



# Alternatives to Constant Observation for Patients with Cognitive Impairment in Acute Care Settings

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*This Rapid Evidence Report was prepared by the Newfoundland & Labrador Centre for Applied Health Research (NLCAHR) at Memorial University. It was developed through the analysis, interpretation and synthesis of scientific research and/or health technology assessments conducted by other parties. It also incorporates selected information provided by expert consultants in the subject area. This document may not fully reflect all the scientific evidence available at the time this report was prepared as other relevant scientific findings may have been reported since its completion.*

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## About This Report

### About NLCAHR

The Newfoundland and Labrador Centre for Applied Health Research was established in 1999 to contribute to the effectiveness of health and community services in Newfoundland and Labrador and to the physical, social, and psychological wellbeing of its population. NLCAHR accomplishes this mandate by building capacity in applied health research, supporting high-quality research, and fostering the effective use of research evidence by decision makers and policy makers in the provincial healthcare system.

### About *Rapid Evidence Reports*

NLCAHR designed *Rapid Evidence Reports* to support evidence-informed decision making in the Newfoundland and Labrador healthcare system on an expedited basis as compared to the lengthier '*Evidence in Context*' reports issued through the Contextualized Health Research Synthesis Program. Through these expedited reports, NLCAHR provides a succinct review of recent research evidence on high-priority research topics selected by decision makers in the province.

*Rapid Evidence Reports* include:

- A clear statement of the topic under consideration and the background to the issue/problem;
- A description of the scope and nature of pertinent English-language scientific literature from the past five years;
- A summary of the principal features of the available evidence – points of consensus, points of disagreement, areas of uncertainty, or knowledge gaps relative to: effectiveness of interventions, potential benefits and harms, risks, costs, and cost-effectiveness; and
- A brief analysis of the types of issues that might affect the applicability of the evidence when applied in the local context.

It is important to note that, unlike our other decision-support product, the '*Evidence in Context*' report, a *Rapid Evidence Report* is not a comprehensive and systematic synthesis of the literature on the topic, nor do we include contextual interviews as part of the research methodology. This rapid report does not offer an exhaustive analysis of the contextual issues involved in applying evidence to the Newfoundland and Labrador healthcare setting. Rather, a *Rapid Evidence Report* provides decision makers with a summary of the scope and nature of the recent scientific literature on the topic in question, an initial assessment of the strengths and gaps in this literature, and a review of the key points of agreement and disagreement among researchers, highlighting for decision makers any potentially relevant contextual considerations that may have an impact when applying the evidence for use in Newfoundland and Labrador.

## Researchers and Consultants

The following researchers from the Newfoundland and Labrador Centre for Applied Health Research worked on this project: Sarah Mallay, Research Officer, Contextualized Health Research Synthesis Program (CHRSP), Pablo Navarro, Senior CHRSP Research Officer, and Dr. Stephen Bornstein, Director of NLCAHR. Our team benefited from the advice and expertise of Dr. Anne Bourbonnais, Associate Professor in the Faculty of Nursing at the Université de Montréal and researcher at the Research Centre of the Institut Universitaire de Gériatrie de Montréal. For more information about our subject matter expert, see Appendix A.

## Background

In 2017, more than 432,000 Canadians aged 65 and older were living with a diagnosis of dementia, an increase of 9% from 2007 (1). In 2011, the cost of caring for Canadians with dementia was estimated to be \$8.3 billion—a figure that is expected to double by 2031 (2). Although the Alzheimer’s Society has not published provincial-level data for Newfoundland and Labrador, we know that there are approximately 9,600 people, or 1.84% of the population in this province living with dementia. By 2035, the number of individuals living with dementia in Newfoundland and Labrador is expected to increase to over 14,000 (21).

Approximately 50% of patients aged 65 and over who are admitted to hospital experience dementia or some form of delirium that puts them at higher risk for adverse outcomes; yet cognitive impairment is often poorly managed and under-detected in acute-care settings (3).

Constant observation is a care approach to help patients with cognitive impairment in acute-care settings by having paid hospital staff provide continuous one-on-one, in-person monitoring of patients to ensure that they remain safe (4).

### Relevance to healthcare decision making in NL

Health system decision makers in Newfoundland and Labrador (NL) are concerned about hospitalized older adults with cognitive impairment who may display challenging behaviors in acute-care settings. Their concerns include patient and health worker safety, quality of care, and healthcare costs. Behaviors associated with cognitive impairment can increase the risk of falls, self-injury, treatment non-compliance, and risk to others. As a result, such behaviours often necessitate constant observation as an intervention. However, safety outcomes associated with one-on-one constant observation are variable, and, not surprisingly, the practice has high associated costs (5).

Health system decision makers in Newfoundland and Labrador understand that identifying alternative strategies to care for elderly patients with cognitive impairment is critical to ensuring the safety of this patient group, while maintaining a high standard of care at a sustainable cost. With these concerns in mind, our provincial health system partners asked the Contextualized Health Research Synthesis Program (CHRSP) team to examine high-level

research evidence that would identify some alternatives to in-person constant observation for older, cognitively-impaired patients in acute-care hospitals.

In consultation with a subject matter expert and provincial health system decision makers working in this area, we arrived at the following research question for this *Rapid Evidence Report*:

*“What alternatives to in-person constant observers for older cognitively-impaired patients in acute-care hospitals are cost-effective while maintaining quality standards?”*

## Key Messages in This Report

Constant observation, a care approach for patients with cognitive impairment in acute-care settings, involves paid hospital staff providing continuous one-on-one, in-person monitoring to ensure that patients remain safe. This report focused on research evidence that examined alternatives to this approach that would be effective in terms of both quality of care and cost. The key findings from the research evidence on this topic are summarized below:

- We did not find a large body of evidence about interventions that are aimed to reduce constant observation hours and requests. The evidence that we did find varied widely in terms of the nature of the interventions studied and the quality of the research. Three studies included in this report looked at interventions that are aimed to reduce constant observation (3,6,7), three looked at interventions that are aimed to improve overall care (4,8,9), and one looked at interventions that are intended to prevent functional and cognitive decline (10).
- The available research evidence suggests that some alternatives to in-person constant observation can help to reduce requests for constant observation and to also reduce the number of constant observation hours required. These interventions can also improve cost efficiency without compromising patient safety. Some of the more promising interventions included in this report had the following components:
  - Multidisciplinary teams;
  - Encouraging patient mobility;
  - Vision and hearing protocols, feeding assistance, and patient orientation;
  - Continence management and maintaining sleep/wake cycles;
  - Staff education; and
  - Creating and using guidelines for constant observation.

