protocols targeted at specific risk factors for delirium and introduces a different view on care organisation and a change in care processes. Trained volunteers play a pivotal role in HELP. The primary aim of this study is quantification of the (cost)-effectiveness of HELP in the Dutch Health care system. The second aim is to describe and understand the experiences of patients, family, professionals and trained volunteers.

Methods/Design:

A multiple baseline (also known as a stepped-wedge design) will be used to evaluate the (cost-) effectiveness of HELP within the Dutch health care system. All patients aged 70 years and over, at risk for delirium, admitted to one of the following hospital units; cardiology, internal medicine, geriatrics, orthopaedics or surgery, of two participating community

hospitals will be included. All eight units are both control and intervention in a successive order. This order will be determined at random. The primary outcome of the study is the incidence of delirium measured with the Confusement Assessment Method. Secondary outcomes include delirium duration, severity, quality of life, length of stay and care consumption up to three months after discharge. With these outcomes, cost effectiveness of the program will be calculated. Satisfaction of patients, families, professionals and volunteers will be investigated using a qualitative design based on the grounded theory (27; 28) Professionals and volunteers will be invited to participate in focus group interviews. A random sample of ten patients and their families of each hospital unit will be interviewed at home after discharge.

Discussion:

Reduction of delirium incidence during hospital admission is expected from the introduction of HELP. A decrease of duration and severity of delirium and in length of hospital stay among elderly patients is also expected. This will lead to reduced health care costs. Result of the study can result in a fundamental different view on the care organization and a change in the care process for patients at risk for delirium. Furthermore, the unique role of volunteers demands a change in the daily ward practice. The stepped wedge design was chosen for ethical, practical and statistical reasons. The study is generalizable to the Dutch hospital care.
After completion of the project, with proven impact on the prevention of delirium in hospitalised elderly, we will spread and guide implementation of the program in order to be able to proclaim the main conclusions and to widely implement the knowledge provided.

Study objective

The Hospital Elder Life Program (HELP) has proven (cost)effectiveness in the reduction of delirium incidence in the USA. The primary aim of this study is quantification of the (cost)-effectiveness of HELP in the Dutch Health care system.

Study design

A multiple baseline (also known as a stepped-wedge design) will be used to evaluate the efficacy and (cost-) effectiveness of the introduction of HELP within the Dutch health care system.

Over a period of 18 months, eight hospital units of the Hospital Gelderse Vallei in Ede and the Diakonessenhuis in Utrecht and Zeist in the Netherlands, will receive the intervention. Every three months two new units will start.

Intervention

The Hospital Elder Life Program (HELP) is an innovative program. It is designed to prevent delirium and cognitive and functional decline in hospitalized older people. The strengths of the program include the targeted nature of the interventions; early intervention focusing on prevention, well-trained staff dedicated to the program, standardized intervention protocols, tracking of adherence to all protocols, and built-in quality assurance procedures. The primary goals of the program are:

1. Maintaining cognitive and physical functioning of high risk older adults throughout hospitalization;

2. Maximizing independence at discharge;

3. Assisting with the transition from hospital to home;

4. Preventing unplanned hospital readmissions.

HELP provides multicomponent protocols targeted at specific risk factors for delirium and introduces a different view on care organisation and a change in care processes. Trained volunteers play a pivotal role in HELP. The volunteers stimulate patients to eat, drink and walk, they read newspapers with patients, do (word)games and other activities. The volunteer training consists of classroom instruction which includes didactic training, small group demonstration, role playing and case discussions. Volunteers have transfer communication with each other, the Nurse Practitioner and the nurses during each volunteer shift. Volunteers are additionally coached and trained quarterly with educational sessions and discussion groups.

Before the unit starts, a team of HELP volunteers is assembled and receives a for HELP developed two day training. Each hospital has created a group of experts that gathers approximately every two months to discuss the HELP plans and its progress. This group can consist of the head of and nurses of the participating hospital units, a doctor, the volunteer coordinator and project leader. Every day a volunteer has a 3 hour shift on a participating intervention department, seeing the included patients.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients are at least 70 years of age;

2. Have no delirium and are considered at risk for delirium at admission.

Exclusion criteria

1. Older Ppatients in life threatening situations or in a terminal palliative phase at admission;

2. Patients with an expected hospital stay of 24 hours or less;

3. Patients who are legally incapable of participating;

4. Patients unable to communicate verbally;

5. Patients unable to communicate in Dutch;

6. Patients with profound aphasia;

7. Patients with intubation or respiratory isolation;

8. Patients with a second hospital admission on one of the participating units during the study period. If patients are transferred to a participating unit, they are treated as a newly admitted patient. If patients are transferred from a participating unit to a not participating unit, they are excluded from the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2012
Enrollment:	1081
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-01-2013
Application type:	First submission

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
NTR-new	NL3672
NTR-old	NTR3842
Other	METC UMC Utrecht : 12-222/E
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A