

Delirium management involving families

**A delirium management intervention involving families following cardiac surgery:  
randomized pilot study**

Short Title:

**Delirium management involving families**

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### **Abstract**

**Aims.** To assess the feasibility, acceptability and preliminary efficacy of a nursing intervention involving family caregivers (FC) in the management of delirium in cardiac surgery patients.

**Background.** Tailored interventions offered by FC could optimise delirium management and FC outcomes.

**Design.** Randomized pilot study.

**Methods.** Thirty patient/FC dyads were randomized to usual care (n=14) or intervention (n=16). The intervention was based on the Human Caring Theory, a mentoring model and sources of self-efficacy. This combination led the mentored FC to intervene with the patient presenting delirium. The primary indicator of acceptability was consent from 75% of approached FC. Data was analyzed using descriptive statistics, ANCOVAs and logistic regressions.

**Results.** The intervention was acceptable and feasible. The primary indicator of consenting FC was achieved (77%). Recruitment was challenging with the number of eligible patients being less than anticipated. Out of the 14 dyads in which the patient was hospitalised for the 3-day intervention duration, 13 received all planned encounters (93%). Intervention group patients presented better recovery scores when compared to control group patients (p=0.01). Results favored the intervention group on preliminary efficacy outcomes, length of postoperative hospital stay, FC anxiety and self-efficacy.

**Conclusion.** To our knowledge the present study is the first to report on a delirium management intervention which involves FC in post cardiac surgery patients. Our findings

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support the potential of family involvement in delirium management, highlight challenges and strategies towards conducting research in this field, and provide a strong basis for a larger study.

**Relevance to Clinical Practice:** FC implication in delirium management has the potential to lead to positive patient and FC outcomes, and should be considered in nursing interventions. **Trial registration:** [www.controlled-trials.com](http://www.controlled-trials.com); #ISRCTN95736036

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### **Introduction**

Delirium occurrence and delay in its management is related to worse psychofunctional recovery, and increased length of hospital stay and mortality (McCusker et al., 2001, Rudolph et al., 2010). Furthermore, witnessing delirium is disturbing for family caregivers (FC), who report anxiety and a low sense of self-efficacy in their ability to care for their relative who presents delirium (O'Malley et al., 2008). In fact, FC asks to be informed on delirium and more involved (O'Malley et al., 2008).

As many delirium manifestations (e.g., hallucinations or fears) are linked to patient's background and personality, it is difficult to understand and reassure each patient in a tailored manner without knowledge of his personality and life story (Barron and Holmes, 2013). In critical and acute care settings, the clinical team has limited knowledge to enable such a personalized approach (Barron & Holmes, 2013).

As highlighted in recent literature reviews, family expertise has emerged as a solution for tailored delirium management interventions (Halloway, 2014, Paulson et al., 2016). However, families' involvement in delirium management has only been assessed in two studies among critical and acute care patients (Black et al., 2011; Martinez et al., 2012). Black et al. (2011) involved families in providing psychological care, for example using reassurance, resulting in patients' enhanced psychosocial recovery. Martinez et al. (2012) taught non-pharmacological interventions to families and observed a lower prevalence of delirium. A central element emerging from these studies is the complementarity of families' and nurses' expertise. An exchange in the families' knowledge of patient's personality and life story and the nurse's knowledge of delirium and acute care could lead to optimally tailored delirium management interventions.

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Because only a few studies have evaluated delirium management interventions tailored to patient's personality and life story by FC in acute care, a randomized pilot study was undertaken to determine the acceptability and feasibility of the study design and experimental nursing intervention [REDACTED] et al., 2014).

### **Background**

#### **Interventions for delirium**

Delirium prevention is the first line of defence. However, delirium cannot always be prevented, especially in vulnerable populations. Best practice guidelines suggest the implementation of interventions such as: orientation, mobilization, facilitate presence of family members and tailor delirium interventions based on each patient's personality and life story (APA, 1999, AGS, 2015, Barr et al., 2013, Cook & APA, 2004, RNAO, 2016). The majority of non-pharmacologic interventions suggested in practice guidelines have been tested in multiple studies, during which they were implemented to prevent delirium, therefore before delirium occurrence. Little is known about the impact of interventions implemented once delirium has occurred or on how to best facilitate presence of family members, answer their concerns and tailor delirium interventions (Barr et al., 2013, Cook & APA, 2004, RNAO, 2016). Out of the four clinical trials conducted with delirium management interventions, the two which showed significant results in lowering delirium length, mortality, length of stay and enhanced recovery, involved nurses and interventions from best practice guidelines in addition to a minimal participation from families, while the two others did not (Cole et al., 1994, Cole et al., 2002, Lundstrom et al., 2005, Pitkälä et al., 2006).

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Considering the available literature, we identified a potential novel intervention in enhancing delirium management, while addressing FC concerns. Based on the work from Sidani and Braden (2011), we developed a nursing intervention aimed at enhancing FC participation in delirium management.

### **Theoretical framework**

Our nursing intervention was based a theoretical framework consisting of three elements and aimed at having FC participate in delirium management interventions. We hypothesized that a nursing approach based on the Caritas Processes from the Human Caring Theory (Watson, 2008), in a mentoring context as described by Anderson and Shannon (1988) while utilising the sources of information described by Bandura (1997) to influence FC's self-efficacy would enhance FC participation. In the present intervention, the nurse-mentor would learn from the FC's expertise on the patient's personality and life story and the FC would learn from the nurse-mentor on delirium management strategies. This exchange in expertise, contextualized in nursing approach based on the Human Caring Theory, was thought to result in the co-creation of tailored delirium management interventions provided by the FC and nurse-mentor (Wagner and Seymour, 2007).

### **Aims**

The primary aim was to examine the acceptability and feasibility of the study design and experimental intervention. The secondary aim was to examine the preliminary efficacy among patients (delirium severity [H1]; complications [H2]; length of stay [H3]; and psycho-functional recovery [H4]) and FC (anxiety levels [H5]; self-efficacy [H6]). In addition to severity, we explored delirium occurrence and duration.



## **METHODS**

The pilot study was approved by the Institutional review board of the Research Center, a Canadian tertiary cardiology hospital (#2012-288, 1420, FWA00003235) and was registered (Controlled Trials #ISRCTN95736036). The protocol of this pilot has been previously published (██████ et al., 2014). Reporting was guided by the CONSORT statement, extension for trials of non-pharmacological treatments. A total of 30 dyads (patient-FC) participated in the study following cardiac surgery and onset of delirium, detected by a score of four or higher on the Intensive Care Delirium Screening Checklist (ICDSC) (Bergeron et al., 2001) and confirmed by a medical diagnosis. As patients were required to present with delirium at study entry, recruitment was achieved through surrogate consent by a FC initially and then confirmed by the patient after delirium resolution. The randomization sequence was generated by an independent statistician. To avoid the FC in the CG witnessing the experimental intervention, each group was randomized to blocks of two weeks. Participant allocation was unveiled using sealed opaque envelopes.

### **Experimental MENTOR\_D nursing intervention**

The intervention aimed to develop FC sense of self-efficacy to intervene in delirium management with their loved one. To achieve this, a nurse acted as a mentor who provided information on delirium and guidance to the FC in his new role of intervening in delirium management. The aim was to have FC and his nurse mentor collaborate together to intervene during delirium. The delirium management interventions provided by the FC were named family caregiver interventions (FCI). A full description of the intervention is detailed in Table 1 (Hoffmann et al., 2014).