- It would appear that more structured interventions that include multiple components result in more consistent improvements in constant observation outcomes, while the results for less structured interventions with a smaller number of components tend to be more variable. For example, the following interventions, all of which include multiple, structured components were found to improve constant observation outcomes: the Hospital Elder Life Program (HELP), multicomponent interventions involving Patient Engagement Specialists, and some volunteer-based programs.
- Although there was considerable overlap in the components included in the alternative interventions reported in the evidence, no two interventions were the same. As a result, we could not draw any firm conclusions as to what combination of components would result in a successful intervention.

## Scope and Nature of the Scientific Literature

For this *Rapid Evidence Report*, we consulted with a health sciences librarian at Memorial University in order to develop a comprehensive search strategy. We then searched PubMed, CINAHL, and Embase for peer-reviewed systematic reviews and primary research articles published in English since 2015.

### Inclusion and exclusion criteria

In consultation with our health system partners, we identified the following key parameters of interest to help us select the most relevant studies for review:

Parameter	Inclusion Criteria	Exclusion Criteria
<b>Population</b>	Patients aged $\geq 65$ years with cognitive impairment	Patients aged $< 65$ years with cognitive impairment
<b>Intervention</b>	Alternatives to constant observation	
<b>Setting</b>	Acute-care hospitals	Other settings(e.g., long-term care)
<b>Outcomes</b>	Primary: Hours of constant observation Frequency of constant observation requests Cost savings Secondary: Total number/frequency of falls Behavioural and Psychological Symptoms of Dementia	Not reporting on any of the primary outcomes

Table 1: Inclusion and exclusion criteria for this report

## Evidence included in this report

This report includes research evidence from one systematic review/meta-analysis, one systematic review only, and five primary studies that were published too recently to have been captured in the review literature. Table 2 below summarizes the study designs and the key interventions included in this report. Each primary study used a different research design:

- retrospective chart review (4);
- small-scale longitudinal study (8);
- prospective randomized controlled pilot study (6);
- prospective controlled non-randomized trial (9); and
- non-randomized controlled trial (7).

Systematic Review Evidence		
Author, Year	Study Design	Intervention
Hshieh, 2018	Systematic review and meta-analysis	Hospital Elder Life Program (HELP)
Gilmore-Bykovskiy, 2020	Systematic review only	Three alternatives to constant observation: Performance improvement group; sitter reduction program; clinical assessment bundle
Primary Research Evidence		
Author, Year	Study Design	Intervention
Sinvani, 2018	1-year retrospective study of chart data	Multicomponent intervention using patient engagement specialists (PES)
Isaac, 2018	Small-scale longitudinal study	TOP5 intervention
Ruff, 2018	Prospective randomized controlled pilot study	Activity aprons
Schroeder, 2018	Prospective controlled non-randomized trial	Individualized music-based intervention
Blair, 2020	Non-randomized controlled trial	Person-centered volunteer program

Table 2: Study designs and interventions included in this report

## Critically appraising the evidence

We critically appraised each of the articles included in Table 2 above. For the two systematic reviews, we used the assessment of multiple systematic reviews (AMSTAR) tool to investigate the methodological quality of these included studies. The AMSTAR instrument consists of 11 items and that measure the methodological quality of systematic reviews to rate the quality of systematic reviews as being low, moderate, or high(11). For the five included primary studies, we used the Downs and Black checklist (12). The scale consists of 28 questions relating to quality of reporting, external validity, internal validity, and statistical power. This checklist enabled us to rate the quality of evidence as poor, fair, good, or excellent (13). A summary of results from our critical appraisals is included in Table 3.

Included Systematic Reviews	AMSTAR* Quality Appraisal Results		Quality Rating
Hshieh, 2018	55%		Moderate
Gilmore-Bykovskiy, 2020	36%		Low
Included Primary Studies	Downs and Black** Quality Appraisal Results		Quality Rating
Blair, 2018	21/28	75%	Good
Ruff, 2018	23/28	82%	Good
Sinvani, 2018	21/28	75%	Good
Schroeder, 2018	18/28	64%	Fair
Isaac, 2018	13/28	46%	Poor

\*AMSTAR scale: low (0-40%), moderate (41-70%), high (71-100%)

\*\*Downs and Black scale: poor (0-50%), fair (51-70%), good (71-92%), excellent (93-100%)

Table 3: Quality Appraisal of Included Evidence

### Characterizing the evidence

The populations, interventions, comparators, and outcomes included in each individual study are outlined in detail in Appendix B of this report. The evidence is characterized, in general, as follows:

### Populations included in the literature

The majority of the evidence included in this *Rapid Evidence Report* examined similar patient populations aged  $\geq 65$  who might require special attention/monitoring:

- One systematic review (3) and two primary studies (4,7) included patients aged  $\geq 65$  with dementia or delirium.
- One systematic review/meta-analysis included patients aged  $\geq 70$  (10)
- One primary study included patients aged  $\geq 70$  with an acute geriatric syndrome<sup>1</sup>(8).
- One primary study included patients aged  $\geq 60$  with acute agitation or a behavioral disorder (9).
- One primary study included adult patients with encephalopathy, dementia, and/or delirium (6).

Generally, we define patients with dementia as having an impairment in their ability to remember, think, or make decisions. This impairment interferes with the ability to carry out everyday activities. Alzheimer's disease is the most common type of dementia. Delirium is a term that describes a serious disturbance in mental abilities that results in confused thinking and reduced awareness of the environment. Acute agitation/ behavioural disorders are indicated by restlessness, often manifested as hostility, tension, excitement, aggression or uncooperativeness. Encephalopathy is a term for any diffuse disease of the brain that alters brain function or structure.

<sup>1</sup> Acute geriatric syndromes are defined in this study as “unique features of common health conditions in older people that do not fit into discrete disease categories” and include delirium, falls, incontinence, and frailty (8).



	Hshieh	Gilmore-Bykovskiy	Blair	Ruff	Sinvani	Schroeder	Isaac
<b>Populations Included in the Literature</b>	<b>Study (Author) ↑</b>						
Patients aged ≥70	X						
Patients ≥65 with dementia or delirium		X	X		X		
Patients ≥70 with acute geriatric syndrome							X
Adult patients with encephalopathy, dementia, and/or delirium				X			
Patients ≥60 with acute agitation or a behavioral disorder						X	

Table 4: Populations included in this report

### Interventions included in the literature

This report examines the evidence for alternatives to constant observation and/or looks at interventions that may reduce the need for constant observation for older adults with cognitive impairment. More specific details about all included interventions, including intervention components and intended outcomes, are included in Appendix B of this report. We summarize the interventions included in this report in Table 5 below.

	Hshieh	Gilmore-Bykovskiy	Blair	Ruff	Sinvani	Schroeder	Isaac
<b>Interventions Reported in the Literature</b>	<b>Included Study (Author) ↑</b>						
Hospital Elder Life Program (HELP) which includes a minimum of 11 components	X						
Performance improvement group; sitter reduction program; clinical assessment bundle		X					
Volunteer-based intervention to reduce constant observation			X				
Activity aprons to reduce behaviors that result in self-harm and restraint use and reducing the need for constant observation				X			
Multicomponent intervention using Patient Engagement Specialists to generally improve care for hospitalized older patients with cognitive impairment					X		
Individualized music-based intervention to improve neuropsychiatric symptoms of patients						X	
TOP5 intervention to improve patient care and healthcare delivery							X

Table 5: Interventions under study in this report

The interventions in included studies are further described as follows:

- **The Hospital Elder Life Program (HELP):** A moderate-quality systematic review/meta-analysis looked at this multicomponent intervention that aims to prevent functional and cognitive decline in hospitalized older individuals. The intervention is made up of a minimum of 11 components and a reduced need for constant observation is noted as a corollary benefit. The core components of HELP are as follows: care is provided by a multidisciplinary team that includes Elder Life Specialists, Elder Life Nurse Specialists, geriatricians, and trained volunteers; interventions are individually tailored to the patient; daily adherence to the program is monitored; other components of care include patient orientation, therapeutic activities, sleep enhancement, early mobilization, vision protocol generally and vision protocol for blindness, hearing protocol, fluid repletion/constipation management; and assistance with feeding (10).
  
- **Performance improvement group; sitter reduction program; clinical assessment bundle:** A low quality systematic review included three primary studies, each of which tested a different intervention aimed to specifically reduce constant observer hours (3):
  - One study looked at a performance improvement group that identified alternative constant observation strategies such as: identifying agitation in patients, then assessing for pain, hunger, thirst, bladder/bowel movement, medications, and oxygenation. The unit hospitalists led lightning rounds for the patient's assigned RN, the patient care coordinator, and unit nursing management. These quick rounds followed a template involving questions on patient diagnosis, age, medical status, overnight events, acute issues, barriers to discharge, and delirium risk. The communication process was streamlined for patient care staff, and electronic medical records were used (14).
  - A second study involved a sitter reduction program in which nurses, rather than physicians, decided on initiation, continuation, and termination of constant observers for patients. Nurses also set bed alarms, put fall precaution magnets on patient doors, put fall prevention stickers on ID bands, provided slip resistant socks to patients, and encouraged family members to visit patients whenever possible (15).
  - A third study examined a clinical assessment bundle that involved a two-phase implementation action plan. Phase I was described as a three-month transition phase in which advanced practice registered nurses coached registered nurses on staff on delirium assessment, hyperactive delirium behavior identification, and nurse-led interventions. Phase II involved the implementation of a nurse-led standard operating procedure for the initiation and termination of constant observers that was based on clinical criteria and safety risk and did not require a provider order (16).

- **Volunteer-based intervention to reduce constant observation:** One good quality primary study looked at the Volunteer Dementia and Delirium Care Implementation and Training resource (© NSW Agency for Clinical Innovation, 2014). This training resource was used by implementation staff working within all study sites to ensure consistency of the intervention across all sites. Volunteers in this program received an orientation and were trained before they started providing patient care over two shifts each weekday. Volunteers worked with nursing staff to determine which patients were most in need of volunteer support, and those patients were prioritized with their care provided by the trained volunteers (7).
- **Activity Aprons:** A good quality primary study examined the use of activity aprons which are commercially- available products with items such as zippers, buttons, and stuffed animals that are used to occupy and distract patients with dementia. The aprons are intended to reduce behaviors that result in self-harm and restraint use and, as a result, the need for constant observation (6).
- **Multicomponent intervention using Patient Engagement Specialists:** A good quality primary study examined a multicomponent intervention that involved the use of Patient Engagement Specialists (PES) in a specialized setting, aiming to generally improve care for hospitalized older patients with cognitive impairment. This intervention was carried out on a specialized open unit with alarms at entrances and exits. The unit also included environmental adaptations such as enhanced lighting, the use of neutral colours in the décor, and a communal area for meals and activities. Unit staff were given 16 education sessions, each lasting a half hour. Patient Engagement Specialists underwent six weeks of training to prepare them for their role on the unit. The first three weeks of training were didactic lessons with the remaining training provided within the unit by more experienced Patient Engagement Specialists. The role of the Patient Engagement Specialists, once trained, was to engage individuals with cognitive impairment and behavioral symptoms to increase patient mobility, preserve the sleep/wake cycle, encourage patients to engage in unit-based diversional activities, proactively take continent patients to the bathroom, and check on patients hourly to address their needs, including checking hourly throughout the night to engage patients with sleep-wake cycle reversal (4).
- **Individualized music-based intervention:** A fair quality primary study examined an individualized music-based intervention that aimed to improve neuropsychiatric symptoms of patients. This intervention involved the creation of 31 music playlists that were organized by decade, genre, and artist. Patients or their carers indicated the type of music the patient liked and playlists were chosen on this basis. Patients listened to music for a recommended 30 minutes each day in the late morning. Nursing staff or Recreational Therapists provided patients with iPod shuffles with Bluetooth-enabled

headphones. The iPods were available for request as long as their use did not interfere with treatments (9).

- The TOP5 Intervention:** Finally, one poor quality primary study looked at the TOP5 intervention, which involves patient carers/families giving nursing staff non-clinical information to help personalize/improve patient care and healthcare delivery. The carer provides up to 5 personalized care strategies that staff can use to help the patient feel more settled and reassured, and to reduce the incidence of risk behaviors. These strategies are documented on a form that is kept in the patient’s bedside notes for easy access (8).

Although no two studies reported on the same intervention, we found considerable overlap in the *components* that were included within each intervention. Table 6 summarizes the key components that were common to several of the interventions described above.

	Hospital Elder Life Program	Patient Engagement Specialists	Performance improvement Group	Sitter reduction program	Clinical assessment bundle	Volunteer program	TOP5	Individualized music intervention	Activity Aprons
<b>Intervention COMPONENTS Reported in the Literature ↓</b>	<b>Included Intervention ↑</b>								
Multidisciplinary team	X	X	X						
Staff education	X	X					X		
Treatments tailored to the individual	X						X	X	
Guidelines for Constant Observer use			X		X				
Nurses decide on the initiation, continuation, termination of Constant observation				X	X	X		X	
Orientation	X					X			
Encouraging engagement in therapeutic activities	X					X			
Maintaining sleep/wake cycle	X	X							
Encouraging patient mobility	X	X				X			
Vision and Hearing protocol	X					X			
Feeding assistance	X					X			
Continence management	X	X							
Use of activity aprons									X

Table 6: Common components in included interventions

### Outcomes included in the literature

Much like the variability of the interventions included in this report, we also found a great deal of variability in the outcomes that were reported.

All included studies were required to examine the effectiveness of interventions on at least one of the following primary outcomes of interest:

- the number of requests for constant observation (4,7–9);
- the duration of constant observation(3,4,6); and
- cost savings (4,13).

We found that several of the included studies also reported on the following common outcomes:

- falls (3,6–8,10);
- length of stay (3,4,6,8,10);
- medication use (3,4,7,9);
- readmissions (4,6,7);
- adverse events (6,7); and
- patient mood and agitation (3,9).

Other outcomes reported in the literature included the following:

- patient outcomes
  - in-hospital mortality (4);
  - institutionalization (10);
  - delirium incidence (10);
  - change in functional cognitive status (10);
  - an aspiration caution (i.e., food/beverages are caught in the airway) (4);
  - behavioral incidents (7);
  - discharge disposition (4);
  - patient care (3);
  - all diagnoses (7);
- process outcomes
  - time in restraints (6);
  - non-physical restraint use (6);
  - palliative care consultation (4);
  - number of volunteer sessions provided (7);
  - discharge destination (6);
- program assessment outcomes
  - staff perception of patient safety (3);
  - staff perception of patient well-being (3);
  - complaints to the hospital (8);
  - safety of the intervention (6); and
  - feasibility of the intervention (6).

Table 7 provides a summary of all included studies and the outcomes reported in each.

	Hshieh (HELP)	Gilmore-Bykovskiy (3 interventions)	Blair (Volunteers)	Ruff (Activity Aprons)	Sinvani (Patient Engagement Specialists)	Schroeder (Music)	Isaac (TOP5)
<b>Outcomes Reported in the Literature</b>	<b>Included Study (Author) ↑</b>						
Duration of constant observation		X		X	X		
Number of constant observation requests			X		X	X	X
Cost savings	X				X		
Falls	X	X	X	X			X
Patient mood		X				X	
Agitation		X				X	
Behavioral incidents			X				
Delirium incidence	X						
Change in functional cognitive status	X						
Length of hospital stay	X	X		X	X		X
Institutionalization	X						
Medication use		X	X		X	X	
Patient care		X					
Staff perception of patient safety		X					
Staff perception of patient well-being		X					
In-hospital mortality					X		
Discharge disposition					X		
Readmissions			X	X	X		
Aspiration caution					X		
Palliative care consultation					X		
Discharge diagnosis of delirium					X		
Diagnoses			X				
Adverse events			X	X			
Number of volunteer sessions provided			X				
Complaints to the hospital							X
Safety of the intervention				X			
Feasibility of the intervention				X			
Time in restraints				X			
Non-physical restraint use				X			
Discharge destination				X			

Table 7: Outcomes included in this report

### Limitations of included studies

Each of the two systematic reviews included in this report limited their searches to articles published in English (3,10). The systematic review that looked at the Hospital Elder Life Program (HELP) included only a limited number of studies in the meta-analysis, with a high level of heterogeneity among included studies. The authors noted that some of the included studies were single-site or quality improvement projects with small sample sizes or no comparator group, which potentially limits their internal and external validity (10). The

systematic review of three separate interventions by Gilmore-Bykovskiy et al. also reported heterogeneity among the included studies, and included only peer-reviewed literature. As such, this systematic review may not have included relevant reports on quality improvement initiatives (3).

Two of the primary studies reported small sample sizes as a limitation (6,9). Without any randomized patient sample, the study by Schroeder et al. had an increased risk of bias. This study also reported a lack of appropriate, previously-published assessment scales, which leads to some concern about internal and external validity (9).

The study of a multi-component intervention with Patient Engagement Specialists by Sinvani et al. was unable to attribute causality to any single aspect of the intervention due to its multicomponent nature. Moreover, this study was also carried out at a single site, thereby limiting its generalizability (4).

The study by Isaac et al. on the TOP5 approach cited “insufficient documentation of patient details” as a limitation. Although the authors were able to determine how many patients required constant observation, they did not state how many of the included patients had a cognitive impairment. Instead, the authors simply noted that “the majority of patients in the study” had a cognitive impairment (8).

Blair et al., when looking at a volunteer intervention, cited a lack of resources to collect nutrition and hydration data for study subjects as a limitation. Moreover, the researchers could not carry out blinded data collection because patient files openly identified which patients received their care from volunteers. The study was therefore at high risk for Type I error or a “false-positive result” in which the researchers can mistakenly conclude that something is a fact. An example of this kind of error would be the case when a test result indicates that you have coronavirus when you actually do not. (7).

## Findings from the Literature

### Interventions studied

As noted previously, each included study within this *Rapid Evidence Report* examined a different intervention.

- The highest quality review evidence in this report was a moderate-quality systematic review/meta-analysis by Hshieh et al. that examined the Hospital Elder Life Program (HELP), which aims to prevent functional and cognitive decline in hospitalized older individuals. (10)
- A second, low-quality systematic review reported on three primary studies that aimed to reduce constant observer hours (3). The first primary study reported on an intervention which involved a multidisciplinary performance improvement group (14). The second primary study reported on a sitter reduction program where nurses provided assessments to determine whether patients required a sitter (15).

The third primary study looked at ways to reduce constant observer hours using a clinical assessment bundle that provides nurses with clinical assessment criteria to help them determine whether sitter use should be initiated or discontinued (16).

- Blair et al. conducted a good quality primary study to examine a volunteer program in rural hospitals that aimed to reduce constant observation by using a training resource and having volunteers do two shifts per day to provide aid where it was most needed (7).
- The poor quality primary study by Isaac et al. looked at ways to improve patient care and healthcare delivery using the TOP5 intervention where carers identify five personalized healthcare strategies that staff can use to reduce the incidence of risk behaviors, help the patient feel more settled and secure, and help the carer feel reassured. This intervention involved an education component for all members of the healthcare team (8).
- Ruff et al., in a good quality primary study, looked at ways to reduce behaviors that result in self-harm and restraint use by using activity aprons that occupy and distract dementia patients(6).
- The fair quality primary study by Schroeder et al., the researchers examined an individualized music-based intervention where 31 music playlists were created based on decade, artist, and genre; patients were assigned playlists based on personal preference; and they listened to music for a recommended 30 minutes per day, but could request to listen more if it did not interfere with medical treatment. This study aimed to improve neuropsychiatric symptoms of patients (9).
- The good quality primary study by Sinvani et al. used a multicomponent intervention with Patient Engagement Specialists, geographic cohorting, a multidisciplinary team, a specialized unit, staff education, and several interventions aimed to improve patient care. (4)

Details on each of these interventions can be found in Appendix B.

### Primary outcomes of interest

As stated above, the primary outcomes of interest in this report were: the number of one-on-one in-person constant observer hours; the frequency of constant observer requests; and the cost savings that might be realized by using the intervention.

Table 8 below identifies the primary outcomes of interest and the interventions under study that included information about these outcomes.



	Hospital Elder Life Program	Patient Engagement Specialists	Performance improvement group	Sitter reduction program	Clinical assessment bundle	Volunteer program	TOP5	Individualized music intervention	Activity aprons
<b>Primary outcome of interest ↓</b>	<b>Intervention ↑</b>								
Constant observation hours		X	X	X	X				X
Constant observation requests		X				X	X	X	
Cost savings	X	X							

Table 8: Reported primary outcomes for included interventions

### The impact of included interventions on constant observation hours

Three included studies reported on the impact of interventions on constant observation hours:

- One low-quality systematic review indicated that constant observation hours were reduced as the result of three interventions (sitter reduction, performance improvement groups and a clinical assessment bundles) (3);
- One good quality primary study reported reduced constant observation hours through a multicomponent intervention using Patient Engagement Specialists (4);
- In contrast, the good quality primary study examining activity aprons as an intervention did not report a significant difference in constant observation hours as an outcome (6).

The low-quality systematic review of three interventions included only three primary studies examining constant observer reduction programs. While each of these included studies resulted in a reduced number of constant observer hours, the authors did not include any quantitative description of the results, nor did they provide a fulsome description of the interventions (3). To address this deficiency in the review literature, we looked more closely at the included primary studies to examine their results in greater detail and found that:

- The primary research on the creation of a performance improvement group that established guidelines for sitter usage resulted in two notable outcomes: the intervention exceeded the goal of reducing sitter usage by 20% and 2.5 full-time equivalents, and simultaneously improved patient outcomes. Moreover, the study reported that prevention and early identification of patients at risk of falls, behavioral issues, and delirium were more effective mechanisms for patient safety than constant observation itself (14).
- The primary study of a sitter reduction program resulted in reduced sitter usage, and nurses being more satisfied because fewer of their coworkers were being assigned to be observers/sitters (15).

- The third included primary study found that using a clinical assessment bundle to reduce sitter usage resulted in a significant decrease in care costs and sitter usage. It is important to note that although sitter usage decreased, quality indicators for falls and the use of restraints did not significantly change (16).

The good quality primary study of a multicomponent intervention using Patient Engagement Specialists resulted in a reduction in constant observation order duration by an average of 47% in the intervention group— a result that reached statistical significance ( $p=0.002$ ) (4). The good quality prospective randomized controlled pilot study by Ruff et al. that looked at the efficacy of activity aprons reported no statistically significant difference in the duration of individual nursing assignments, with an average of 6.4 days in the intervention group and 9.1 days in the control group ( $p=0.39$ ); however, as noted in the limitations above, this study had a small sample size (6).

In looking at common components in included interventions, it is notable that both the Patient Engagement Specialist and performance improvement group interventions included multidisciplinary teams (4,14). Both the clinical assessment bundle and the performance improvement group involved creating and using guidelines for constant observer use (14,16). Studies of both the sitter reduction program and the clinical assessment bundles involved nurses making decisions about constant observer assignments (15,16).

#### The impact of interventions on constant observation request frequency

Four primary studies (4,7–9) reported on the frequency of constant observation requests. Authors reporting on the multicomponent intervention, the TOP5 intervention, and the volunteer intervention all noted reduced numbers of patients requiring constant observers (4,7,8); whereas the authors studying an individualized music-based intervention reported no significant difference (9). The impact of the interventions on constant observation frequency varied across studies:

- The multicomponent intervention involving Patient Engagement Specialists led to a significant reduction in constant observation requests. The likelihood of having a constant observation request was 12.0% in the intervention group, and 45.8% in the control group ( $p<0.01$ ). The likelihood of having an enhanced observation request was 22.1% in the intervention group and 79.6% in the control group ( $p<0.01$ ) (4).
- The TOP5 intervention resulted in significantly fewer constant observation requests as well. In this study there was a 66% reduction in the number of patients cared for by sitters ( $n=30$  in the intervention group vs.  $n=89$  in the control group,  $p<0.05$ ) (8).
- The volunteer intervention resulted in a reduced number of patients requiring a one-to-one observation by a nurse or security guard. In the control group, 11.2% of patients required this type of observation, while only 4.8% of patients in the intervention group did ( $p=0.011$ ) (7).

- For the individualized music-based intervention, the difference in the number of constant observation requests between the intervention and control groups was 0.61 in the intervention group vs. 1.67 in the control group, (p=0.05) (9).

Common components of included interventions are worth pointing out. Two studies (Patient Engagement Specialists and TOP5) include staff education (4,8). Both the Patient Engagement Specialist and volunteer-based interventions included encouraging patient mobility as a key component (4,7). Both the TOP5 and the music-based interventions involved individually tailoring treatment (8,9). The interventions involving volunteers and music both had nurses making decisions regarding constant observation initiation, continuation, and termination (7,9). We found no further overlap among intervention components in these studies.

### The impact of interventions on cost savings

The best evidence for cost savings was reported in the moderate quality systematic review that looked at the Hospital Elder Life Program (HELP) and in the primary study that looked at a multicomponent intervention using Patient Engagement Specialists. Both studies reported reduced costs of care as the result of the reduction in constant observation hours (4,10). The interventions used in these studies had several components in common, including: multidisciplinary teams, staff education, maintenance of sleep/wake cycles, encouraging patient mobility, and continence management (4,10).

The systematic review of HELP included nine primary studies that examined cost, each of which reported cost savings with the introduction of the program (10). One primary study reported that \$91,678 (2018 USD) could be saved annually on constant observer costs by preventing hyperactive delirium in patients (10).

The good quality primary study on the impact of a multicomponent intervention with Patient Engagement Specialists also reported cost savings. An average of 16.88 constant observation hours were saved per patient in the intervention group. The authors based their cost savings estimates on 720 visits with the Patient Engagement Specialist (PES) per year and a salary of \$22 USD per hour:

$$16.88 \text{ hours} \times 720 \text{ visits} \times \$22 \text{ per hour} = \$267,379.20$$

This cost savings estimate translates to 5.94 full time equivalents at a \$45,000 salary saved per year. The authors also reported that the salary of a Patient Engagement Specialist was roughly 10% lower than that of a nursing assistant and concluded that, regardless of whether or not there would be a need for additional staffing using this model, the intervention would still result in overall cost savings (4).

### Secondary outcomes of interest

The secondary outcomes examined in this report were related to falls as well as to behavioral and psychological symptoms of dementia.

### *Falls*

Fall-related outcomes were reported in studies of activity aprons, volunteer interventions and the TOP5 intervention. For the reports on activity aprons and volunteers, no significant difference in the number of falls was indicated between intervention and control groups (6,7). It is notable that the study that reported on activity aprons indicated no falls in either the intervention or the control group (6). The authors studying the TOP5 intervention reported a 27% reduction in the average number of falls from baseline to the pilot phase (not statistically significant) and a 45% reduction from baseline to the establishment phase (a statistically significant reduction –  $p < 0.05$ .) (8). The authors reporting on the volunteer-based intervention reported that 8.6% of patients in the control group and 9.6% of patients in the intervention group fell between 1 and 3 times with no significant difference in the number of falls per day between the intervention and control groups ( $p = 0.667$ ).

### *Behavioral and Psychological Symptoms of Dementia*

The studies reporting on music-based and volunteer-based interventions examined the impact of these interventions on the behavioral and psychological symptoms of dementia in patients (7,9). The authors reporting on the individualized music-based intervention noted significantly lower scores on the agitation scales (1.81 vs. 4.08,  $p \leq 0.01$ ) and on the negative mood scales (4.51 vs. 6.84,  $p \leq 0.01$ ) in the intervention group. The intervention group also scored significantly higher on the positive mood scale (11.84 vs. 9.28,  $p \leq 0.01$ ). These differences remained statistically significant when a subgroup analysis of patients with major neurocognitive disorders was completed (9). However, the authors examining the volunteer-based intervention reported no significant difference in the mean number of behavioral incidents per day between the intervention and control groups ( $p = 0.084$ ) (7).

### *Examining the components included in studied interventions*

Based on the considerable variability among the studies included in this report, it is not possible to determine with any confidence what particular intervention component or combination of components results in improved efficacy of the interventions under study. Each study used a different combination of components. Moreover, because the researchers examined multiple components at the same time, it was not possible for them to attribute the efficacy of their respective interventions to any single factor. Rather, they could only report on whether or not the combination of components they used resulted in improved constant observation outcomes. The variability in the combination of components included in each study makes it impossible for us to determine with any confidence which components, or combination of components, result in an effective intervention.

We have noted previously that while the interventions we examined for this *Rapid Evidence Report* varied in their efficacy, several interventions did include overlapping components. One notable outlier in this regard was the good quality study by Ruff et al. that used activity aprons, an intervention that shared no common components with any of the other included studies (6).

Our findings suggest that the individual tailoring of interventions, while common to many of the included studies in this report, is not a determining factor in improving constant observation outcomes. While individual tailoring was a common component to the following studies, the resulting outcomes were all different:

- The authors of the study on an individualized music-based intervention did not report a significant reduction in the number of Constant observation requests (9).
- The study of the TOP5 intervention reported a significant reduction in Constant observation requests (8).
- The study of HELP reported cost savings (10).

Three out of four included studies that involved nurses making decisions on the initiation, continuation, and termination of constant observation as an intervention component reported similar findings (7,15,16) with one study showing a different outcome.

- The studies on a sitter reduction program and on a clinical assessment bundle both reported significant reductions in constant observation hours (15,16).
- The study of a volunteer program reported a significant reduction in constant observation requests (7).
- The study on an individualized music intervention did not report a significant reduction in constant observation requests (9).

This indicates that asking nurses to decide on constant observation use in hospital settings may be helpful but may not be the determining factor in the efficacy of a given intervention.

Each of the following components were associated with significant reductions in constant observation hours and requests, and/or improved cost efficiency:

- Encouraging patient mobility (4,7,10).
- Vision protocols, hearing protocols, feeding assistance, and an orientation (7,10).
- Continence management and maintaining sleep/wake cycle (4,10).
- Using multidisciplinary teams (4,10,14).
- Staff education (4,8,10).
- Creating and using guidelines for constant observer use (3,14,16).

The Hospital Elder Life Program, the multicomponent intervention involving Patient Engagement Specialists, and the volunteer program, all of which improved constant observation outcomes, used several components to construct their interventions (4,7,10):

- The HELP intervention uses a minimum of eleven components, but several primary studies also included additional elements while carrying it out (10).
- The volunteer program used seven components (7).
- The multicomponent intervention involving Patient Engagement Specialists used five components (4).

