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Evaluation of a nurse mentoring intervention to family caregivers in the management of delirium after cardiac surgery (MENTOR_D)

Submission date
19/02/2013

Recruitment status
No longer recruiting

Registration date
27/03/2013

Overall study status
Completed

Last Edited
24/06/2015

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
We are carrying out a study of 30 patients with post-cardiac surgery delirium (acute confusional state) to evaluate the acceptability and feasibility of a nursing intervention aimed at mentoring family caregivers in the management of delirium. Our goal is to mentor caregivers in adopting specific behaviours, for example communication strategies, which have been linked to lowering delirium severity in patients. We will also want to look at the preliminary effect of the intervention on the severity of delirium, delirium-related complications, length of hospital stay and the patient's recovery, as well as caregiver anxiety and sense of self-efficacy. In addition, the validity of a physiological indicator of delirium, cerebral oximetry, will be explored and compared to standard measures of delirium. The study's findings should help us determine if such an intervention is feasible and acceptable within a critical care context as well as suggest adjustments for a larger trial.

Who can participate?
The MENTOR_D study aims to recruit 30 patients paired with 30 family caregivers from a cardiology center in Canada. The patients must undergo heart surgery and be at high risk of delirium and the family caregivers must be aged > 18 years and be available for daily visits at the patient's bedside.

What does the study involve?
Over a period of three days following delirium onset, the family caregivers participants who were randomly assigned to the intervention group will be mentored by a nurse to enhance their participation in delirium management. The intervention will mentor caregivers in adopting specific behaviours, for example communication strategies, which have been linked to lowering delirium severity in patients. The nurse mentor will provide two daily meetings for three consecutive days after the onset of delirium aimed at enabling the caregiver to respond appropriately at the bedside of the delirious patient. At the end of the study, we will compare patient and family caregiver outcomes in the control group to the outcomes in the intervention group. Patient outcomes will include delirium severity, delirium related complications and recovery. Family caregiver outcomes will include anxiety level and self-efficacy. Finally, cerebral

oxygen saturation measurements will also be taken on the 30 patients. These measures will be compared to standard delirium rating scales such as the Confusion Assessment Method.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But there should be benefits to future patients and family caregivers affected by post-cardiac surgery delirium, as this study will inform nurses on how to better intervene with this clientele. This study does not implicate any particular physical risks, although the time required to complete the questionnaires can be a disadvantage.

Where is the study run from?
The study has been set up by the Montreal Heart Institute Research Center.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start mid-winter 2013. Participants will be enrolled in the study for a period of 1 month.

Who is funding the study?
Funding has been provided from Quebec Interuniversity Nursing Intervention Research Group and Quebecs Minister of Education, Recreation and Sports.

Who is the main contact?
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PhD candidate Tanya Mailhot, t.mailhot@umontreal.ca

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ICM-12-1420

Study information

Scientific Title
Evaluation of a nurse mentoring intervention to family caregivers in the management of delirium after cardiac surgery (MENTOR_D): a randomized pilot study

Acronym
MENTOR_D

Study objectives
The purpose of this pilot trial is to assess the acceptability, feasibility and preliminary efficacy of the intervention.

The study hypothesis was that following the onset of delirium, compared with patients in the control group, those in the intervention group would present less severe delirium and a lower number of adverse clinical events in the first 3 days, as well as a shorter length of hospital stay and a better psychosocial profile at one month. Additionally, compared with caregivers in the control group, those in the intervention group will present a lower level of anxiety and a higher sense of self-efficacy at 4 days following the intervention, at hospital discharge, and at 1 month post-discharge.

On 12/06/2014 the following changes were made to the trial record:
1. The public title was changed from 'Evaluation of a nursing intervention aimed at MENTORing family caregivers in the management of Delirium following cardiac surgery' to 'Evaluation of a nurse mentoring intervention to family caregivers in the management of delirium after cardiac surgery (MENTOR_D)'
2. The scientific title was changed from 'Evaluation of a nursing intervention aimed at mentoring family caregivers in the management of delirium following cardiac surgery: a randomized pilot study' to 'Evaluation of a nurse mentoring intervention to family caregivers in the management of delirium after cardiac surgery (MENTOR_D): a randomized pilot study'

Ethics approval required
Old ethics approval format

Ethics approval(s)
Montreal Heart Institute, 17/01/2013, ref: 12-1420

Study design
Two groups randomized pilot study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Post cardiac surgery delirium

Interventions
Control group:
No specific intervention, other than usual care, is planned for the control group.

Intervention group:
The nursing intervention consists of seven meetings between the nurse-mentor and the family caregiver: two daily meetings during the first three consecutive days following a delirium episode and the seventh meeting before hospital discharge. This number of meetings was chosen because of the intensity required to observe an effect, the involvement required from caregivers, and the constraints of an acute care patient following cardiac surgery (visiting hours, fragility, critical care). The six daily meetings will enable the nurse to mentor caregivers in adopting key behaviors when at the delirious patient's bedside. The mentorship is based on Bandura's (1986) social-cognitive theory with principles of self-efficacy based on Watson's caring theory (2008). Using this framework of learned behaviour, the nurse-mentor will focus on enhancing the caregiver's perception of his capacity to manage the manifestations of delirium. Several behaviors will be suggested to the caregivers and can be classified into three categories: 1) being attentive, 2) maintaining contact with the delirious person using communication strategies and 3) being a reassuring presence.
Finally, a seventh meeting will be offered to caregivers and patients just before hospital discharge, to better prepare participants for home and enable them to discuss the delirium experienced during hospitalization.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Assessing the acceptability and feasibility of the intervention and the methodology of the study.

Secondary outcome measures
Assessing the preliminary efficacy of the experimental nursing intervention on:
1. Delirium severity Days 1-3, measured with the Delirium Index
2. Adverse clinical events Days 1-3 (dehiscence, falls, respiratory tract infection, accidental removal of urinary catheters, drains or arterial lines or endotracheal tubes)
3. Length of hospital stay (in the intensive care unit and overall)
4. Patient psychosocial profile at one month, measured with the Sickness Impact Profile
5. Caregiver anxiety at 4 days post-intervention, hospital discharge and one month post-

discharge measured with the State-Trait-Anxiety-Inventory
6. Caregiver self-efficacy at 4 days post-intervention, hospital discharge and one month post-discharge measured with a self-efficacy scale

Assessing the relationship between cerebral oximetry values and standard tools for detecting and assessing the severity of delirium.

Overall study start date
18/02/2013

Completion date
31/08/2014

Eligibility

Key inclusion criteria
Current inclusion criteria as of 24/06/2015:
For patients and caregivers:
1. Be 18 years of age or older
2. Speak and read French
3. Present physical and cognitive abilities (before surgery) to agree to participate in the study

For patients:
1. Have delirium following a surgical procedure of coronary artery bypass graft (CABG), heart valve plasty or replacement. Delirium is defined by a score of 4 or higher on the Intensive Care Delirium Screening Checklist (ICDSC-Bergeron, et al., 2001) and confirmed by a medical diagnosis

For caregivers:
1. Identify oneself as the caregiver to the patient who will undergo surgery
2. Be available to go to the bedside twice daily for three consecutive days after the detection of delirium

Previous inclusion criteria from 12/06/2014 to 24/06/2015:
For patients and caregivers:
1. Be 18 years of age or older
2. Speak and read French
3. Present physical and cognitive abilities (before surgery) to agree to participate in the study

For patients:
1. Have had a surgical procedure of coronary artery bypass graft (CABG), heart valve plasty or replacement
2. Planning to spend the full length of the postoperative stay in the research center (patients from a referring center will not be eligible as their length of stay in the research environment is shorter than the time required for this protocol, even in the presence of delirium)
3. Present postoperative delirium defined by a score of 4 or higher on the Intensive Care Delirium Screening Checklist (ICDSC-Bergeron, et al., 2001) and confirmed by a medical diagnosis

For caregivers:
1. Identify oneself as the caregiver to the patient who will undergo surgery
2. Be available to go to the bedside twice daily for three consecutive days after the detection of delirium

Original inclusion criteria until 12/06/2014:
For patients and caregivers:
1. Be 18 years of age or older
2. Speak and read French
3. Present physical and cognitive abilities (before surgery) to agree to participate in the study

For patients:
1. Have had a surgical procedure of coronary artery bypass graft (CABG), heart valve plasty or replacement
2. Planning to spend the full length of the postoperative stay in the research center (patients from a referring center will not be eligible as their length of stay in the research environment is shorter than the time required for this protocol, even in the presence of delirium)
3. Present a high risk of delirium before surgery according to the presence of at least three risk factors identified in systematic reviews: age ≥ 65 years; history of delirium; active smoker; take three or more alcoholic drinks per day; have a cognitive impairment (prior dementia, prior cognitive decline) or a sensory impairment (hearing)
4. Present delirium after cardiac surgery defined by a score of 4 or higher on the Intensive Care Delirium Screening Checklist (ICDSC-Bergeron, et al., 2001), used each shift in usual care, and confirmed by diagnosis.

For caregivers:
1. Be identified in the first study information meeting as the caregiver the patient who will undergo surgery
2. Be available to go to the bedside twice daily for three consecutive days after the detection of delirium

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30 dyads (30 patients and 30 family caregivers) (N = 15 dyads/group)

Key exclusion criteria
Current exclusion criteria as of 12/06/2014:
For patients:
1. Expressing a refusal to participate in the study after delirium
2. Be referred to the palliative care team due to severe post-operative complications

Previous exclusion criteria:
For patients:
1. Undergo an emergency cardiac surgery that prevents obtaining informed consent before the procedure

Date of first enrolment
18/02/2013

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
Canada

Study participating centre
Montreal Heart Institute Research Centre
Montreal
Canada
H1T 1C8

Sponsor information

Organisation
Montreal Heart Institute Research Center (Canada)

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Sponsor type
Research organisation

Website
http://www.icm-mhi.org/en/index.html

ROR
https://ror.org/03vs03g62

Funder(s)

Funder type

Government

Funder Name
Quebec Interuniversity Nursing Intervention Research Group [Groupe de recherche interuniversitaire en interventions en sciences infirmières du Québec (GRIISIQ)] (Canada)

Funder Name
Ministry of Education, Sports and Leisure of Quebec [Ministère de l'éducation, du sport et des loisirs du Québec] (MELS) (Canada)

Funder Name
Québec Research Fund-Health [Fonds de recherche du Québec-Santé] (FRQ-S) (Canada)

Funder Name
Research Network Nursing Intervention Quebec [Réseau de recherche en interventions en sciences infirmières du Québec] (RRISIQ) (Canada)

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	30/07/2014		Yes	No