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### **Measurements and analyses**

The primary indicator of acceptability was to obtain consent from 75% of the FC approached for participation. Additionally, we used the following variables to assess **acceptability and feasibility of the study design** (Richards and Hallberg, 2015, Sidani and Braden, 2011): number of eligible patients, FC refusal reasons and length of recruitment. The following variables were based on work from Sidani and Braden (2011) and used to assess the **acceptability and feasibility of the intervention**: score on the Treatment Acceptability and Preference Questionnaire (TAPQ) (Sidani et al., 2009), most frequently provided FCI.

The **preliminary efficacy** outcome of delirium severity (H1) was measured using the Delirium Index (DI), a 7 item scale with a maximum score of 21 indicating more severe delirium (McCusker et al., 2004). Patient complications during delirium (H2) and length of postoperative hospital stay (H3) were collected from the medical chart by a research assistant. The psycho-functional recovery (H4) was assessed using the Sickness Impact Profile (SIP), a 48 true or false items for a possible score of 48 reflecting worse recovery (Chwalow et al., 1992). The FC's anxiety (H5) was assessed with the State Trait Anxiety Inventory state (STAIS) a 20 item likert scale with a maximum score of 80 reflecting higher anxiety (Bergeron et al., 1983). The self-efficacy (H6) was assessed using a 14 item likert scale adapted from Bandura's guide with a maximum of 140 indicating higher sense of self-efficacy (Bandura, 2006). The Confusion Assessment Method-Intensive Care Unit (CAM-ICU) was also used to measure the occurrence of delirium (Ely et al., 2001). Finally, delirium duration was recorded using onset and end dates from the medical charts.

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Sociodemographic information, such as gender and age, and clinical variables were collected from medical records. The clinical variables were selected from the literature and our clinical practice for their potential influence on delirium was assessed as potential covariates (Gosselt et al., 2015).

### **Statistical Methods**

For acceptability and feasibility of the study design and intervention, in addition to sociodemographic and clinical data, descriptive statistics were used. Between-group differences for **H1** on delirium severity, **H3** on length of postoperative hospital stay, **H4** on psycho-functional recovery, **H5** on FC anxiety, and **H6** on FC self-efficacy were analyzed using a repeated measure analysis of covariance (ANCOVA) with one within-subject factor (day 1, 2 and 3 scores for H1 and day 4, 15 and 30 for H5 and H6), one between-subject factor (CG or IG), and finally, the covariates described below. A logistic regression was performed for **H2** on complications. For each questionnaire, reliability was assessed using either the Alpha coefficients for continuous variables or the Kuder-Richardson-20 for the dichotomous variables. Descriptive statistics were used to report on delirium occurrence reflected by the CAM-ICU scores and delirium duration in both groups. Sensitivity analyses were conducted by replicating analyses without outliers, who were determined based on clinical data before delirium onset. Because of the small sample size, no imputation of missing data was planned. All hypothesis testing were performed by biostatistician, without knowledge of allocation, using SAS and all other descriptive statistics were performed using version 21.0, SPSS Inc., Chicago, USA. The significance level was set at 0.05 (two tailed) for all tests.

### **Results**

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Participants were enrolled from July 2<sup>nd</sup> 2013 to June 6<sup>th</sup> 2015, including the follow-up up to day 30 following delirium onset (Figure 1). They were generally male aged an average of 75 years old in both groups. Compared to the IG, fewer CG patients drank alcohol (CG: n=1; IG: n=2), or had experienced past episodes of delirium (CG: n=1; IG: n=4) or depression (CG: n=3; IG: n=7). In terms of surgical and postoperative characteristics before delirium, CG patients had longer cardiopulmonary bypass (CG: 89 min; standard deviation [SD]: 9 min; IG: 72 min; SD: 7 min), clamp (CG: 64 min; SD: 8 min; IG: 56 min; SD: 7 min), and intubation durations (CG: 23h 3 min; SD: 38 h 2 min; IG: 7 h 5 min; SD: 6 h 6 min), these later differences being explained in part to two CG patients that had longer cardiopulmonary bypass duration, showing clinical instability during the surgery. Imbalances between the two groups were observed following delirium onset. Control group patients had higher rates of in-room surveillance, physical restraints and two of the CG patients had to be re-intubated on day 3. In sum, the CG patients had clinical characteristics, which may not favor their postoperative recovery including delirium resorption.

### **Results for Acceptability and Feasibility**

As for the **study design**, we obtained an acceptance rate of 77 % from FC approached. Patients were excluded mainly because there was no FC available to be present at the bedside to provide surrogate consent within 24 hours of delirium onset (n=214), or they were transferred to another hospital before the intervention could begin (n=96), resulting in 64 eligible patients (Figure 1). Nine FC refused either because they were uncomfortable with surrogate consent (n=1), or were unavailable/felt incapable due to

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advanced age (n=1), work (n=2), or living too far away (n=5). This resulted in a recruitment period of close to two years.

As for the **intervention**, the results from the TAPQ were highly positive with a majority of the 16 FC in the IG indicating the intervention was “extremely” appropriate (n=11) and acceptable (n=12) as well as “extremely” (n=10) or “very” (n=6) effective in helping them intervene at the bedside. All FC responded that they would agree to participate in the intervention again (“very” n=3 and “extremely” n=13). Out of the 14 dyads in which the patient was hospitalised for the full duration of the intervention, 13 received the all planned encounters (93%). Finally, the following FCI were used by more than 50% the FC for the bedside phase: “observe signs of delirium”, “verify if my loved one is wearing eyeglasses or hearing aid” and “talk about family memories that your loved one enjoys”.

### **Results for Preliminary Efficacy**

The observed Alpha coefficients or the Kuder-Richardson-20 were of 0.60 to 0.90 for the DI, 0.84 for the SIP, 0.89 to 0.92 for the STAIS, 0.92 to 0.93 for the self-efficacy scale and finally between 0.90 to 0.95 for the CAM-ICU.

Mean delirium severity (H1) scores (SD) showed similar trajectories on days 1, 2 and 3 in both groups (**CG**: day 1: 12.07(4.05), day 2: 8(6.34), day 3: 5.5(7) and **IG**: day 1: 10.56(3.5), day 2: 5.38(5.45), day 3: 3.43(4.96), p=0.27 in ANCOVA model). Results remained unchanged after removing two patients with clinical instability during surgery in the CG. The number of patients who had any clinical complications on days 1, 2 or 3 following delirium onset (H2) was similar in the two groups (CG: n= 3 versus IG: n =2, p=0.90 in logistic regression analyses).

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All other between-group differences favoured the IG. The mean (SD) length of postoperative hospital stay (H3) was almost half in the IG (mean 6.30 days (7.00) versus CG (mean 12.10 days (11.10),  $p=0.34$  in ANCOVA model). Patients' psycho-functional recovery (H4), assessed at day 30 using the Sickness Impact Profile (SIP), showed the IG (mean SIP score 4.80 (3.20)) was almost half than that of the CG (mean SIP score 9.50 (6.30),  $p=0.01$ ), indicating a more favorable recovery for the IG in the ANCOVA model.

All scores on mean anxiety (H5) favored the FC in the IG but this difference was not statistically significant in ANCOVA models (CG: day 4: 43.86(11.46), day 15: 41(9.22), day 30: 37.42(9.96) and IG: day 4: 36.62(7.36), day 15: 36.69(7.72), day 30: 36.87(11.43),  $p=0.21$  in ANCOVA model). Similar results were observed for H5 on self-efficacy (H6) (CG: day 4: 110.43(16.87), day 15: 112.58(15.52), day 30: 115.36(15.81) and IG: day 4: 124.25(9.16), day 15: 123.06(7.05), day 30: 124.93(6.1),  $p=0.15$  in ANCOVA model).

In terms of other delirium assessments, the CAM-ICU scores favored the IG. A lower proportion of IG patients had positive CAM-ICU scores on day 2 (43.8%) compared to CG patients (71.4%) on the same day. Similarly, delirium duration showed a tendency to be shorter in the IG (mean days: 1.94 (1.34), CG (mean days: 4.14 (4.04)).

## Discussion

The objective of this pilot study was to examine the acceptability and feasibility of the study design and experimental nursing intervention, in addition to its preliminary efficacy. This study was acceptable and feasible for a majority of indicators, including our primary indicator of design acceptability: obtaining consent from  $\geq 75\%$  of approached FC.

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Our primary indicator of design acceptability was met, but the number of eligible patients was less than anticipated, possibly attributable to two reasons. First, delirium prevalence was lower than the expected 30% found in similar settings (van Eijk et al., 2009). We used the ICDSC detection tool as it was the one used in usual care. However, the ICDSC has been reported as less sensitive (reported sensitivity 43%) to hypoactive delirium, in comparison to the CAM-ICU (reported sensitivity 64%, van Eijk et al., 2011). As hypoactive delirium was more frequent in the present study, this reduced sensitivity could have resulted in a lower detection rate (van Eijk et al., 2011). Second, among patients with delirium, the two main reasons for exclusion were unavailability of FC to consent within 24 hours of delirium onset, or planned transfer to another hospital following surgery. Both reasons are attributable to the tertiary hospital setting where about one third of patients are referred from as far as hundreds of miles away. This can result in problems obtaining families' consent within 24 hours of delirium onset. This time frame was chosen to allow a rapid response to delirium. Indeed, as delirium duration is positively correlated with delirium related complications, it was thought to enhance the possibility of observing better patient outcomes (Jackson et al., 2016, Pisani et al., 2009). However, facing the recruitment challenges related to lack of family presence in the 24-hour time frame, future studies could consider a wider time frame for study entry (>24 hours following delirium onset), and control for this variability in the analyses.

Aside from these issues, we observed a low refusal and high satisfaction rate, with all FC indicating that they would agree to re-enter the study. Furthermore, it was feasible to tailor the intervention with the "FCI checklist" since all FC did not retain the same intervention types during the encounters. Additionally, the same FC showed variability in

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the selection of intervention types, suggesting the ability to offer tailored interventions adjusted to the patient's situation.

In terms of preliminary efficacy, delirium severity scores showed similar trends over three days for both groups. As our two groups were unbalanced possibly due to the small sample size, we replicated the analyses without the two patients with clinical instability during surgery. Trends remained the same, suggesting that the lack of difference between the two groups on delirium severity was not due to sicker patients in the CG. Two hypotheses are offered to better understand these results. Our first explanation relates to the measures of delirium: severity, occurrence and duration. Even though the two groups did not differ on delirium severity scores, they differed on delirium occurrence at day two (scores on the CAM-ICU) and on delirium duration, suggesting that there could have been an impact of our intervention on delirium occurrence and duration. Our observations on delirium occurrence favoring the IG are in line with a previous study which examined a family approach to delirium prevention and management in acute settings, in which authors observed lower rates of delirium occurrence in the IG (Martinez et al., 2012). Another explanation is insufficient intervention intensity. Tailored interventions, offered by FC twice daily, might have been lost among all other interventions provided by usual care teams. Among the two previous studies in similar context little information on duration of FC presence and extent of their involvement is reported (Black et al., 2011; Martinez et al., 2012). To provide more intense intervention to reduce delirium severity, future studies should consider providing the intervention by FC and usual care nurses, allowing tailored delirium management interventions to be provided all day instead of twice a day.



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We observed a statistically significant lower score on the SIP, meaning better psycho-functional recovery in the intervention group. This observation is consistent with findings by Black et al. (2011) in which an intervention facilitating family involvement led to enhanced psycho-functional recovery up to 12 weeks following admission to the ICU. Black et al. suggest this lasting impact to be potentially related to two factors: length of stay and their intervention which led families to learn skills they could have continued using following the intervention, in turn, supporting patient recovery. As results from both Black et al, and our study suggest the potential for long-lasting impacts of a family approach to delirium management, this merits further research.

It seems that even if the intensity of our intervention might have been insufficient to impact delirium severity, it was beneficial for FC who were less anxious and felt more efficacious. Our observations suggest the potential of our theoretical framework in allowing FC to be involved in the care of acutely ill patients who present delirium, while being less anxious and feeling capable of being involved. However, it is important to note that both groups presented high self-efficacy scores. It is possible that FC who agreed to participate in the study already felt more self-efficacious towards an active role in the patient's care and were prone to high scores and high involvement in the intervention. Nevertheless, our observations are in line with that of other studies in the field of dementia, where involvement of FC in the management of aggressive symptoms lead to diminished anxiety and enhanced self-efficacy (Brodaty and Arasaratnam, 2012).

### **Study strengths and limitations**

Strengths of this study include the randomized design and intervention checklists, allowing close follow-up of intervention delivery. Limitations are mostly related to pilot

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study characteristics. First, the sample size, although adequate for a pilot, was possibly responsible for the imbalance between groups in surgical procedure characteristics before delirium onset. Second, the single center design limits generalization of recruitment issues and other features.

### **Implications for research**

We conclude that it is acceptable and feasible to involve FC in an acute care environment with patients who present delirium. The preliminary effect of this novel intervention show a potential to diminish length of postoperative hospital stay, improve patient recovery, FC anxiety and self-efficacy.

To alleviate recruitment issues, future studies should consider using a detection tool highly sensitive both to hypoactive and hyperactive delirium and a research assistant screening all patients. Although, the experimental intervention was found to be acceptable and feasible, increasing its intensity might lead to better results on delirium. Our choice of measuring delirium severity was based on literature suggesting it is the most precise option to monitor delirium (Trzepacz et al., 2008). As we did not observe any difference between the two groups on the delirium severity score, but did on delirium occurrence other delirium measurements should be considered.

## **WHAT IS KNOWN ABOUT THE SUBJECT**

- Delirium cannot always be prevented in vulnerable patients
- There is an urgent need for tailored non-pharmacological interventions to manage delirium optimally and result in better outcomes for patients and families
- Expertise of families on patient's personality and life story has recently emerged as a solution to enhance delirium management, but the implication of family members during delirium in a post-cardiac surgery setting has not been assessed

## **WHAT THIS PAPER CONTRIBUTES**

- It is acceptable and feasible to involve families in an acute care environment with patients who present delirium
- The preliminary effect of this novel intervention show a potential to diminish length of postoperative hospital stay, improve patient recovery, FC anxiety and self-efficacy

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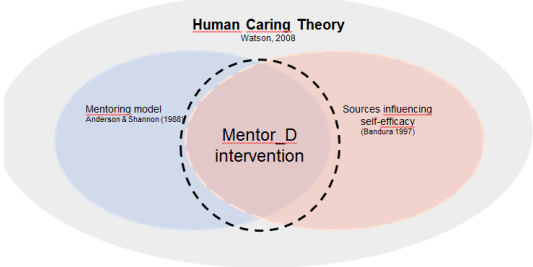
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# Delirium management involving families

Table 1. Description of the MENTOR D Experimental Intervention Based on the TIDieR Template.