In contrast, there was variable efficacy in the studies that used a smaller number of intervention components. The study that used activity aprons did not significantly change constant observation hours (6), and this study did not share any common components with the other interventions we examined. Similarly, the individualized music-based intervention did not result in a significant change in constant observation request frequency, and this study only included two components used in other interventions (9). In contrast, the TOP5 program as well as the three primary studies in the systematic review by Gilmore-Bykovskiy et al. reported improved constant observation outcomes, and had few intervention components that overlapped (3,8). Based on these findings, we might consider that developing a more structured intervention involving multiple components may help to improve constant observation outcomes more consistently than interventions with fewer components and less structure.

## Potentially Relevant Contextual Issues

Throughout the course of this project, we have tried to identify contextual factors in Newfoundland and Labrador (NL) that may impact the relevance and applicability of interventions to reduce the need for constant observers.

**An aging population:** The NL population is aging, and has a higher percentage of older individuals than the rest of Canada. In 2019, the percentage of the NL population aged 65+ was 21.5% (17). In the same year, the percentage of Canadians aged 65+ was 17.5% (18). From 2000 to 2016, the population of Canadians aged 65+ has increased by 56% and in 2016 there were more Canadian seniors than children. People aged 65 and over account for roughly 45% of healthcare spending in Canada, and require 10 times more hospital care days than the rest of the population (19).

**A growing need to care for people with cognitive impairments:** In 2019, the number of Canadians living with dementia was over 500,000, which translated to 1.34% of the population (20). Although the Alzheimer's Society has not published provincial-level data for NL, we know that there are approximately 9,600 people, or 1.84% of the population in this province living with dementia. By 2035, the number of individuals living with dementia in NL is expected to increase to over 14,000 (21).

**Workforce training:** A 2019 report by the Royal College of Physicians and Surgeons of Canada indicated that there was little data to tell us how healthcare professionals in this country are caring for older Canadians. The report notes that geriatricians are experts in delirium, and are the only medical specialty that is specifically trained to care for medically complex and medically ill persons with dementia. The report noted the lack of comparable statistics on how physicians, nurses, personal support workers, physiotherapists, pharmacists, social workers, and other healthcare providers are trained in geriatric care and how they care for this patient group (19).

**Health system sustainability:** All of the foregoing statistics point to a growing need to provide quality acute care for people with cognitive impairment. Currently, older patients with cognitive impairments in our province’s acute care settings often require constant observation— a costly and resource-intensive practice (5). To help ensure high value and lower costs in healthcare, identifying safe and effective strategies to reduce constant observation hours in acute care may be an effective measure that can help to reduce costs and resource use, while maintaining a high standard of patient-centered care.

## Summary of Key Findings

Constant observation is a care approach for patients with cognitive impairment in acute-care settings that involves having paid hospital staff providing continuous one-on-one, in-person monitoring to ensure that patients remain safe. When looking at the research evidence that examined alternatives to this care approach, we found the following:

- Research evidence about interventions aimed to reduce the need for constant observation is neither plentiful nor consistent. The evidence that we were able to find varied widely in terms of the nature of the interventions studied and the quality of the research. Three studies included in this report aimed to reduce constant observation, three aimed to improve care overall, and one aimed to prevent functional and cognitive decline.
- The available research evidence suggests that some alternatives to in-person constant observation can help to reduce constant observation hours and requests and that these interventions can also improve cost efficiency without compromising patient safety. Some of the more promising interventions under study included the following components:
  - Multidisciplinary teams;
  - Encouraging patient mobility;
  - Vision and hearing protocols, feeding assistance, and patient orientation;
  - Continence management and maintaining sleep/wake cycle;
  - Staff education; and
  - Creating and using guidelines for constant observation.
- It would appear that more structured interventions with several components result in more consistent improvements in constant observation outcomes, while the results for less structured interventions with a smaller number of components tend to be more variable. For example, the following interventions, all of which improved constant observation outcomes, included multiple, structured components: the Hospital Elder Life Program (HELP), multicomponent interventions involving Patient Engagement Specialists, and some volunteer-based programs.

- Although we found considerable overlap in the components that were included in the interventions studied, no two interventions were the same. As a result, we could not draw any firm conclusions as to what combination of components would result in a successful alternative to constant observation.



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## Appendix A: Our Consultant

### **Anne Bourbonnais**

Dr. Anne Bourbonnais holds a Bachelor of Science in Nursing, a Master's of Science in Nursing, and a Ph.D. (2009) in Nursing Sciences from the Université de Montréal. She completed a research fellowship in geriatrics at the Centre Gériatrique Maimonides Donald Berman, which is affiliated with McGill University. She has been a Research Chair in Nursing Care for Older People and their Families since June 2015, and was appointed a Canada Research Chair in Care for Older People in 2020. Dr. Bourbonnais is a member of the Quebec Nursing Intervention Research Network ([RRISIQ](#)), and the Quebec Network for Research on Aging ([RQRV](#)). She is currently an Associate Professor in the Faculty of Nursing at the Université de Montréal.

### **Research Program**

Dr. Bourbonnais' research focuses on improving the wellbeing, health, and quality of life of older people living with a major neurocognitive disorder and their families. She uses qualitative, quantitative, and mixed-methods approaches to understand the experiences and behaviors of these older patients. She aims to improve the quality of care they receive through innovative interventions.

## Appendix B- Summaries of Included Studies

<b>Hshieh et al, 2018</b>	
Population studied	No age range specified in the inclusion criteria. The included studies reported on patients aged $\geq 70$ .
Comparators	Not reported.
Intervention	<p>Multicomponent HELP program.</p> <p>Components:</p> <ul style="list-style-type: none"> <li>• Multidisciplinary team: Elder Life Specialists, Elder Life Nurse Specialists, geriatricians, and trained volunteers.</li> <li>• Interventions implemented on an individual basis depending on the presence of delirium risk factors.</li> <li>• Adherence monitored daily.</li> <li>• Core interventions: orientation, therapeutic activities, sleep enhancement, early mobilization, vision protocol and vision protocol for blindness, hearing protocol, fluid repletion/constipation, and feeding assistance.</li> <li>• Additional interventions: hand hygiene, aspiration prevention, CAUTI preventions (inappropriate short-term catheter use), constipation management, pain management, and hygiene management.</li> <li>• Other interventions: delirium protocol, dementia protocol, psychoactive medications, discharge planning, optimizing length of stay, additional areas, geriatric consultation, interdisciplinary rounds, ongoing educational programs, community linkages and telephone follow-up.</li> </ul>
Outcomes	Falls, delirium incidence, length of stay, cost, institutionalization, and change in functional cognitive status.

