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Optimising acute delirium care in Tan Tock Seng Hospital

Submission date
05/06/2011

Recruitment status
No longer recruiting

Registration date
13/06/2011

Overall study status
Completed

Last Edited
24/05/2017

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Delirium is a state of mental confusion that affects 30-40% of elderly people admitted to hospital. Studies have shown that one in four geriatric patients suffers from an episode of delirium at least once during their stay in the hospital. It is associated with poor outcomes at hospital discharge as the condition of delirium could persist for as long as 6 to 12 months after discharge, resulting in the need for rehabilitation services, nursing home placement or home care services. The Geriatric Monitoring Unit (GMU) is a specialised 5-bed unit for delirious patients, supported by 24-hour intensive nursing care. The GMU provides a controlled environment for the treatment of delirious patients. In this unit, the medical team is able to treat the delirious patients in an optimal environment where aggravating factors of delirium such as the use of physical constraint, medication, changes to surrounding environment and source of noise and distracters can be minimised or removed entirely. The aim of this study is to look at outcomes in patients with delirium who are admitted to the Geriatric Monitoring Unit (GMU), compared to usual clinical care in a general ward setting.

Who can participate?
Patients aged 65 and over with delirium

What does the study involve?
Participants are randomly allocated either to be admitted to GMU or to be put on a waiting list and receive the usual good care in the geriatric medicine department. The duration of delirium, length of hospital stay, rate of falls, types of injuries (if falls occur), reduction in use of physical restraints, medication use, urinary catheter use, pressure ulcers, infections, and family/caregiver satisfaction are all measured when the participants are followed up 6 and 12 months later.

What are the possible benefits and risks of participating?
The results of this study may help the healthcare system by improving patient safety, quality of care, and patient/family/caregiver satisfaction. There are no risks to participants as this is an observational study and no additional specific treatments are carried out.

Where is the study run from?
Tan Tock Seng Hospital (Singapore)

When is the study starting and how long is it expected to run for?
November 2010 to November 2011

Who is funding the study?
Ministry of Health Healthcare Quality Improvement Funding (Singapore)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HQIF 2011/19

Study information

Scientific Title
A new model of hospital care for frail elderly persons admitted to hospital with delirium

Study objectives
The trialists describe a new model of delirium care in the acute care setting, titled Geriatric Monitoring Unit (GMU) where the important concepts of delirium prevention and management are integrated. The primary aim of this study is to compare delirious patients admitted to the Geriatric Monitoring Unit (GMU), compared to usual geriatric care in general ward setting. The trialists postulate better outcomes in patients admitted to GMU versus usual geriatric care. The

secondary aims include looking at which specific aspects of the interventions would yield the greatest benefit for future translation on a larger scale. The trialists hypothesize that patients with delirium admitted to the GMU will have better clinical outcomes with less need for physical and psychotropic restraints compared to usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Healthcare Group Domain Specific Review Board (DSRB), October 2010, latest approval 03/06/2011, ref: A/10/510

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Delirium care in frail older persons admitted to the geriatric medicine department

Interventions
1. The Geriatric Monitoring Unit (GMU) is a specialised 5 bedded unit which incorporates specific room design for an elder-friendly environment, lower staff-patient ratio, coupled with structured core, supported by 24-hour intensive nursing care
2. Multicomponent intervention and bright light therapy on sleep of these patients as well as the effect in antipsychotic and sedative-hypnotic use
3. The trialists wanted to study if patients with delirium admitted to GMU had better outcomes compared to those managed with usual care in the geriatric medicine department
4. The GMU consist of the interventions as listed above
5. The study consists of a pre/post GMU implementation as well as a concurrent GMU patients versus patients with delirium managed in the geriatric ward as controls

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Duration of delirium and severity of delirium
2. Use of physical and chemical restraints
3. Falls rate
4. Physical injury rate due to agitated behavior
5. Functional outcomes/gains in the elderly geriatric patients
6. Morbidity (such as nosocomial infection rate, urinary catheter use and catheter days, pressure ulcer rate)
7. Patient and family satisfaction score in elderly persons with delirium

Secondary outcome measures
1. Looking at which specific aspects of the interventions would yield the greatest benefit for future translation on a larger scale
2. The effects of the multicomponent intervention and bright light therapy on sleep of these patients as well as their effect on antipsychotic and sedative hypnotic use

Overall study start date
01/11/2010

Completion date
01/11/2011

Eligibility

Key inclusion criteria
1. Patients above age of 65 years old
2. Admitted to the geriatric medicine department in Tan Tock Seng Hospital who were assessed to have delirium (either on admission or incident delirium during hospital stay)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Medical illnesses which requires special monitoring (e.g. telemetry for arrhythmias or acute myocardial infarction)
2. Deemed to be dangerously ill, in coma or had terminal illness
3. Uncommunicative patients or patients with severe aphasia
4. Severely combative behaviour with high risk of harm
5. Patients with mania or other severe eye disorders and other contraindications to bright light therapy (such as patients on photosensitising medications)

6. Patients with respiratory or contact precautions, or there was verbal refusal of GMU stay by family, patient or physician in charge

Date of first enrolment
01/11/2010

Date of final enrolment
01/11/2011

Locations

Countries of recruitment
Singapore

Study participating centre
Tan Tock Seng Hospital
Singapore
Singapore
S308433

Sponsor information

Organisation
Ministry of Health (Singapore)

Sponsor details
College of Medicine Building
16 College Road
169854
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179854

Sponsor type
Government

Website
http://www.moh.gov.sg

ROR
https://ror.org/00mrhvv69

Funder(s)

Funder type
Government

Funder Name
Ministry of Health Healthcare Quality Improvement Funding (HQIF2) (Singapore)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/08/2011		Yes	No
Results article	results	08/04/2014		Yes	No