<b>Title</b>	Mentoring of family caregivers concerning delirium management in post-cardiac surgery patients ( <b>MENTOR_D</b> )	
<b>What</b>	<p><b>Structure:</b> MENTOR_D Starts within 24 hours of delirium onset with a total of 7 encounters.</p> <p><b>Content:</b> MENTOR_D’s main objective was to offer guidance to the FC in their new role of intervening with the patient presenting delirium. The content is illustrated here:</p>	
	<p><b>Theoretical framework:</b> guided the nurse-mentor’s interventions</p>	<p><b>Empirical framework:</b> guided the family caregiver interventions (FCI)</p>
	 <p>The diagram illustrates the theoretical framework of the MENTOR_D intervention. At the center is a dashed circle labeled 'Mentor_D intervention'. This central circle is partially overlapped by two larger, semi-transparent circles: a blue one on the left labeled 'Mentoring model Anderson &amp; Shannon (1998)' and a red one on the right labeled 'Sources influencing self-efficacy (Bandura 1997)'. All three circles are contained within a larger, light grey oval labeled 'Human Caring Theory Watson, 2008'.</p>	<p><b>1. Best-practice guidelines:</b> Interventions from the HELP model of Inouye et al., 1999; Barr et al., 2013, Cook and APA, 2004, Day et al, 2011, Small et al., 2003, Virani, 2010, Sendelbach and Guthrie, 2009, RNAO, 2016</p> <p><b>2. Studies in dementia populations</b> Brodaty &amp; Arasaratnam,2012; Mason-Baughman &amp; Lander, 2012; Eggenberger, Heimerl &amp; Bennett, 2013; Small et al., 2003</p>
	<p><i>Examples of nurse-mentor interventions:</i></p> <p>Give information on appropriated actions to be taken by the FC at the bedside of the patient with delirium, encourage FC to use delirium management interventions at the bedside during delirium, give feedback.</p>	<p><i>Examples of FCI:</i></p> <p>Observe signs of delirium, communicate observations with the nurse, talk about family memories, use clear and simple sentences, verify if my loved one is wearing eyeglasses or hearing aids</p>
<b>Who</b>	The nurse-mentor was a doctoral student with a bachelor’s in nursing and previous experience working with cardiac surgery patients.	
<b>How</b>	Face-to-face encounters.	
<b>How much, where</b>	The planned duration of the first 6 encounters was of 60 minutes: with 30 minutes for pre-bedside phase, 15 minutes for the bedside phase and 15 minutes for post-bedside phase; and of 30 minutes for the 7 <sup>th</sup> discharge encounter. Pre- and post-bedside phases occurred either in the visitors’ lounge or research office, while the bedside phase occurred in the patient’s hospital room.	
<b>Tailor</b>	The intervention was tailored by the FC depending on their personal knowledge of the patient, and delirium manifestations at the time.	
<b>How well</b>	A “nurse-mentor intervention checklist” was completed by the nurse-mentor following each encounter. An “FCI checklist” was completed by the FC and nurse-mentor following each encounter.	



## Delirium management involving families

Table 2. *Preliminary efficacy of the Mentor\_D intervention.*

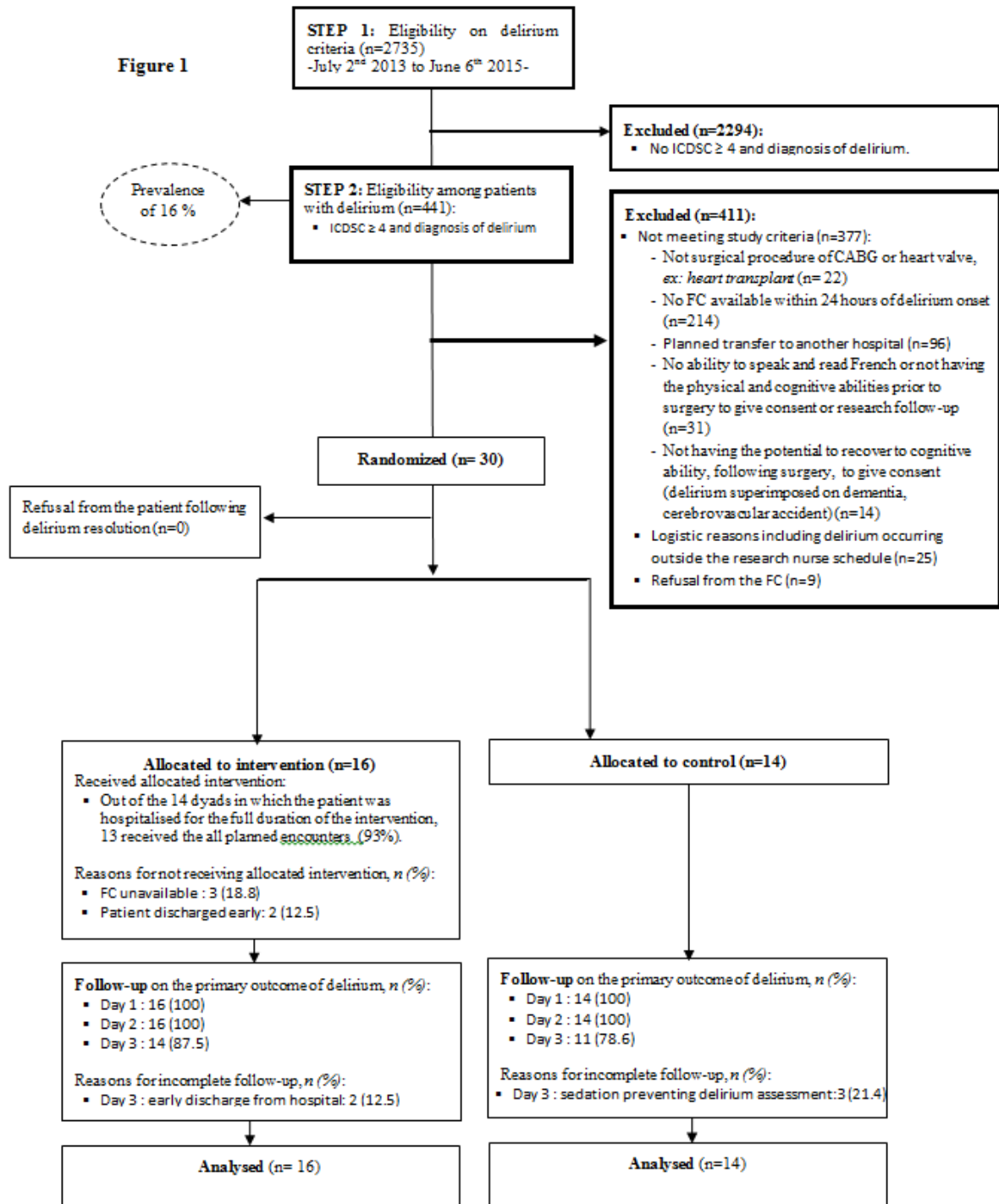
Preliminary efficacy outcome	Control group (n=14) Mean (Standard deviation) Frequency (percentage)	Intervention group (n=16) Mean (Standard deviation) Frequency (percentage)
H1- Delirium severity score <sup>a</sup>		
Day 1	12.07 (4.05)	10.56 (3.5)
Day 2	8 (6.34)	5.38 (5.45)
Day 3	5.5 (7)	3.43 (4.96)
H2 - Complications	3	2
H3 - Length of stay, <i>days</i>	6.30 (7.00)	12.10 (11.10)
H4 - Psycho-functional recovery score <sup>a</sup>	9.50 (6.30)	4.80 (3.20)
H5 - FC anxiety score <sup>a</sup>		
Day 4	43.86 (11.46)	36.62 (7.36)
Day 15	41 (9.22)	36.69 (7.72)
Day 30	37.42 (9.96)	36.87 (11.43)
H6 - FC self-efficacy score		
Day 4	110.43 (16.87)	124.25 (9.16)
Day 15	112.58 (15.52)	123.06 (7.05)
Day 30	115.36 (15.81)	124.93 (6.1)

<sup>a</sup> Higher scores equals worse outcome.

# Delirium management involving families

Figure 1. CONSORT flow diagram.

Consolidated Standards of Reporting Trials flow diagram for the MENTOR\_D pilot trial. FC: family caregiver, CABG: coronary artery bypass graft.



## Delirium management involving families