Table B1: Summary of the Systematic Review and Meta-analysis by Hshieh et al, 2018

Gilmore-Bykovskiy et al, 2020	
Population studied	Patients $\geq 65$ with dementia or delirium.
Comparators	Not reported.
Intervention	<p>Direct observation practices and interventions.</p> <p>Three constant observation reductions programs:</p> <ul style="list-style-type: none"> <li>• Performance improvement group created guidelines for sitter usage, completed a literature review, identified alternative constant observation strategies, implemented lightning rounds, enhanced communication processes, and used electronic medical records (14).</li> <li>• Sitter reduction program. Nurses provided assessment to determine whether patients required a sitter, or whether it was safe to discontinue sitter use. Nurses also used several tools such as bed alarms, fall prevention stickers on ID bands, and slip resistant socks to prevent harm (15).</li> <li>• Clinical assessment bundle to provide nurses with clinical assessment criteria to help determine whether sitter use should be initiated or discontinued (16).</li> </ul>
Outcomes	Falls, length of stay, cost, patient mood, patient agitation, medication use, patient care, staff perception of patient safety, staff perception of patient well-being, staff work satisfaction, and change in the rate of direct observation.

Table B2: Summary of the Systematic Review by Gilmore-Bykovskiy et al, 2020

Blair et al, 2018	
Population studied	Patients >65 with a diagnosis of dementia or delirium or risk factors for delirium and received volunteer services.
Comparators	Usual care.
Intervention	<p>Volunteer program in rural hospitals.</p> <p>Components:</p> <ul style="list-style-type: none"> <li>• “Volunteer Dementia and Delirium Care Implementation and Training resource © (NSW Agency for Clinical Innovation, 2014).”</li> <li>• Volunteers provided supports in two shifts on weekdays, one in the morning and one in the afternoon.</li> <li>• Volunteers provided support where it was most needed, as determined by nursing staff.</li> <li>• Interventions provided by volunteers: “Supporting orientation and interaction with others; engagement in therapeutic activities; promoting the use of visual and hearing aids; assisting with eating and drinking; and where safe and appropriate, encouraging regular walking” (7).</li> </ul>
Outcomes	Length of stay, falls, hospital readmissions, pro re nata (PRN) <sup>2</sup> medication use, adverse events, behavioral incidents, and number of volunteer sessions.

Table B3: Summary of the Primary study by Blair et al, 2018.

<sup>2</sup> Pro re nata: Medication that is taken as needed as opposed to administered as scheduled (22).

<b>Isaac et al, 2018</b>	
Population studied	Patients $\geq 70$ with acute geriatric syndrome.
Comparators	Usual care.
Intervention	TOP5: <ul style="list-style-type: none"> <li>• Carers identified five personalized healthcare strategies the staff could use to reduce the incidence of risk behaviors, help the patient feel more settled and secure, and help the carer feel reassured.</li> <li>• Information was made easily accessible to staff by placing it near the patient’s bedside.</li> <li>• All members of the healthcare team received education on cognitive impairment and the TOP5 intervention.</li> </ul>
Outcomes	Length of stay, falls, one-on-one nursing use, and number of complaints.

Table B4: Summary of the Primary study by Isaac et al, 2018.

<b>Ruff et al, 2018</b>	
Population studied	Adult patients with encephalopathy, dementia, and/or delirium.
Comparators	Usual care.
Intervention	Activity aprons with stuffed animals, zippers, buttons, etc. to occupy patients, and prevent behaviors that result in self-harm, increased nursing supervision, and the use of restraints.
Outcomes	Length of stay, falls, hospital readmissions, individual nursing assignment, safety of apron use, feasibility of apron use, time in restrains, apron-related complications, and discharge destination.

Table B5: Summary of the Primary study by Ruff et al, 2018.

<b>Schroeder et al, 2018</b>	
Population studied	Patients $\geq$ 60 with acute agitation or a behavioral disorder.
Comparators	Usual care.
Intervention	<p>Individualized music based intervention:</p> <ul style="list-style-type: none"> <li>• 31 music playlists were created and organized by decade, genre, and in some cases by artist.</li> <li>• Playlists were assigned based on patient preferences.</li> <li>• Patients were provided with iPod shuffles and wireless Bluetooth headphones in the late morning. Listening for at least 30 minutes was recommended.</li> <li>• iPods were available on an as needed or as requested basis if they did not interfere with treatment.</li> <li>• Nursing staff and/or recreational therapists set up and provided iPods to the patients.</li> </ul>
Outcomes	PRN medication use, number of one-on-one staff interventions, level of agitation, positive mood, negative mood, and resistance to care.

Table B6: Summary of the Primary study by Schroeder et al, 2018.



<b>Sinvani et al, 2018</b>	
Population studied	Patients $\geq 65$ admitted to the medicine service in a hospital who required a high level of observation because of dementia or delirium.
Comparators	9 telemetry or medical units. Ratio of nurses to patients was 1 to 6, and ratio of nursing assistants to patients was 1 to 8. Nursing assistants performed CO and enhanced observation, but did not have training specific to dementia patients or behavioral symptoms.
Intervention	Multicomponent intervention using PES. Components: <ul style="list-style-type: none"> <li>• Geographic cohorting.</li> <li>• Multidisciplinary team.</li> <li>• Specialized patient unit staffed with PES.</li> <li>• Staff education.</li> <li>• Interventions: increasing patient mobility, preserving sleep/wake cycle, encouraging patients to engage in unit-based diversional activities, proactively taking continent patients to the bathroom, and checking on patients hourly to address needs, including through the night to engage patients with sleep-wake cycle reversal.</li> </ul>
Outcomes	Length of stay, hospital readmissions, proportion of constant observation, duration of constant observation, in-hospital mortality, discharge disposition, prescription for sedatives, prescription for anticholinergics, prescription for antipsychotics, an aspiration precaution, a palliative care consultation, and a discharge diagnosis of delirium.

Table B7: Summary of the Primary study by Sinvani et al, 2018.