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# Validation study of a delirium detection tool completed by families

**Submission date**
23/05/2018

**Recruitment status**
No longer recruiting

**Registration date**
01/06/2018

**Overall study status**
Completed

**Last Edited**
10/01/2019

**Condition category**
Mental and Behavioural Disorders

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

## Plain English summary of protocol

Background and study aims
Delirium among patients hospitalized in cardiology is widespread but challenging to identify. Family members are an untapped resource for detecting delirium as they know the patients' baseline level of cognitive function, which is key in detecting subtle cognitive changes occurring in delirium. The family confusion assessment method (FAM-CAM), is a tool that could support family involvement in the detection of delirium. However, the French version of the FAM-CAM has not yet been validated, which limits its use. The aim of this study is to translate, culturally adapt and validate the French version of the FAM-CAM among a cardiology population.

Who can participate?
Hospitalized patients and their family caregivers (spouse, child, other family, friend), aged 18 or older

What does the study involve?
For participants this study involves completing the translated FAM-CAM (an 11 item questionnaire) at the bedside of their loved one.

What are the possible benefits and risks of participating?
Participants will not derive any personal benefit from their participation in this study. However, the results that are obtained could contribute to the advancement of knowledge in this area. Aside from time spent completing the questionnaire, there are no other anticipated consequences or risks associated with participation.

Where is the study run from?
Montreal Heart Institute (Canada)

When is the study starting and how long is it expected to run for?
June 2018 to June 2019

Who is funding the study?
Montreal Heart Institute Foundation (Canada)

Who is the main contact?
Tanya Mailhot

# Contact information

### Type(s)
Scientific

### Contact name
Miss Tanya Mailhot

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# Additional identifiers

### Protocol serial number
ICM 2019-2426

# Study information

### Scientific Title
Evaluation of the psychometric properties of a delirium detection tool completed by families in cardiology

### Acronym
Detect_D

### Study objectives
The trialists performed the translation and cultural adaptation of the FAM-CAM according to the rigorous approach proposed by Sousa and Rojjanasrirat (2011). Following this, the psychometric properties of the French version of FAM-CAM were assessed among hospitalized patients in in cardiovascular care. To do so, the first aim (Aim#1) of this study was to assess the sensitivity and specificity of the French FAM-CAM by contrasting it with the reference standard (medical diagnosis according to DSM-5 criteria). The secondary aim was to assess the sensitivity and specificity of the French FAM-CAM by contrasting it with (Aim#2a) delirium defined from a set of keywords associated with delirium (encephalopathy, confusion, agitation, hallucination, somnolence, haldol [Puelle et al., 2015]) and with (Aim#2b) scores on the Confusion Assessment Method (CAM). The third aim (Aim#3) consisted of assessing the FAMCAM's predictive value by contrasting it with the reference standard using a ROC curve. Finally, the last aim (Aim#4) was to assess the reliability of the FAM-CAM by contrasting it with the CAM.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Montreal Heart Institute Ethics Board - approval pending

### Study design
Validation study

### Primary study design
Observational

### Study type(s)
Screening

### Health condition(s) or problem(s) studied
Delirium

### Interventions
The original English version of the FAM-CAM was translated and culturally adapted to French for Quebec, Canada with the method suggested by Sousa and Rojjanasrirat (2011). The process included obtaining the copyright clearance from the author for use and translation; double forward and backward translations; expert committee decision making and assessment of degree of clarity of the translated version by members of the population. Following this a validation study was performed using the French FAM-CAM. There is no follow-up planned in this study.

### Intervention Type
Other

### Primary outcome(s)
The sensitivity and specificity of the French FAM-CAM compared with the reference standard (medical diagnosis according to DSM-5 criteria)

### Key secondary outcome(s))
1. The sensitivity and specificity of the French FAM-CAM compared with delirium defined from a set of keywords associated with delirium (encephalopathy, confusion, agitation, hallucination, somnolence, haldol [Puelle et al., 2015]) and with scores on the Confusion Assessment Method (CAM)
2. The FAMCAM's predictive value compared with the reference standard using a ROC curve
3. The reliability of the FAM-CAM compared with the CAM

### Completion date
15/06/2019

## Eligibility

### Key inclusion criteria
1. The family caregiver had to identify as a family caregiver (spouse, child, other family, friend) of an inpatient

2. Report having regular contact before hospitalization (≥ once a week). In the literature, this frequency of interaction was considered sufficient for the family member to report the usual cognitive and functional state of the patient, a knowledge necessary to be able to identify changes (Martins et al., 2014; Steis et al., 2012)
3. Have visited the patient at the hospital at least twice
4. Have the capacity to provide informed consent
5. 18 years old or older
6. Understand and read French
7. The hospitalized patient had to have the ability to provide informed consent or have a legal representative if their cognitive functioning was altered and present a stable clinical condition, allowing the evaluation of delirium using a questionnaire such as FAMCAM

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
18/06/2018

### Date of final enrolment
31/12/2018

## Locations

### Countries of recruitment
Canada

### Study participating centre
**Montreal Heart Institute**
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# Sponsor information

### Organisation
Montreal Heart Institute Research Center

### ROR
https://ror.org/03vs03g62

# Funder(s)

### Funder type
Charity

### Funder Name
Montreal Heart Institute Foundation

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to policies of the ethics committee.

### IPD sharing plan summary
Not expected to be made available

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |