One-to-One Observation: A Systematic Review

August 2019

Prepared for:
Department of Veterans Affairs
Veterans Health Administration
Health Services Research & Development Service
Washington, DC 20420

Prepared by:
Evidence Synthesis Program (ESP) Center
West Los Angeles VA Medical Center
Los Angeles, CA
Paul G. Shekelle, MD, PhD, Director

Authors:
Principal Investigator:
Paul G. Shekelle, MD, PhD

Co-Investigators:
Adela M. Greeley, MD
Elizabeth P. Tanner, MD

Research Associates:
Selene S. Mak, MPH, PhD
Meron M. Begashaw, MPH
Isomi M. Miake-Lye, PhD
Jessica M. Beroes-Severin, BS

U.S. Department of Veterans Affairs
Veterans Health Administration
Health Services Research & Development Service

PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted health care topics of importance to clinicians, managers, and policymakers as they work to improve the health and health care of Veterans. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The program is comprised of 4 ESP Centers across the US and a Coordinating Center located in Portland, Oregon. Center Directors are VA clinicians and recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Center Program and Cochrane Collaboration. The Coordinating Center was created to manage program operations, ensure methodological consistency and quality of products, and interface with stakeholders. To ensure responsiveness to the needs of decision-makers, the program is governed by a Steering Committee comprised of health system leadership and researchers. The program solicits nominations for review topics several times a year via the program website.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, Deputy Director, ESP Coordinating Center at Nicole.Floyd@va.gov.

Recommended citation: Shekelle PG, Greeley AM, Tanner EP, Mak SS, Begashaw MM, Miake-Lye IM, Beroes-Severin JM, One-to-One Observation: A Systematic Review. Washington, DC: Evidence Synthesis Program, Health Services Research and Development Service, Office of Research and Development, Department of Veterans Affairs. VA ESP Project #05-226; 2019. Posted final reports are located on the ESP search page.

This report is based on research conducted by the Evidence Synthesis Program (ESP) Center located at the **West Los Angeles VA Medical Center, Los Angeles, CA,** funded by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (*eg*, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

ACKNOWLEDGMENTS

This topic was developed in response to a nomination by Julia Neily, Associate Director, Field Office of the National Center for Patient Safety, and William Gunnar, Executive Director of the National Center for Patient Safety, for the purpose of supporting decisions related to determining whether to add patient sitters or one-to-one observation interventions to a patient safety assessment tool (PSAT) for falls. The scope was further developed with input from the topic nominators (*ie*, Operational Partners), the ESP Coordinating Center, the review team, and the technical expert panel (TEP).

In designing the study questions and methodology at the outset of this report, the ESP consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

The authors gratefully acknowledge Roberta Shanman, MLS and the following individuals for their contributions to this project:

Operational Partners

Operational partners are system-level stakeholders who have requested the report to inform decision-making. They recommend Technical Expert Panel (TEP) participants; assure VA relevance; help develop and approve final project scope and timeframe for completion; provide feedback on draft report; and provide consultation on strategies for dissemination of the report to field and relevant groups.

Julia Neily, RN, MS, MPH
Associate Director, Field Office
National Center for Patient Safety

William Gunnar, MD
Executive Director
National Center for Patient Safety

Technical Expert Panel (TEP)

To ensure robust, scientifically relevant work, the TEP guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members are listed below:

Christine Engstrom, PhD, CRNP, AOCN, FAANP
Acting Program Manager, Research & Analytics, Office of Nursing Services

Tatjana Bulat, MD, CMD
Director, VISN 8 Patient Safety Center of Inquiry
Associate Chief of Staff for Geriatrics and Extended Care, James A. Haley VA Hospital and

Clinics, Tampa, FL
Associate Professor of Medicine, Morsani College of Medicine

David A. Ganz, MD, PhD
Associate Director, VA HSR&D Center for the Study of Healthcare Innovation, Implementation & Policy, VA Greater LA Healthcare System
Staff Physician, VA Greater LA Healthcare System, Geriatric Research, Education and Clinical Center (GRECC)
Associate Professor of Medicine, UCLA

Peer Reviewers

The Coordinating Center sought input from external peer reviewers to review the draft report and provide feedback on the objectives, scope, methods used, perception of bias, and omitted evidence. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The Coordinating Center and the ESP Center work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

INTRODUCTION

Preventing adverse events in hospitalized patients is a priority goal of patient safety programs. In-facility falls and in-facility suicide are 2 priority conditions that are thought to be preventable. One-to-one sitters or constant observation is an intervention that has long been used, rooted in tradition: staff that are immediately at hand can help prevent a fall or redirect a patient from engaging in a harmful act. However, one-to-one sitters is a costly intervention, and evidence that it is effective is uncertain; hence, VA policymakers asked for an up-to-date review to inform policy and practice.

METHODS

Data Sources and Searches

This topic was developed in response to a nomination by Julia Neily, Associate Director, Field Office for the National Center for Patient Safety and William Gunnar, Executive Director for the National Center for Patient Safety. Key questions were then developed with input from the topic nominator, the ESP Coordinating Center, the review team, and the technical expert panel (TEP).

The Key Questions were:

KQ1. What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing falls?

KQ2. What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing suicide or self-harm?

KQ3. What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing wandering?

KQ4. What is the cost-effectiveness of one-to-one observations compared to usual care for patients at risk of falls, suicide, or wandering?

Study Selection

We conducted searches in PubMed from inception to 12/18/2018, Web of Science from inception to 11/29/2018, Cochrane Database of Systematic Reviews and Cochrane Trials and PsycINFO from 01/01/1970 to 12/04/2018, and CINAHL from inception to 11/30/2018. In order to be included, a study had to include one-to-one sitters as an intervention in an acute hospital's general medical/surgical or psychiatric hospital setting, and report an outcome of interest (falls, wandering, suicide/self-harm), and that preventing this outcome was the primary goal of the intervention. Observational studies were included.

Data Abstraction and Quality Assessment

Data extraction was completed in duplicate. All discrepancies were resolved with full group discussion. We abstracted data on the following: setting, sample size, study design, use of existing theory/logic model, control/pre-intervention sitter practice, alternative(s) to sitters,

implementation details, outcomes, and post-implementation follow-up interval. We used the Risk of Bias In Non-randomized Studies – of Interventions (ROBINS-I) for observational studies to assess study quality/risk of bias.

Data Synthesis and Analysis

The observational studies were too clinically heterogeneous to support meta-analysis; hence our synthesis is narrative. We used the principles of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group to assess the certainty of evidence.

RESULTS

Results of Literature Search

We identified 4,106 potentially relevant citations for a total of 1,845 articles whose titles were screened. Nineteen publications were identified at full-text review as meeting initial inclusion criteria. Only 2 studies assessed the effect of adding sitters to a usual care that did not include sitters; both assessed only falls as an outcome. The remaining 17 studies all assessed the effect of interventions aimed at reducing sitter use. All 17 of these studies assessed falls as the outcome of interest. There were no studies that assessed wandering or suicide-related measures as the outcome of interest.

Summary of Results for Key Questions

Key Question 1: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, etc) for reducing falls?

Regarding the use of sitters added to usual care, there are only 2 observational, time series studies identified, and both also used designated space as part of their intervention. The 2 studies reported conflicting results with regards to change in fall rate, and the baseline rate of falls in these 2 Australian studies was 3 to 4 times that in a typical US acute care hospital.

Regarding alternatives to sitter use, the most evidence was identified for the use of video monitoring, with 8 studies (5 of which used a time series design) reporting mostly consistent results, with either no change or a decrease in falls following implementation, and a dramatic drop in sitter use. Although formal statistical testing was often not performed in these articles, the differences or lack thereof have face validity based on figures presenting the time series data. Most articles reported cost savings in terms of sitter use, but not costs associated with the acquisition of the information technology system, training, and maintenance. Two studies of designating space for close observation were difficult to interpret because 1 study had numerous additional co-interventions and the other study was limited by design (pre/post) and lacked precision (clinically significant higher falls risk in the close observation unit, but not statistically significant). Three studies of nurse assessment and decision tools were limited by design (2 studies were pre/post), inconsistent results, and by co-interventions in the single time series study (for example, the observed reduction in use of sitters may have been due to a co-intervention, such as the requirement that nursing units report their monthly use of sitter utilization). Among the miscellaneous intervention studies, 1 time series study described a well-planned and conducted quality improvement intervention that convincingly shows that a multicomponent intervention tailored to meet local needs and challenges can reduce sitter use while not adversely influencing fall rates.

Key Question 2: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, etc) for reducing suicide or self-harm?

We identified no studies reporting the effects of sitters, or alternatives to removing sitters, on the outcomes of suicide or self-harm.

Key Question 3: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, etc) for reducing wandering?

We identified no studies reporting the effects of sitters, or alternatives to removing sitters, on the outcome of wandering.

Key Question 4: What is the cost-effectiveness of one-to-one observations compared to usual care for patients at risk of falls, suicide, or wandering?

We identified no studies reporting the cost-effectiveness of sitters. Many studies of alternatives to sitters reported cost savings due to less use of sitters, and these amounts could be quite substantial, but rarely were the costs of the alternative intervention included in the reporting.

DISCUSSION

Key Findings and Strength of Evidence

The key finding of this review is that, despite the strong mechanistic rationale for the use of one-to-one sitters, there is surprisingly little evidence of its effect, with only 2 studies assessing the effect on falls and no studies assessing the effect on wandering or suicide/self-harm. Of the alternatives to sitters that have published results, the use of interventions with video monitoring is the most promising, although like any information technology intervention, the success is likely to be highly context-dependent.

Certainty of Evidence for One-to-One Sitters

Intervention/Outcome	Study Limitations	Consistency	Directness	Precision	Certainty of Evidence
Adding Sitters to Usual Care					
Preventing falls	Observational studies: High	Inconsistent	Direct	Imprecise	Very Low
Removing Sitters					
Using video monitoring to reduce sitter use and not adversely influence falls	Time Series: Low Pre/post: High	Consistent	Direct	Imprecise	Moderate
Using designated spaces to reduce sitter use and not adversely influence falls	Time Series: High Pre/post: High	Inconsistent	Direct	Imprecise	Very Low
Using nurse assessment and decision tools to reduce	Time Series: Low	Inconsistent	Direct	Imprecise	Very Low

sitter use and not adversely influence falls	Pre/post: High				
Using a multicomponent intervention tailored to meet local needs and challenges to reduce sitter use and not adversely influence falls	Time Series: Low	N/A	Direct	N/A	Low

Applicability

We did not identify any studies in VA populations. We can only speculate as to the applicability of these findings to VA populations.

Research Gaps/Future Research

The fundamental value of one-to-one sitters remains a question in search of an answer. Their use may be so ingrained into usual care that a standard randomized control trial comparing sitter use to no sitter use is not feasible to conduct, in which case the "alternatives to sitters" research route should be pursued. This can be done as controlled before-and-after studies within a hospital, which will provide a much stronger basis for causal conclusions than a pre/post study, or as a time series study with incremental additions of intervention components.

Conclusions

The effect of one-to-one sitters on reducing falls, wandering, or suicide/self-harm has yet to be established. The available data are most compatible with a hypothesis that sitters are at best only modestly effective for fall prevention.

ABBREVIATIONS TABLE

Agency for Healthcare Research and Quality	AHRQ
Centers for Disease Control and Prevention	CDC
Close Observation Unit	COU
Continuous Video Monitoring	CVM
Evidence Synthesis Program	ESP
Grading of Recommendations Assessment, Development and Evaluation	GRADE
Occupied Bed Days	OBD
Patient Care Assistant	PCA
Patient Safety Assessment Tool	PSAT
Risk of Bias in Non-Randomized Studies- of Interventions	ROBINS-I
Safety Technicians	ST
St. Thomas Risk Assessment Tool in Falling elderly patients	STRATIFY
Technical Expert Panel	TEP
Veterans Health Administration	VHA
Video Monitor Technician	VMT

EVIDENCE REPORT

INTRODUCTION

Preventing adverse events in hospitalized patients is a priority goal of patient safety programs. In-facility falls and in-facility suicide are 2 conditions identified as a priority by the technical expert panel involved in the Agency for Healthcare Research and Quality (AHRQ) 2013 report Making Health Care Safer II.[1] The patient safety practices reviewed in that report included multicomponent interventions to prevent falls, and did not explicitly deal with the use of sitters. Regarding suicide prevention, the report found that "use of staff to observe at-risk patients is frequently employed, but there is no evidence from controlled trials…." The rate of falls in acute-care hospitals is estimated to range from 1.3 to 8.9 per 1,000 patient days, which translates into well over 1,000 falls per year in a large hospital.[2] The rate of in-facility suicide is not well estimated, but it has been a Joint Commission patient safety goal since 2011. The Joint Commission has previously reported approximately 3% to 20% of inpatients fall at least once during their hospitalization and, in acute and rehabilitation hospitals, injurious falls ranged from 30% to 51% of falls.[3,4] Falls with serious injury are consistently among the Top 10 sentinel events reported to The Joint Commission's Sentinel Event database, with a majority of these falls occurring in hospitals. An estimated 700,000 to 1,000,000 hospitalized patients fall each year, and as much as one-third of these falls are considered preventable.[5,6] The Centers for Disease Control and Prevention (CDC) reported medical costs for falls totaled more than $50 billion in 2015 with evidence suggesting the annual cost is rising, especially with a rising older adult population who have an increased risk of falls with age.[5] In addition to their direct medical costs, these events cost hospitals an average of $55,000 in legal claims and proceedings and also the potential for revenue loss due to reputational concerns, since fall safety performance is frequently publicly reported.[7]

These adverse events are thought to be preventable to some degree. Nurses or other personnel have been used to monitor patient behavior in continuous or constant observation for more than 35 years[8] to prevent falls and reduce elopements and suicide/self-harm. The rationale is intuitive and rooted in tradition: with staff immediately at hand to help prevent a fall or redirect a patient from engaging in a harmful act, it has historically been considered proper to utilize the constant observation practice as a protective measure.[8] But the practice is costly. US acute care hospitals can each spend more than $1 million annually on sitters.[9]

With high costs and uncertain evidence for effectiveness, and even a lack of consensus in the literature about how constant observation should be carried out, our operational partners requested an up-to-date review of sitter use and its impact on patient outcomes, to better inform policy and practice regarding sitter use.

METHODS

TOPIC DEVELOPMENT

This topic was developed in response to a nomination by Julia Neily, Associate Director, Field Office for the National Center for Patient Safety and William Gunnar, Executive Director for the National Center for Patient Safety. Key questions were then developed with input from the topic nominator, the ESP coordinating center, the review team, and the technical expert panel (TEP).

The Key Questions were:

KQ1. What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing falls?

KQ2. What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing suicide or self-harm?

KQ3. What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing wandering?

KQ4. What is the cost-effectiveness of one-to-one observations compared to usual care for patients at risk of falls, suicide, or wandering?

The review was registered in PROSPERO: CRD42019127424.

SEARCH STRATEGY

The search strategy, including the search terms and databases used, was created by a reference librarian with more than 25 years of experience performing searches for systematic reviews. We conducted searches in PubMed from inception to 12/18/2018, Web of Science from inception to 11/29/2018, Cochrane Database of Systematic Reviews and Cochrane Trials and PsycINFO from 01/01/1970 to 12/04/2018, and CINAHL from inception to 11/30/2018. The searches used included “sitter,” “patient-sitter,” and “one-to-one observation” as the set of terms. See Appendix A for complete search strategy. We performed a gray literature search on 7/10/19, using Google and the terms “patient sitter effectiveness”. From this search, we reviewed the first 30 hits for studies that would meet eligibility criteria. We also attempted to contact 1 original author for additional detail regarding her study, but she replied that those details of the study were no longer known to her.

STUDY SELECTION

Three team members (AMG, EPT, PGS), working independently, screened the titles of retrieved citations. For titles deemed relevant by at least 1 person, abstracts were then screened independently in triplicate by team members. All disagreements were reconciled through group discussion. Full-text review was conducted in duplicate by 2 independent team members, with any disagreements resolved through discussion. Because we expected few, if any, randomized trials, we did not reject observational studies, and included both time series studies and pre/post studies. In order to be included, a study had to include “one-to-one sitters” (or “specialing,” as it is called in some other countries) or “close observation” unit as an intervention in an acute

hospital general medical/surgical or psychiatric hospital setting, and report an outcome of interest (falls, wandering, suicide/self-harm), and report that preventing this outcome was the primary goal of the intervention. Thus, we rejected several studies that were multicomponent interventions that included one-to-one sitters to prevent delirium, and which then also reported falls.[10,11] We excluded these studies because they are prone to selective outcome reporting bias. We also rejected studies in rehabilitation settings, as the focus of our partner was the acute care hospital setting.

DATA ABSTRACTION

Data extraction was completed in duplicate (AMG/EPT). All discrepancies were resolved with full group discussion. We abstracted data on the following: setting, sample size, study design, use of existing theory/logic model, control/pre-intervention sitter practice, alternative(s) to sitters, implementation details, outcomes, and post-implementation follow-up interval.

QUALITY ASSESSMENT

We used the Risk of Bias In Non-randomized Studies – of Interventions (ROBINS-I) for observational studies.[12] This tool requires an assessment of whether a study is at critical, serious, moderate, or low risk of bias (or no information) in 7 domains: confounding, selection bias, bias in measurement classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported result (see Appendix B for tool; Table 1 for ROBINS-I table). Since observational studies are not required to have published an *a priori* protocol, we operationalized the last domain (bias in selection of the reported result) as requiring that studies report the most common outcomes. We used the latest advice from the Cochrane Methods group on the application of ROBINS-I to time series studies of interventions.

DATA SYNTHESIS

The observational studies were too clinically heterogeneous to support meta-analysis; hence our synthesis is narrative.

RATING THE BODY OF EVIDENCE

Where possible, a summary of findings and quality of evidence table was used to summarize the existing evidence. We used the principles of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) working group[13] plus those advocated by Howick and colleagues[14] to assess the quality of the evidence as follows:

High: We are very confident that the true effect lies close to that of the estimate of the effect.

Moderate: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.

Very Low/Insufficient: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

PEER REVIEW

A draft version of the report was reviewed by technical experts. Reviewer comments and our response are documented in Appendix C.

RESULTS

LITERATURE FLOW

We identified 4,106 potentially relevant citations for a total of 1,845 articles whose titles were screened. Of these, 131 were included at the abstract screening. From these, a total of 75 abstracts were excluded. Excluded abstracts were categorized as background (n=32), commentary (n=1), duplicate (n=1), wrong intervention (n=18), no original data (n=3), non-systematic review (n=6), no outcome of interest (n=5), not a population of interest (n=1), and setting (n=8). This left 71 publications for full-text review, of which 52 publications were excluded for the following reasons: background (n=15), condition (n=1), duplicate (n=1), wrong intervention (n=4), letter (n=2), no outcome of interest (n=12), systematic review (n=4), and unavailable (n=13). A full list of studies excluded at full-text review is included in Appendix D. A total of 19 publications were identified at full-text review as meeting initial inclusion criteria. (See Figure 1 for literature flow.) Only 2 studies[15,16] assessed the effect of adding sitters to usual care that did not include sitters; both assessed only falls as an outcome. The remaining 17 studies all assessed the effect of interventions aimed at reducing sitter use. All 17 of these studies assessed falls as the outcome of interest. There were no studies that assessed wandering or suicide-related measures as the outcome of interest. Descriptions of these studies are available in the Evidence Table (Appendix E).

The quality of the evidence was limited in that we identified no randomized trials of the intervention. Therefore, the data presented here are all from observational studies, primarily time series analyses of the effect of an intervention that may have been implemented as part of routine hospital care. Due to their design, observational studies are in general less able than randomized studies to support causal conclusions about the effectiveness of interventions. However, among our 19 observational studies we did identify 12 studies that used a time series design, and in some situations well-done time series studies can provide nearly as much support for causal conclusion as randomized studies. Our assessment of the methodologic quality/risk of bias of the included studies is presented in Table 1, using the ROBINS-I tool. Time series studies with at least 3 pre-intervention data points and 3 post-intervention datapoints were rated as low risk of bias due to confounding, since we are unaware of seasonal changes in rate of in-facility falls. Pre/post studies were rated as high risk of bias due to the possibility of confounding. As most studies were of entire wards or even hospitals, we rated them as low risk of selection bias. Bias in measurement of classification of interventions or deviations from intended interventions was rated uniformly as low risk of bias, again due to the nature of the study design and intervention, which in general was a time series or pre/post design of an entire ward or hospital before and after the implementation of an intervention. After implementation of the intervention, certainly some patients may not have gotten the intended intervention exactly the way it was intended, but we viewed this as an issue of real-world effectiveness rather than an issue of bias. Again, because of the nature of the intervention – affecting whole wards or hospitals – we judged bias due to missing data to be at low risk of bias. However, nearly all studies were judged as being at high risk of bias in measurement of outcomes, because they did not define what constituted a “fall”, and the person recording whether or not an event was a fall was not blinded to the presence or absence of the intervention. Since almost all studies were about reducing sitter use while not adversely effecting fall rates, and reported falls as their outcome, we judged almost all

studies as being at low risk of bias for selection of the reported result. Overall, all but 1 study had at least 1 domain judged as being at high risk of bias.

Figure 1: Literature Flow Chart

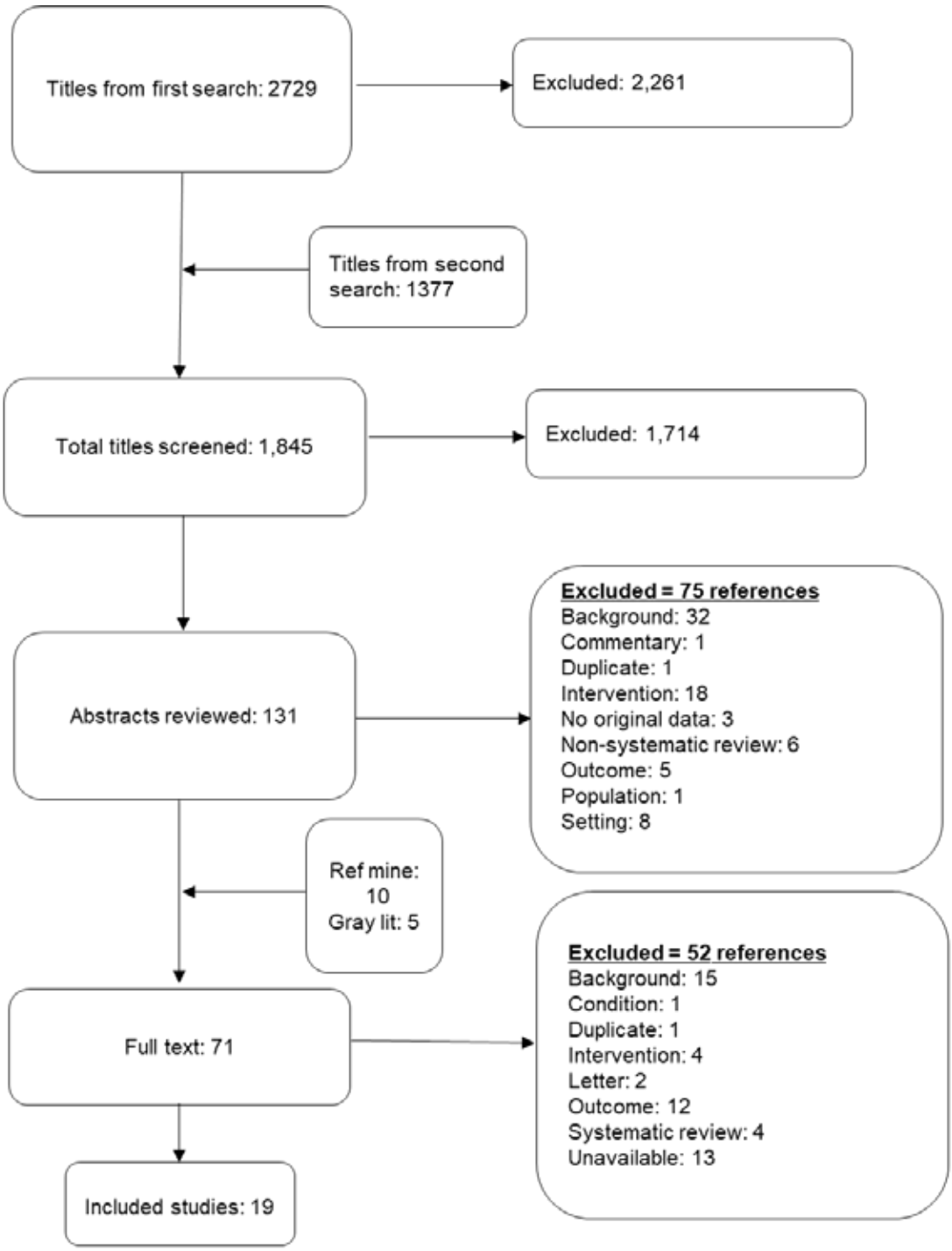

Table 1: ROBINS-I Table

	Confounding	Selection bias	Bias in measurement classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
Adams, 2013[17]	Low	Low	Low	Low	Low	High	Low
Bock, 2016[18]	High	Low	Low	Low	Low	High	Low
Burston, 2015[19]	Low	Low	Low	Low	Low	High	Low
Cournan, 2018[20]	High	Low	Low	Low	Low	High	Low
Davis, 2017[21]	High	Low	Low	Low	Low	Low for falls Low for self-harm	Low
Donoghue, 2005[16]	Low	Low	Low	Low	Low	High	Low
Giles, 2006[15]	Low	Low	Low	Low	Low	High	Low
Jeffers, 2013[22]	Low	Low	Low	Low	Low	High	Low
McNicoll, 2013[23]	Low	Low	Low	Low	Low	High	Low
Rausch, 2010[24]	Low	Low	Low	Low	Low	High	Low
Sand-Jecklin, 2016[25]	High	Low	Low	Low	Low	High	Low
Skowronsky, 2015[26]	High	Low	Low	Low	Low	High	Low
Spano-Szekely, 2018[27]	Low	Low	Low	Low	Low	High	Low
Spiva, 2012[9]	High	Low	Low	Low	Low	High	Low

	Confounding	Selection bias	Bias in measurement classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result
Tzeng, 2008[28]	High	Low	Low	Low	Low	High	Low
Vortuba, 2016[29]	High	Low	Low	Low	Low	High	High
Weeks, 2011[30]	High	Low	Low	Low	Low	High for falls Low for fracture	Low
Westle, 2019[31]	Low	Low	Low	Low	Low	High	Low
Wray, 2014[32]	Low	Low	Low	Low	Low	High	Low

KEY QUESTION 1: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing falls?

We identified 19 studies relevant to this question.[9,15-29,30,31,32] Of these, only 2 studies[15,16] assessed adding sitters as an intervention in order to reduce falls, whereas all other studies assessed some alternative such that sitter use could be reduced without a worsening of the number of falls or the fall rate. Nearly all studies assessed multicomponent interventions, which could include education, environmental interventions, use of formal assessment tools, video monitoring, *etc*). The components included in each study's intervention are presented in Table 2.

Table 2: Intervention Components

Intervention Components	Adams, 2013[17]	Bock, 2016[18]	Burtson, 2015[19]	Cournan, 2018[20]	Davis, 2017[21]	Donoghue, 2005[16]	Giles, 2006[15]	Jeffers, 2013[22]	McNicoll, 2013[23]	Rausch, 2010[24]	Sand-Jecklin, 2016[25]	Skowronsky, 2015[26]	Spano-Szekely, 2018[27]	Spiva, 2012[9]	Tzeng, 2008[28]	Votruba, 2016[29]	Weeks, 2011[30]	Westle, 2019[31]	Wray, 2014[32]
Video monitoring			X	X	X			X			X		X			X		X	
Creation of multi-bed close observation room						X	X		X			X							
New patient companion program (where one did not previously exist)						X	X												
Formal criteria/ guideline(s) for sitter implementation	X		X													X		X	
Nurse Assessment Tool													X	X	X				X
Gap analysis of best practices for fall prevention		X																	
Staff education	X	X	X		X		X		X		X	X				X	X	X	
Increased rounding	X										X		X						X
Intentional rounding		X								X									X
Geriatrician rounding									X										
Medication review/ avoidance														X	X				
Pain management															X				
Physical/ chemical restraints										X									
Sleep hygiene															X				

Intervention Components	Adams, 2013[17]	Bock, 2016[18]	Burtson, 2015[19]	Cournan, 2018[20]	Davis, 2017[21]	Donoghue, 2005[16]	Giles, 2006[15]	Jeffers, 2013[22]	McNicoll, 2013[23]	Rausch, 2010[24]	Sand-Jecklin, 2016[25]	Skowronsky, 2015[26]	Spano-Szekely, 2018[27]	Spiva, 2012[9]	Tzeng, 2008[28]	Votruba, 2016[29]	Weeks, 2011[30]	Westle, 2019[31]	Wray, 2014[32]
Diversional activities (*eg*, activity aprons, massage, music, *etc*)	X					X			X						X				
Frequent reorientation															X				
Encourage/ request family member presence															X		X		X
Environmental intervention not otherwise specified									X		X								
Wristbands, posters, other identifying tools	X										X		X		X		X		
Move patient closer to nursing station						X					X	X		X					
Alarms (bed or chair)	X	X		X					X		X		X				X		
Raised toilet seat									X										
Cordless chairs		X																	
Low beds	X			X					X		X	X			X				
Fall mats									X		X								X
No-skid socks	X																X		
Mobility support equipment		X																	
Non-restraint roll belts		X																	

Adding Sitters as an Intervention to Reduce Falls

We identified 2 studies[15,16] that added sitters as an intervention to reduce falls. The first of these studies[16] introduced the use of volunteer sitters, "companion-observers", on an acute aged care ward in Australia. The volunteer sitters/companion observers staffed a 4-bed room of patients (from 08:00-20:00) who were assessed by the nursing staff to be high risk for falls. Companion observer duties included engaging the patients in conversation, playing cards, listening to music, providing assistance with finding belongings, and meal set-up. They additionally observed the patients for increasing agitation or risky behavior and would use the call bell to summon the nurse if the patients attempted to move from the bed or chair without assistance. Unit fall rates were expressed as falls per 1,000 occupied bed days (OBD). During the 6-month pilot phase, there was a 51% reduction in the rate of falls on the unit (16.4 falls/1000 OBD to 8.4 falls/1000 OBD). Eighteen-month post-pilot data also demonstrated a decrease in the fall rate (15.6/1000 OBD to 8.8/1000 OBD). This was calculated by the authors to be a 44% reduction of risk (Fisher's exact Chi square, $p<0.000$; Odds Ratio (OR) 0.56, 95% Confidence Interval (CI) 0.45-0.68) which equated to an average monthly reduction of 6.8 falls per 1,000 bed days. Additionally, the percent of patients falling repeatedly decreased during the companion observer intervention from 32% to 15.5% ($p<0.01$; OR 0.39; 95% CI 0.20-0.77).

The second study[15] also used volunteer companions/sitters to staff 2 Australian 4-bed "safety bay" rooms from 09:00-17:00 Monday through Friday and a 4-hour morning shift on Saturday. One "safety bay" was located in an acute general medicine unit and the second in a dementia and behavioral unit. Patients at high risk for falls were identified with the STRATIFY (St. Thomas Risk Assessment Tool in Falling elderly patients) risk screening tool and clinical judgement. The role of the volunteer companion/sitter was to notify the nursing staff of all observed actions that could result in a fall, in addition to engaging the patients in social interactions and diversional activities. Four months of pre-implementation data (February to May 2002) was compared to 4 months of post-implementation data (February to May 2003) and demonstrated a non-statistically significant increase in falls from 14.5 falls/1,000 OBD to 15.5 falls/1,000 OBD (Incidence Rate Ratio =1.07; 95% CI 0.77-1.49; $p=0.346$). Twenty-four percent of the falls during the post-implementation period occurred in the "safety bays" when the volunteer companions were not present. The companion volunteers donated a total of 2,345 hours, which was calculated to represent a value of $56,866 ($AU 24.25/hr).

Using Alternatives to Try and Reduce Sitter Use

We identified 17 studies that assessed an alternative to try and reduce sitter use while not adversely affecting the rate or number of falls.[9,17-32] Almost all of these alternatives were multicomponent interventions. We further divided these studies into 4 categories, based on the kind of intervention, and discuss the evidence for each in turn:

- Interventions that include video monitoring of patients
- Interventions that involve designation of physical space specific for higher risk patients, such as a "close observation" unit
- Interventions that featured nurse assessment and decision tools
- Miscellaneous sitter reduction interventions

Interventions that Include Video Monitoring of Patients

We identified 8 studies that included video monitoring of patients. Five studies used a time series design[19,21,22,27,31] and 3 studies used a pre/post design.[20,25,29]

The first time series study[19] introduced the use of a mobile video monitoring program combined with a nursing-driven sitter protocol in a 595-bed Magnet academic health system with 2 university-affiliated hospitals. Criteria for video monitoring were established and included high fall risk, low risk for elopement (low mobility, low intent), pulling tubes/lines, low-moderate risk for suicide, and potential harm to others (with appropriate level of observation documented by psychiatry in their consultation note). Video monitor technicians (VMTs) received an initial 2-hour training and were required to complete a competency. A VMT station was located close to a nursing station and standardized work flows were created to assist with handoff for initiation of video monitoring, shift reports, and order of call for when staff intervention was required. Baseline pre-intervention data were collected for 6 quarters (1.5 years) and post-intervention data for 8 quarters (2 years). After the intervention, the use of sitters dropped dramatically, from about 5,000-6,000 hours per month to approximately 2,000 hours per month. Post-intervention data demonstrated that there was no change in falls per 1,000 patient days (between about 2.1 and 2.7 falls per 1,000 patient days). Falls with injury decreased from 0.6-0.8 per 1,000 patient days to 0.3-0.6 per 1,000 patient-days. Formal statistical testing was not done for comparisons. Also, falls with injury was not defined in the study. The combined video monitoring and nursing driven sitter protocol resulted in an estimated savings of $771,919 in the first year and $1,718,823 in the second year. This was based upon a 23.9% (16 FTE) and 53.6% (33.9 FTE) reduction in combined VMT and sitter staffing, respectively. Although elopement and suicide were included in the admission criteria for video monitoring, there were no results reported for these 2 outcomes. The authors estimated the return on investment over a 2-year period was 29.2 times the initial investment.

The second time series study[27] added a video monitoring component into the fall prevention program (nurse assessment tool, injury risk assessment tool, medication review, mobility assessment, standardized bed and chair alarm settings, purposeful hourly rounding, and post-fall debriefing) implemented in a 245-bed Magnet community hospital. The video monitoring component was introduced 5 quarters after the fall prevention program started due to persistent falls being noted in a subset of patients with impulsive behaviors. Unlicensed patient care assistants (PCAs) were trained as safety technicians (STs). Responsibilities included monitoring up to 12 patients at one time, verbally redirecting the patients via intercom and notifying the care team members to go in and help a patient attempting to get up. Baseline fall data were collected for 4 quarters. Combined post-fall prevention program and video monitoring intervention data was also collected for 4 quarters and demonstrated a 54% reduction in falls (2.51 falls/1,000 patient days to 1.15 falls/1,000 patient days; no formal statistical testing performed). A baseline falls with injury rate of 0.77 was reported in the background of the study; however, there were no post-intervention data provided for this outcome. Additionally, the authors report a 72% reduction in sitter usage with an estimated $84,000 annual cost savings, but no data are presented to support these conclusions.

The third time series study[22] implemented a continuous video monitoring (CVM) program into a 525-bed acute care facility. The program reallocated certified nursing assistants (CNAs) from the role of sitter to that of video monitor technicians (VMTs). A centralized monitoring room was

constructed which allowed immediate audio contact with nursing staff and patients. VMTs underwent competency evaluations and ancillary staff were educated regarding the surveillance program. A standardized workflow was introduced including formalized hand-off of information, daily rounding on each nursing unit, admission to the program, escalating procedures, and downtime operations. Post-implementation falls per 1,000 patient-days decreased slightly (from 4.7-5.0 falls per 1,000 patient days to 3.9-4.7 falls per 1,000 patient days; formal statistical testing not performed). Falls with injury were not reported in this study. A deferred cost savings of $392,000 in the first quarter post-implementation exceeded the original technology investment of $305,000 with an overall $2.02 million deferred cost savings in 1.5 years. The study additionally reported that within the first 3 months post-implementation, 57 falls were prevented by VMT interventions resulting in an estimated savings of $24,225. Due to the static camera view, which allowed patients to move outside of the camera's range, patients at risk for elopement did not meet criteria for video monitoring and this outcome was not measured.

The fourth time series study compared a "virtual sitter" technology (which consisted of an infrared camera that can visualize full body 3-D movement) versus traditional sitters.[31] The outcomes were falls, falls with injuries (not defined), and staffing/cost savings. The authors first performed a pilot study on a neuroscience unit where the patients with the highest risk for falls were assigned to the "virtual sitter". During the 3-month pilot, there were no falls or falls with injuries in the patients with "virtual sitters" compared with a fall rate/fall with injury rate of 4.06/2.45 for the remainder of the patients on the unit. Based on these favorable results, the pilot was then expanded to 12 months on the neuroscience unit. Compared to 12 months of pre-intervention, there was a 28% reduction in fall rate and a 19% reduction in the rate of falls with injury ($p<.001$). Before implementation of the "virtual sitter", the hospital was spending $680,000 a year on sitters, with an average cost of $350 per patient per day for whom a sitter was ordered. The authors estimated that with the "virtual sitter" this would drop to $29 per patient per day. Based on these favorable results, hospital administration decided to "scale up" the "virtual sitter" program, from 6 cameras on 1 unit to 21 cameras on 3 units. A pre/post analysis of the scaled-up implementation showed similar reductions in falls and falls with injury.

The fifth time series study assessed yearly outcomes of a video monitoring intervention implemented on 2 units.[21] The outcomes reported were falls, self-harm events, and costs. The yearly results demonstrated no statistically significant change in fall rates post-implementation, but with a decreasing trend in falls. Self-harm events were too rare to perform inferential statistics. Both units demonstrated a decrease in monthly expense for sitters at year 4 ($p<.05$) and a statistically significant decrease of in-room sitter days at year 2 (Unit 1 $p<.05$ and Unit 2 $p<.001$) and year 4 ($p<.001$, both units).

The remaining 3 studies used a pre/post study design. The first study[20] implemented a video monitoring system in a 115-bed freestanding inpatient rehabilitation facility which included a brain injury unit. Although rehabilitation units were in general an exclusion for this review, we included this one as the authors describe the facility as a "hospital" and the description of other services available in the facility makes it seem more similar to an acute care hospital than a traditional rehabilitation facility. A video monitoring room was established, and the VMTs were trained to look for behaviors in the patients that could lead to falls. Exclusion criteria for being placed on video monitor included patients pulling at tubes/devices, restlessness and agitation requiring undivided attention, and suicidal patients. This study reported a statistically significant

decrease in the brain injury unit fall rate per 1,000 patient days (10.26 pre-video to 6.87 post-video, t (18) = 2.647, p=.016), as well as the hospital-wide falls per month (6.34 pre-video to 5.09 post-video, t (31) = 2.043, p=.0496). Since not all patients could be video monitored, the authors compared the fall rate between patients who were or were not video monitored. There was no statistically significant difference in falls per 1,000 patient days over a 12-month post-implementation period on the brain injury unit when comparing video monitored and non-monitored patients (7.63 vs 6.70). An estimated $40,000 cost savings due to reduction in falls and fall-related injuries over a 21-month time period and $186,120 one-year staff cost savings were reported. The second study[25] created a video monitoring program on 2 units, including a neuroscience unit, in a large academic medical center. An algorithm was used to determine high fall risk patients appropriate for video monitoring. The VMTs observed patients for "at risk behaviors" and were able to redirect the patients via communication into the room, a telephone call to the nurse or nursing assistant, or use of the patient call bell to sound an alarm. The study reported a 28.5% statistically significant reduction in falls per 1,000 patient days (3.9 to 2.8; z = 1.85, p=.032). Falls with injuries of monitored (0/15) versus unmonitored (6/34) patients in the post-implementation period were reported; however, statistical testing was not performed. A cost savings due to reduction in sitter hours was reported. No data were provided to confirm this reported cost savings. The final study[29] implemented a video monitoring program into a critical care/intermediate care, neuroscience and senior care unit of a 350-bed Magnet hospital. The VMTs/telesitters received 8 hours of cognitive, affective, and psychomotor training and protocols were developed for how to react to potential patient falls or other safety concerns. All patients admitted to 1 of the 3 study units were eligible to be selected for video monitoring with the exception of those with behavioral restraints or at risk of harm to self or others. There was a statistically significant 35% decrease in falls reported (85 to 53; p<.0001, 95% CI) comparing 9 months of baseline pre-intervention data with 9 months of intervention data on the 3 units. The authors estimated an avoidance of 3 to 5 injurious falls annually; however, this was based upon a fall with injury estimate from another source referenced in their article. Projected fall cost avoidance of $52,000 to $87,000/year and decrease in sitter costs of $25,200/year were calculated using extrapolated data from the CDC and not internal institution costs. These combined cost savings were reported to offset the annual telesitter cost of $120,000/year. The authors note that based on the results of their study, the hospital "chose to continue funding the telesitter FTE after completion of the study". The study also reported that nursing staff used the video monitors to prevent elopement; however, no data were provided for this outcome.

Interventions that Involve Designation of Physical Space Specific for Higher Risk Patients, such as a "Close Observation" Unit

We identified 2 studies[23,26] that focused on designating some physical space specifically for higher-risk patients. This intervention will be referred to here as the creation of a close observation unit (COU). The study by McNicoll and colleagues[23] involved designating existing hospital space to create a COU. Alternatively, in the study by Skowronsky and colleagues,[26] this involved construction of a newly designed COU for their quality improvement initiative and reported in-hospital falls data in the newly constructed COU. Both studies were conducted at single hospitals in US. The study by McNicoll and colleagues used a time series design for analysis of fall rates while the study by Skowronsky and colleagues used a complicated design that was a low-quality time series (too few data points) in terms of sitter use and a variant of a non-randomized intervention study for the assessment of falls.

In the study by McNicoll and colleagues, presented only in poster form,[23] an 8-bed area of the Medicine-Surgery ward was re-designated as an Acute Care for the Elderly Unit, allowing close observation of patients from a central area. Criteria for admission to the new unit included age >70, brittle bones and risk of falls and fractures, coagulopathy and risk of bleeding, and delirium or dementia, as these patients were found to be the highest risk in a preliminary analysis and 4 times more likely to have falls, pressure ulcers, and restraints. Falls and falls with injuries were monitored for the entire 24-bed unit, although only 8 beds were within the COU. Unit falls were analyzed for 1 calendar year pre- and post-intervention. While fall rates did not improve for the entire unit, injurious fall rates decreased by 12% and monthly constant observation hours decreased by 23%. Additional benefits included improvements in Press Ganey scores in patient satisfaction, communication of nurses, and pain satisfaction. However, in addition to the designated space, the intervention also included environmental modifications (*eg*, low beds, floor mats, gait belts, walking aides, a walking path, scheduled walking times, *etc*), diversional activities (*eg*, game times, pet therapy, music therapy, evening entertainment, and social hour to prevent delirium), increased nursing staff, and a gerontological nurse practitioner who rounded twice weekly to provide support and consultation to staff.

A second study, by Skowronsky and colleagues,[26] created a 4-bed COU by opening a wall between 2 semi-private patient rooms. Glass partitions and 2 nursing workstations were placed in the central area to increase visibility of and access to patients. No baseline fall rate was reported for the internal medicine unit. Patients could be admitted to either the COU or the internal medicine unit, based on "nursing assessment and judgment" that the patient was at higher risk of falling and "general need for closer observation". Sitters continued to be used in the internal medicine unit when the clinicians so ordered them, while sitters were not used at all in the COU. After implementation of the COU, the overall use of sitters across both units dropped by more than 50%, from about 240 shifts per month to about 57 shifts per month. While there are no data presented on pre-intervention fall rates in the internal medicine unit, after the intervention there was no statistically significant difference in fall rates between the internal medicine unit (29/1878; 1.5%) and COU (3/145; 1.6%) (p=.476), despite the patients on the COU being selected as being at higher risk for falls and having more neurologic and psychiatric problems. On the basis of falls per 100 patient-days, fall rates were 31 of 8,408 (0.369%) in the internal medicine unit and 4 of 700 (0.571%) in the COU. The relative risk and 95% confidence intervals of a fall in the COU compared with the internal medicine unit were 1.55 (0.45- 5.30) (p=.486). After adjusting for hospital length of stay and discharge disposition, the relative risk and 95% confidence intervals of a fall in the COU compared with the internal medicine unit were 1.40 (0.42-4.75) (p=.584).

Two additional studies, one by Donoghue and another by Giles, also designated in-patient bed areas for the purpose of constant close observation; however, the primary intervention in these studies was initiation of a constant observation program where there was not one previously implemented.[15,16] Those studies are discussed separately above in the appropriate context ("Adding Sitters as an Intervention to Reduce Falls").

Nurse Assessment and Decision Tools

We identified 3 studies[9,28,32] that assessed interventions that included nurse assessment and decision tools to reduce the use of sitters. All 3 studies were at single hospitals in the US, and all

3 used locally developed tools. Two of the studies[28,32] printed their tool. One study used a time series design for the analysis,[32] while the other 2 presented only pre/post data.[9,28]

The time series study assessed "Safety Watch", a locally developed tool for management of patients at risk of harm.[32] Patients who were considered a suicide risk were not eligible, and all such patients were channeled to constant observation. For patients at risk of falls or injury, the tool used an algorithmic approach to assess and treat possible causes, re-evaluation of effect, and escalation of interventions, if needed. It was accompanied by instructions to initially utilize unit resources for observation, the discouragement from calling physicians for constant observation orders except in cases of suicide risk, the encouragement of family members to stay with the patient, and the requirement that nursing units report their unit constant observation utilization data. It also encouraged safety rounds every 15 minutes, and re-assessment of need every 4 hours. Lastly, nurses could implement and discontinue interventions, whereas prior to this constant observation was initiated and discontinued on physician orders. The number of hours of constant observation hours per 100 patient days dropped from 48.4 before the intervention to 26.4 after the intervention, a reduction of 45%, although statistical testing was not performed. The authors report that after the intervention the hospital was able to eliminate 15 full-time equivalent positions as a result of decreased constant observation use. The rate of falls also decreased, from 3.2 to 2.9 per 1000 patient-days, although again no statistical testing was done. Lastly, the authors report that the hospital spent $534,000 less on constant observation following implementation of the intervention.

The other 2 studies used a pre/post design. The first study[28] assessed the use of the locally developed Patient Attendant Assessment Tool, which was triggered after an order for a sitter had been placed. This tool assessed various risks and assigned a numeric score, and patients with scores below a certain threshold were recommended to receive alternatives to sitter use from a long list of alternatives (this included items like "requesting the patient's family members' help", "using door barrier", and "having the patient seat in the corridor"). This study reported decreases in sitter use of about 10% on 1 unit where it was implemented, but an increase of about 4% on another unit. The rate of falls per 1,000 patient days decreased after implementation in both units (about 10%), but the falls with injuries increased (from 0.25 to 0.59 per 1,000 patient days in 1 unit, and from 0.49 to 0.58 per 1000 patient days in the other unit). The authors report that only the increase in injurious falls was statistically significant at the 0.05 level. The second pre/post study assessed a locally developed sitter reduction program that included a sitter decision tree, sitter justification and evaluation form, letters to nurses and physicians, and scripting for family and patient by nursing staff. The sitter decision tree was not presented but was described as "an algorithm for the nurse to refer to when making decisions about sitter use". Following implementation of the program, the number of sitter hours decreased by 63% with a reported total cost savings of $321,822. Both of these reductions were reported as statistically significant (p=.001). The overall number of falls and rate of falls were both unchanged.

Miscellaneous Sitter Reduction Interventions

We identified 4 remaining studies[17,24,30] which assessed interventions that we could not place into any of the previous classifications, and thus discuss them here. One study[30] described the intervention as "no more sitters" and on a certain date, stopped physicians from writing orders for sitters. It went on to state that "with RNs able to make decisions regarding patient safety, sitters are now rarely recommended". The author reports that after implementation of this

intervention, the hospital "uses fewer companions", although no data are presented about sitter use. The rate of falls and fall-related fractures were lower post-intervention (from 5.43 to 4.36 falls per 1,000 patient days and from .065 to .058 falls with fractures per 1,000 patient days), but no statistical testing was reported. The second study[24] reported the intervention as the hiring of a "psychiatric liaison nurse" to act as a resource to "support and educate bedside nursing staff to collaboratively identify and implement alternatives". After hiring this nurse, the number of constant observation hours decreased by about half (from 1,280 shifts to 606 shifts in the 4 months before to 4 months after "well-established" implementation) with an estimated cost saving of $97,000. The rate of falls over this period of time remained approximately constant. No statistical testing was performed.

The third of these studies tested described the development over time of a multicomponent intervention designed to reduce sitter use while not adversely affecting the rate of patient falls.[17] The authors describe a careful process seeking to understand local motivators for use of sitters and potential alternative strategies to prevent falls. These alternatives went through a local vetting process which resulted in a few being selected for implementation: low beds, chair alarms, activity aprons, arm bands, and non-skid socks, which were then coupled with implementation strategies including education, benchmarking to other similar hospitals and information technology-enabled order packages. In a time series design, different components of the intervention were phased in. Sitter reduction dropped by more than half in the first year and has been maintained since then. Expenditures on the agency providing sitters dropped more than 80%, from $477,000 to $92,000. The rate of falls remained unchanged at around 4 per 1,000 patient-days. The use of restraints was reduced from around 12% of patients to less than 4% of patients. No statistical testing was performed for any of these comparisons.

The last study is a dissertation that describes a quality improvement project implemented on 2 hospital units with the aim of reducing sitter use while also reducing falls and falls with injuries.[18] The intervention was the introduction of best practices for fall prevention that was done via a gap-analysis, plus the use of new vendor products (including cordless chairs, non-restraint roll belts, and patient mobility support equipment). Compared to pre-intervention data, there was a decrease in sitter use (that was not statistically significant) and slight increase in fall rates in the units (which was also not statistically significant) over 60 days of post-intervention data. Falls with injuries were not analyzed for statistical significance due to the extreme infrequency of such events.

Summary of Findings

Regarding the use of sitters added to usual care, there are only 2 observational, time series studies identified, and both also used designated space as part of their intervention. The 2 studies reported conflicting results with regards to change in fall rate, and the baseline rate of falls in these Australian studies was 3 to 4 times that in a typical US acute care hospital.

Regarding alternatives to sitter use, the most evidence was identified for the use of video monitoring, with 8 studies (5 of which used a time series design) reporting mostly consistent results, with either no change or a decrease in falls following implementation, and a dramatic drop in sitter use. Although formal statistical testing was often not performed in these articles, the differences or lack thereof have face validity based on figures presenting the time series data. Most articles reported cost savings in terms of sitter use, but not costs associated with the

acquisition of the information technology system, training, and/or maintenance. Some studies explicitly stated that hospital administration decided to continue or even scale-up the intervention based on the results of the study. Two studies of designating space for close observation were difficult to interpret because 1 study had numerous additional co-interventions and the other study was limited by design (pre/post) and lacked precision (clinically significant higher falls risk in the COU, but not statistically significant). Three studies of nurse assessment and decision tools were limited by design (2 studies were pre/post), inconsistent results, and by co-interventions in the single time series study (for example, the observed reduction in use of sitters may have been due to a co-intervention such as the requirement that nursing units report their monthly use of sitter utilization, or the use of 15-minute rounding). Among the miscellaneous intervention studies, 1 time series study described a well-planned and conducted quality improvement intervention that convincingly shows that a multicomponent intervention tailored to meet local needs and challenges reduced sitter use while not adversely influencing fall rates in this setting.

Certainty of Evidence for Key Question 1

While adding one-to-one sitters to usual care to prevent falls has a strong mechanistic rationale (if someone is there to help assist a patient, they are less likely to fall), the empiric evidence base for it is surprisingly thin, and the only 2 studies we identified reached conflicting results. Therefore, despite the strong rationale, we judged the certainty of evidence as Very Low that the use of one-to-one sitters reduces falls. Regarding interventions to reduce the use of sitters without adversely affecting fall rates, we judged that the use of video monitoring interventions had Moderate certainty evidence that it would achieve these aims, although we note that every study used a different kind of video intervention, and thus there is no “off-the-shelf” video monitoring intervention that can be recommended. The remaining interventions were all judged by us as having Very Low certainty evidence that they would achieve their aims, based on study design limitations, inconsistent results, and the possibility of confounding due to co-interventions. The 1 exception to this was the study by Adams and colleagues that described the result of a customized intervention. We judged this as being Low certainty evidence that the process followed by Adams, meaning not the particular components chosen but rather the careful consideration of challenges and barriers and the selection of specific intervention components customized to the local challenges and barriers, would achieve the aims of decreasing sitter use while not adversely affecting fall rates. See Table 3 below for certainty of evidence for one-to-one sitters.

Table 3. Certainty of Evidence for One-to-One Sitters

Intervention/Outcome	Study Limitations	Consistency	Directness	Precision	Certainty of Evidence
Adding Sitters to Usual Care					
Preventing falls	Observational studies: High	Inconsistent	Direct	Imprecise	Very Low
Removing Sitters					
Using video monitoring to reduce sitter use and not adversely influence falls	Time Series: Low Pre/post: High	Consistent	Direct	Imprecise	Moderate
Using designated spaces to reduce sitter use and not adversely influence falls	Time Series: High Pre/post: High	Inconsistent	Direct	Imprecise	Very Low
Using nurse assessment and decision tools to reduce sitter use and not adversely influence falls	Time Series: Low Pre/post: High	Inconsistent	Direct	Imprecise	Very Low
Using a multicomponent intervention tailored to meet local needs and challenges to reduce sitter use and not adversely influence falls	Time Series: Low	N/A	Direct	N/A	Low

KEY QUESTION 2: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing suicide or self-harm?

We identified no studies reporting the effects of sitters, or alternatives to removing sitters, on the outcomes of suicide or self-harm.

Summary of Findings

No studies were identified.

Certainty of Evidence for Key Question 2

Since no studies were identified, the certainty of evidence for this outcome is Very Low.

KEY QUESTION 3: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing wandering?

We identified no studies reporting the effects of sitters, or alternatives to removing sitters, on the outcome of wandering.

Summary of Findings

No studies were identified.

Quality of Evidence for Key Question 3

Since no studies were identified, the certainty of evidence for this outcome is Very Low.

KEY QUESTION 4: What is the cost-effectiveness of one-to-one observations compared to usual care for patients at risk of falls, suicide, or wandering?

We identified 1 older (2001) study that called itself a cost-effectiveness study.[7] However, despite having as its title, "The cost-effectiveness of a patient-sitter program in an acute care hospital: a test of the impact of sitters on the incidence of falls and patient satisfaction", we had to reject this study as we could not determine where the parameter estimates came from for the effect of sitters on falls. Also, the number of falls with injury and the costs associated with falls from injury were not measured directly but rather extrapolated from data now nearly 25 years old.

Thus, we have no data about the cost-effectiveness of sitters for the prevention of any of the outcomes of interest. However, costs or cost savings were reported in many of the studies assessing alternatives to sitters. These are summarized in Table 4, below. These costs were almost always the costs saved by not using sitters and did not include the costs of the alternative interventions.

Table 4: Cost Savings

Interventions that Include Video Monitoring of Patients

Author, Year	Cost Savings
Burtson, 2015[19]	Estimated savings $772,000 year 1, $1,720,000 year 2
Cournan, 2018[20]	Net $40,000 savings in 21-month period for Falls and fall-related injuries. $186,120 saved on one-to-one sitters in 12 months
Jeffers, 2013[22]	$2.02 million in deferred cost savings in 1.5 years $24,225 in first 3 months from 57 prevented falls First quarter deferred staff savings of $392,000 exceeded original technology investment of $305,000
Spano-Szekely, 2018[27]	$84,000 annual savings
Votruba, 2016[29]	Projected fall cost avoidance of $52,000-$87,500/year (using the CDC's 2013 estimate of $17,500 per fall, not internal data) Projected decrease in sitter cost of $25,200/year (extrapolated from CDC data rather than internal institution costs) 24/7 telesitter cost ($120,000) almost completely offset by combined fall cost avoidance and sitter reduction savings ($77,200-$112,700)

Nurse Assessment and Decision Tools

Author, Year	Cost Savings
Spiva, 2012[9]	Decreased from $536,955 to $215,132, total cost savings of $321,822. (t=4.76, p=.001).
Wray, 2014[32]	41.3% ($533,917) decrease in CO expenditures ($1,292,228 to $758,311)

Miscellaneous Sitter Reduction Interventions

Author, Year	Cost Savings
Adams, 2013[17]	$1.2 million annual savings; $400,000 sitter agency savings ($477, 561.86 FY09 to $491,991.27 FY10)

Summary of Findings

We identified no studies reporting the cost-effectiveness of sitters.

Certainty of Evidence for Key Question 4

Since no studies were identified, the certainty of evidence for this outcome is Very Low.

SUMMARY AND DISCUSSION

The key finding of this review is that, despite the strong mechanistic rationale for the use of one-to-one sitters, there is surprisingly little evidence of its effect, with only 2 studies assessing the effect on falls and no studies assessing the effect on wandering or suicide/self-harm. Of the alternatives to sitters that have published results, the use of interventions with video monitoring is the most promising, although like any information technology intervention, the success is likely to be highly context-dependent.

SUMMARY OF EVIDENCE BY KEY QUESTION

Key Question 1: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing falls?

Regarding the use of sitters added to usual care, there are only 2 observational, time series studies identified, and both also used designated space as part of their intervention. The 2 studies reported conflicting results with regards to change in fall rate, and the baseline rate of falls in these Australian studies was 3 to 4 times that in a typical US acute care hospital.

Regarding alternatives to sitter use, the most evidence was identified for the use of video monitoring, with 8 studies (5 of which used a time series design) reporting mostly consistent results, with either no change or a decrease in falls following implementation, and a dramatic drop in sitter use. Although formal statistical testing was often not performed in these articles, the differences or lack thereof have face validity based on figures presenting the time series data. Most articles reported cost savings in terms of sitter use, but not costs associated with the acquisition of the information technology system, training, and/or maintenance. Two studies of designating space for close observation were difficult to interpret because 1 study had numerous additional co-interventions and the other study was limited by design (pre/post) and lacked precision (clinically significant higher falls risk in the close observation unit, but not statistically significant). Three studies of nurse assessment and decision tools were limited by design (2 studies were pre/post), inconsistent results, and by co-interventions in the single time series study (for example, the observed reduction in use of sitters may have been due to a co-intervention such as the requirement that nursing units report their monthly use of sitter utilization). Among the miscellaneous intervention studies, 1 time series study described a well-planned and well-conducted quality improvement intervention that convincingly shows that a multicomponent intervention tailored to meet local needs and challenges can reduce sitter use while not adversely influencing fall rates.

Key Question 2: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing suicide or self-harm?

We identified no studies reporting the effects of sitters, or alternatives to removing sitters, on the outcomes of suicide or self-harm.

Key Question 3: What is the effectiveness of patient sitters (one-to-one observation, patient safety companions, *etc*) for reducing wandering?

We identified no studies reporting the effects of sitters, or alternatives to removing sitters, on the outcome of wandering.

Key Question 4: What is the cost-effectiveness of one-to-one observations compared to usual care for patients at risk of falls, suicide, or wandering?

We identified no studies reporting the cost-effectiveness of sitters. Many studies of alternatives to sitters reported cost savings due to less use of sitters, and these amounts could be quite substantial, but rarely were the costs of the alternative intervention included in the reporting.

LIMITATIONS

Publication Bias

Publication bias is a major concern for a topic such as this. Particularly for the "alternatives to sitters" articles, it is highly likely that unsuccessful alternative interventions are less likely to be published. This colors the evidence base for each topic and was considered in our overall rating of the certainty of evidence.

Study Quality

Study quality is a major concern for this topic. While some of the studies used a time series design sufficient to support causal relationships, most did not. Study quality was considered in our overall rating of the certainty of evidence.

Heterogeneity

Heterogeneity is a major concern for this topic. Studies' interventions most often included multiple components, and these were all idiosyncratic—no study tested the same intervention, in all its components, as any other study. We attempted to group study interventions into categories of interventions that shared some similarities, but nevertheless within each category there is still substantial heterogeneity in interventions.

Applicability of Findings to the VA Population

We did not identify any studies in VA populations. We can only speculate as to the applicability of these findings to VA populations.

RESEARCH GAPS/FUTURE RESEARCH

The fundamental value of one-to-one sitters remains a question in search of an answer. Their use may be so ingrained into usual care that a standard randomized control trial comparing sitter use to no sitter use is not feasible to conduct, in which case the "alternatives to sitters" research route should be pursued. This can be done as controlled before-and-after studies within hospital, which will provide a much stronger basis for causal conclusions than a pre/post study, or as a time series study with incremental additions of intervention components.

CONCLUSIONS

The effect of one-to-one sitters on reducing falls, wandering, or suicide/self-harm has yet to be established. Of the alternatives to sitters that have published results, the use of interventions with video monitoring is the most promising, although success is likely to be highly context-dependent.

REFERENCES

1. Miake-Lye IM, Hempel S, Ganz DA, Shekelle PG. Inpatient fall prevention programs as a patient safety strategy: a systematic review. *Annals of internal medicine.* 2013;158(5 Pt 2):390-396.
2. Oliver D, Healey F, Haines TP. Preventing falls and fall-related injuries in hospitals. *Clin Geriatr Med.* 2010;26(4):645-692.
3. Zubkoff L, Neily J, Quigley P, et al. Virtual Breakthrough Series, Part 2: Improving Fall Prevention Practices in the Veterans Health Administration. *Joint Commission journal on quality and patient safety.* 2016;42(1553-7250 (Print)):497-ap412.
4. Joint C. Preventing falls and fall-related injuries in health care facilities. *Sentinel Event Alert.* 2015(55):1-5.
5. Control NCfIPa. Costs of Falls Among Older Adults. Centers for Disease Control and Prevention. https://www.cdc.gov/homeandrecreationalsafety/falls/fallcost.html. Published 2016. Accessed.
6. Quality AfHRa. Preventing Falls in Hospitals. https://www.ahrq.gov/professionals/systems/hospital/fallpxtoolkit/index.html. Published 2018. Updated Jul-Aug. Accessed.
7. Boswell DJ, Ramsey J, Smith MA, Wagers B. The cost-effectiveness of a patient-sitter program in an acute care hospital: a test of the impact of sitters on the incidence of falls and patient satisfaction. *Quality management in health care.* 2001;10(1):10-16.
8. Manna M. Effectiveness of formal observation in inpatient psychiatry in preventing adverse outcomes: the state of the science. *Journal of psychiatric and mental health nursing.* 2010;17(3):268-273.
9. Spiva L, Feiner T, Jones D, Hunter D, Petefish J, VanBrackle L. An Evaluation of a Sitter Reduction Program Intervention. *Journal of nursing care quality.* 2012;27(4):341-345.
10. Laws D, Crawford CL. Alternative strategies to constant patient observation and sitters: a proactive approach. *The Journal of nursing administration.* 2013;43(1539-0721 (Electronic)):497-501.
11. Pinkhasov A, Singh D, Chavali S, Legrand L, Calixte R. A Proactive Behavioral Health Service Model to Address Use of Constant Observation in a General Hospital. *Psychiatric Services.* 2018;69(3):251-253.
12. Sterne JA, Hernan MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ (Clinical research ed).* 2016;355:i4919.
13. group Gw. 2014. http://www.gradeworkinggroup.org.
14. Howick J, Glasziou P, Aronson JK. The evolution of evidence hierarchies: what can Bradford Hill's 'guidelines for causation' contribute? *J R Soc Med.* 2009;102(5):186-194.
15. Giles LC, Bolch D, Rouvray R, et al. Can volunteer companions prevent falls among inpatients? A feasibility study using a pre-post comparative design. *BMC geriatrics.* 2006;6:11.
16. Donoghue J, Graham J, Mitten-Lewis S, Murphy M, Gibbs J. A volunteer companion-observer intervention reduces falls on an acute aged care ward. *Int J Health Care Qual Assur Inc Leadersh Health Serv.* 2005;18(1):24-31.
17. Adams J, Kaplow R. A Sitter-Reduction Program In an Acute Health Care System. *Nurs Econ.* 2013;31(2):83-89.
18. Bock TJ. *Patient Care Sitter Reduction and Fall Safety Improvement.* University of San Francisco;2016.

19. Burtson PL, Vento L. Sitter Reduction Through Mobile Video Monitoring A Nurse-Driven Sitter Protocol and Administrative Oversight. *Journal of Nursing Administration.* 2015;45(7-8):363-369.
20. Cournan M, Fusco-Gessick B, Wright L. Improving Patient Safety Through Video Monitoring. *Rehabilitation nursing : the official journal of the Association of Rehabilitation Nurses.* 2018;43(2):111-115.
21. Davis J, Kutash M, Whyte IV J. A comparative study of patient sitters with video monitoring versus in-room sitters. *Journal of Nursing Education and Practice.* 2017;7(3):137-142.
22. Jeffers S, Searcey P, Boyle K, et al. Centralized video monitoring for patient safety: a Denver Health Lean journey. *Nursing economic$.* 2013;31(0746-1739 (Print)):298-306.
23. McNicoll L, Cournoyer C, Roach R, et al. Close Observation Medical Unit: A Model for Nursing and Geriatrics Collaboration. In. Providence, Rhode Island: Alpert Medical School of Brown University; Rhode Island Hospital; 2013.
24. Rausch DL, Bjorklund P. Decreasing the Costs of Constant Observation. *Journal of Nursing Administration.* 2010;40(2):75-81.
25. Sand-Jecklin K, Johnson JR, Tylka S. Protecting Patient Safety: Can Video Monitoring Prevent Falls in High-Risk Patient Populations? *Journal of nursing care quality.* 2016;31(1550-5065 (Electronic)):131-138.
26. Skowronsky C, Bena JF, Albert NM. Close Observation Unit to Prevent Falls and Minimize Use of Patient Care Companions. *Journal of nursing care quality.* 2015;30(1):38-43.
27. Spano-Szekely L, Winkler A, Waters C, et al. Individualized Fall Prevention Program in an Acute Care Setting: An Evidence-Based Practice Improvement. *Journal of nursing care quality.* 2018.
28. Tzeng HM, Yin CY, Grunawalt J. Effective assessment of use of sitters by nurses in inpatient care settings. *Journal of advanced nursing.* 2008;64(2):176-183.
29. Votruba L, Graham B, Wisinski J, Syed A. Video Monitoring to Reduce Falls And Patient Companion Costs For Adult Inpatients. *Nursing economic$.* 2016;34(0746-1739 (Print)):185-189.
30. Weeks SK. Falls/ambulation: Reducing sitter use: Decision outcomes. *Nursing management.* 2011;42(12):37-38.
31. Westle M, Burkert G, Paulus R. Reducing Inpatient Falls and Injury Rates by Integrating New Technology with Workflow Redesign. *New England Journal of Medicine Catalyst.* 2019.
32. Wray K, Rajab-Ali R. Safety Watch Reducing Constant Observation Through Nurse Empowerment and Accountability. *Journal of Nursing Administration.* 2014;44(4):237-243.

APPENDIX A. SEARCH STRATEGIES

PATIENT SITTERS
SEARCH METHODOLOGY

DATABASE SEARCHED & TIME PERIOD COVERED:
Web of Science – From inception to 11/29/2018

LANGUAGE:
English

SEARCH STRATEGY:
"FORWARD SEARCHES" ON THE FOLLOWING ARTICLES:

Boswell, D. J., J. Ramsey, M. A. Smith and B. Wagers. (2001) "The cost-effectiveness of a patient-sitter program in an acute care hospital: a test of the impact of sitters on the incidence of falls and patient satisfaction." Qual Manag Health Care **10**(1): 10-6.

Carr, F. M. "The role of sitters in delirium: an update." (2013) Can Geriatr J **16**(1): 22-36.

Chu S. Special observations in the care of psychiatric inpatients: A review of the literature and developments in practice. (2016) ARC Journal of Psychiatry. 1(1):21-31.

Cox, A., M. Hayter and J. Ruane. "Alternative approaches to 'enhanced observations' in acute inpatient mental health care: a review of the literature." (2010) J Psychiatr Ment Health Nurs **17**(2): 162-71.

Feil M, Wallace S. The use of patient sitters to reduce falls: Best practices. (2014) Pennsylvania Patient
Safety Advisory. 11(1):8-14.

Lang, C. E. "Do sitters prevent falls? A review of the literature." (2014) J Gerontol Nurs **40**(5): 24-33; quiz 34-5.

Manna, M. "Effectiveness of formal observation in inpatient psychiatry in preventing adverse outcomes: the state of the science." (2010) J Psychiatr Ment Health Nurs **17**(3): 268-73.

Muralidharan, S. and M. Fenton. "Containment strategies for people with serious mental illness." (2006) Cochrane Database Syst Rev(3): Cd002084.

Salamon, L. and M. Lennon. "Decreasing companion usage without negatively affecting patient outcomes: a performance improvement project." (2003) Medsurg Nurs **12**(4): 230-6; quiz 237.

Xu, C., T. X. Audrey, S. L. Shi, Y. W. Shanel, J. M. Tan, K. Premarani, R. Parasuram and S. V. Kumar. "Effectiveness of interventions for the assessment and prevention of falls in adult psychiatric patients: A systematic review." (2012) JBI Libr Syst Rev **10**(9): 513-573.

DATABASE SEARCHED & TIME PERIOD COVERED:
PubMed – From inception to 12/18/2018

LANGUAGE:
English

SEARCH STRATEGY:
sitter*[tiab] OR sitter*[ot] OR patient-sitter* OR "enhanced observation" OR "formal observation" OR "continuous observation" OR "constant observation" OR "special observation" OR one-to-one observation* OR "close observation" OR patient observ* OR "patient safety assistant" OR "patient safety assistants" OR patient attendant* OR liaison nurse* OR ((virtual observ* OR video observ* OR video monitor* OR remote observ*) AND (patient OR patients)) OR "patient companion" OR "patient companions"
AND
safety management[mh] OR safety[mh] OR patient safety[mh] OR patient satisfaction[mh] OR accidental falls[mh] OR risk management[mh] OR suicide,attempted[mh] OR mental disorders[mh] OR crisis intervention[mh] OR self-injurious behavior[mh] OR violence[mh] OR nursing care[mh] OR wandering behavior[mh] OR accident prevention[mh] OR safe[tiab] OR safe[ot] OR safety[tiab] OR safety[ot] OR fall[tiab] OR fall[ot] OR falls[tiab] OR falls[ot] OR falling[tiab] OR falling[ot] OR wander*[tiab] OR wander[ot] OR suicid*[tiab] OR suicid*[ot] OR accident*[tiab] OR accident*[ot] OR self-harm*[tiab] OR self-harm*[ot] OR self harm*[tiab] OR self harm*[ot]
AND
cost-benefit analysis OR cost OR costs OR costly OR cost effective OR finance OR financial OR expense* OR expensive OR economic OR expenditure* OR effective OR effectiveness OR ineffective OR inefficient OR benefit* OR burden* OR intrusive OR deleterious OR reduction OR reduce OR reducing

---

DATABASE SEARCHED & TIME PERIOD COVERED:
CINAHL – From inception to 11/30/2018

LANGUAGE:
English

SEARCH STRATEGY #1:
TI (sitter* OR patient-sitter* OR "enhanced observation" OR "formal observation" OR "continuous observation" OR "constant observation" OR "special observation" OR "one-to-one observation" OR "close observation" OR "patient safety assistant" OR "patient safety assistants" OR "patient attendant" OR "patient attendants") OR AB (sitter* OR patient-sitter* OR "enhanced observation" OR "formal observation" OR "continuous observation" OR "constant observation" OR "special observation" OR "one-to-one observation" OR "close observation" OR "patient safety assistant" OR "patient safety assistants" OR "patient attendant" OR "patient attendants") OR TI ((virtual OR video OR remote*) AND (observ* OR monitor*) AND (patient OR patients)) OR AB ((virtual OR video OR remote*) AND (observ* OR monitor*) AND (patient OR patients))

AND
MH "Injuries, Self-Inflicted/PC" OR "accident prevention" OR MH "Accidents" OR MH "Suicide, Attempted" OR MH "Behavioral Symptoms" OR MH "Suicidal Ideation" OR MH "Accidental Falls" OR MH "Patient Safety+"

NOT
cardio OR heart OR defibrill* OR cardiac OR diabetes OR fibrill*

SEARCH STRATEGY #2:
TI (sitter* OR patient-sitter* OR "enhanced observation" OR "formal observation" OR "continuous observation" OR "constant observation" OR "special observation" OR "one-to-one observation" OR "close observation") OR TI ("patient safety assistant" OR "patient safety assistants" OR "patient attendant" OR "patient attendants") OR TI ((virtual OR video OR remote*) AND (observ* OR monitor*) AND (patient OR patients))
NOT
cardio OR heart OR defibrill* OR cardiac OR diabetes OR fibrill*
==========

DATABASE SEARCHED & TIME PERIOD COVERED:
Cochrane Database of Systematic Reviews and Cochrane Trials – 1/1/1970 to 12/4/2018

LANGUAGE:
English

SEARCH STRATEGY:
sitter* OR patient-sitter* OR "enhanced observation" OR "formal observation" OR "continuous observation" OR "constant observation" OR "special observation" OR "one-to-one observation" OR "close observation"):ti,ab,kw (Word variations have been searched

OR
[("patient safety assistant" OR "patient safety assistants" OR (patient attendant" OR "patient attendants") OR (virtual OR video OR remote*) AND (observ* OR monitor*) AND (patient OR patients)):ti,ab,kw(Word variations have been searched)
AND
MeSH descriptor: [Patient Safety] explode all trees OR MeSH Descriptor: [Patient Harm] explode all trees OR MeSH descriptor: [Safety Management] explode all trees OR MeSH descriptor: [Accident Prevention] explode all trees OR MeSH descriptor: [Accidental Falls] explode all trees OR MeSH descriptor: [Accidents] this term only OR MeSH descriptor: [Suicidal Ideation] explode all trees OR MeSH descriptor: [Suicide, Attempted] explode all trees OR MeSH descriptor: [Suicide] this term only OR MeSH descriptor: [Self-Injurious Behavior] explode all trees]

==========
DATABASE SEARCHED & TIME PERIOD COVERED:
PsycINFO – 1/1/1970 to 12/4/2018

LANGUAGE:

English

SEARCH STRATEGY:

TI (sitter* OR patient-sitter* OR "enhanced observation" OR "formal observation" OR "continuous observation" OR "constant observation" OR "special observation" OR "one-to-one observation" OR "close observation") OR AB (sitter* OR patient-sitter* OR "enhanced observation" OR "formal observation" OR "continuous observation" OR "constant observation" OR "special observation" OR "one-to-one observation" OR "close observation") OR TI "patient safety assistant" OR "patient safety assistants" OR "patient attendant" OR "patient attendants") OR AB ("patient safety assistant" OR "patient safety assistants" OR "patient attendant" OR "patient attendants")
OR
[TI ((virtual OR video OR remote*) AND (observ* OR monitor*) AND (patient OR patients)) OR SU ((virtual OR video OR remote*) AND (observ* OR monitor*) AND (patient OR patients)) OR AB ((virtual OR video OR remote*) AND (observ* OR monitor*) AND (patient OR patients)))
AND
DE "Patient Safety" OR DE "Falls" OR DE "Accident Prevention" OR DE "Self-Injurious Behavior" OR DE "Self-Destructive Behavior" OR DE "Head Banging" OR DE "Self-Inflicted Wounds" OR DE "Self-Mutilation" OR DE "Attempted Suicide"]

APPENDIX B. RISK OF BIAS IN NON-RANDOMISED STUDIES – OF INTERVENTIONS (ROBINS-I) TOOL

Bias Domains Included in ROBINS-I[12]

Pre-intervention	Risk of bias assessment is mainly distinct from assessments of randomised trials
Bias due to confounding	Baseline confounding occurs when one or more prognostic variables (factors that predict the outcome of interest) also predicts the intervention received at baseline ROBINS-I can also address time-varying confounding, which occurs when individuals switch between the interventions being compared and when post-baseline prognostic factors affect the intervention received after baseline
Bias in selection of participants into the study	When exclusion of some eligible participants, or the initial follow-up time of some participants, or some outcome events is related to both intervention and outcome, there will be an association between interventions and outcome even if the effects of the interventions are identical This form of selection bias is distinct from confounding—A specific example is bias due to the inclusion of prevalent users, rather than new users, of an intervention
At intervention	Risk of bias assessment is mainly distinct from assessments of randomised trials
Bias in classification of interventions	Bias introduced by either differential or non-differential misclassification of intervention status Non-differential misclassification is unrelated to the outcome and will usually bias the estimated effect of intervention towards the null Differential misclassification occurs when misclassification of intervention status is related to the outcome or the risk of the outcome, and is likely to lead to bias
Post-intervention	Risk of bias assessment has substantial overlap with assessments of randomised trials
Bias due to deviations from intended interventions	Bias that arises when there are systematic differences between experimental intervention and comparator groups in the care provided, which represent a deviation from the intended intervention(s) Assessment of bias in this domain will depend on the type of effect of interest (either the effect of assignment to intervention or the effect of starting and adhering to intervention).
Bias due to missing data	Bias that arises when later follow-up is missing for individuals initially included and followed (such as differential loss to follow-up that is affected by prognostic factors); bias due to exclusion of individuals with missing information about intervention status or other variables such as confounders
Bias in measurement of outcomes	Bias introduced by either differential or non-differential errors in measurement of outcome data. Such bias can arise when outcome assessors are aware of intervention status, if different methods are used to assess outcomes in different intervention groups, or if measurement errors are related to intervention status or effects
Bias in selection of the reported result	Selective reporting of results in a way that depends on the findings and prevents the estimate from being included in a meta-analysis (or other synthesis)

APPENDIX C. PEER REVIEW COMMENTS/AUTHOR RESPONSES

Question	Reviewer comment	Authors' response
Are there any published or unpublished studies that we may have overlooked?	Yes - Unclear. Authors did not search SCOPUS, EMBASE, or search for gray literature.	See below for a detailed discussion of our search strategy.
	Yes - I realize this one may have come out after you did your search. Sand-Jecklin Et. al. Video Monitoring for Fall Prevention and Patient Safety 2018 J Nurs Care Qual Vol 34 No. 2 pp145-150 Would like to understand why excluded for background, thank you. Quigley et. al. Outcomes of Patient-Engaged Video Surveillance on Falls and Other Adverse Events. Clin Geriatr Med 35 (2019) 253-263	The paper by Sand-Jecklin (2018) was about outcomes rather than falls, and hence we could not include it. We did include as evidence the earlier paper by Sand-Jecklin (2016). The paper by Quigley and colleagues could not be included as evidence as it did not report any pre-intervention data points; it was thus excluded.
Additional suggestions or comments can be provided below. If applicable, please indicate the page and line numbers from the draft report.	Excellent report addressing the request	Thank you for your comment.
	I have added comments in the manuscript using the notes.	Thank you for your comments. We have read the attached document and incorporated the comments in this table.
	Great job!!! No comments except would like to edit my info listed under Technical Expert Panel to read: Tatjana Bulat, MD,CMD Director, VISN 8 Patient Safety Center of Inquiry Associate Chief of Staff for Geriatrics and Extended Care, James A. Haley VA Hospital and Clinics, Tampa, FL Associate Professor of Medicine, Morsani College of Medicine	Thank you for your comments. We have now made these changes to the text.
	General comments: this report serves a very useful purpose in synthesizing the evidence to date on safety attendants and related interventions for the prevention of falls. The report was well-written.	Thank you for your comment.
	The interventions focused on video monitoring seem relevant to the VA, but the business case does not seem fully established by the publications reviewed, in part because the cost of acquiring the video technology was not always factored into the cost calculations, if I understood correctly. Did any of the articles comment on sustainability of the video interventions? It would seem likely that if there was a true business case for the video intervention (i.e., if it truly paid for itself) and stakeholders perceived clinical value, then the intervention would be likely to be sustained.	This is a great question. A few of the video monitoring studies noted things like ROI or reported that the hospital administration had scaled up the intervention, which implies that leadership judged the costs to be worth the benefit. We added text to those studies.

	Page 1, line 12 -- delete "can" from "help can prevent"	We re-phrased this to “staff…at hand can help prevent a fall”
	Page 6, lines 43-44 -- It is noted that "US acute care hospitals can spend more than $1 million annually on sitters" -- is this the cost per hospital (more plausible) or the cost across all US acute care hospitals combined?	It is the cost-per-hospital. We rephrased this to make it clearer.
	Page 9, line 30 -- It's written that "...the data presented here are all from observational studies." This confused me when I first read it, because when I hear the term "observational study," it makes me think that no intervention was conducted, i.e., a cohort study where the people with sitters and without sitters were followed to observe their fall rates. Consider defining the term "observational studies" or using an alternative like "non-randomized intervention studies" or "quasi-experimental studies."	We changed this to “observational studies, primarily time series analyses of the effect of an intervention.”
	Page 9, line 52-53 -- another potential issue related to bias in outcome ascertainment is that the individuals collecting the data on falls may or may not have been blinded to the interventions that were ongoing.	We have added this to the list of issues.
	Table 2 (intervention components) -- found this table to be a useful compilation of the interventions that have been tried in the literature to date.	Thank you for your comment.
	Page 14, line 56 -- p values is reported as "p<0.000" -- is this a typo or is it how the study reported it? P value must be a positive number.	That is how it is reported in the original article. We presume that what the authors mean is that it is a positive number, but even smaller than 0.000 (for example, 0.0001).
	Page 14, line 58 -- should be "percent of patients" rather than "number of patients"	Thank you for your comments. We have now made these changes to the text.
	Page 18, line 11 -- what does "an indicated cost savings" mean? Did they give a number or just qualitatively report that there was cost savings?	We took out the “indicated”, so it is just “a cost savings was reported”.
	Page 19, line 35 -- is "Donoghue and Giles" referring to a single study by those two authors or to two separate studies, one by Donoghue and one by Giles?	These are two different studies; we have re-phrased to make that clear.
	Thank you for the opportunity to review this report. This is an important issue, but unfortunately the authors have displayed that the currently available literature does not provide adequate guidance to improve decision making. I reviewed this report with the attached PRISMA checklist. There appear to be a couple of issues that could be clarified/improved in items 11-15 and 17. Please see attached comments.	Thank you for your comment. See responses to individual comments, below.

	Cleaning up these issues may help others avoid the compulsion to spend their time repeating this work. Thanks again for your contribution.	
	Thank you so much for doing this important review. This issue is critically important since falls can cause loss of function and loss of life. Sitters use many resources and we are not even sure they help. This could also be helpful for families who may wonder why their loved one didn't get one to one observation.	Thank you for your comment.
	This is my error for not noticing sooner: KQ1: ideally this would address the effectiveness of reducing falls and fall-related injuries. I see that when possible you mentioned outcomes that measured falls with injury. I think it would be worth it to state this in KQ1 and whenever possible state the impact on fall-related injuries. I realize there is probably not much more on this but just to close the loop on this would be valuable.	We specifically looked for and abstracted when it was present the outcome of fall was with injury. Unfortunately, this was not common, as most articles reported only falls.
	Study selection: My error for not noticing sooner but the papers were pulled from acute care only. So much of VA falls are in CLC- could you also look at papers from long term care? I realize there may not be more literature addressing long term care settings for falls but also important to let readers know you looked for this.	The limitation of the eligible settings to acute care only was made very early in this process, and we can't go back and easily retrieve the long-term care articles, as they would have been rejected and included in the 1,700+ rejects. If evidence on sitters and alternatives to sitters is desired, we suggest nominating it to the ESP as a new topic.
	Excellent introduction, well referenced and covered important points about falls.	Thank you for your comment.
	Pg 4, Lines 29-30: poor grammar here, don't end the sentence with "at"....	Thank you for your comment. We have now made this change to the text.
	Pg 6, Line 44: Is that the total cost for the US for one year or in one hospital for one year? It seems very low if it is the US.	This is the cost-per-hospital. Re-phrased to make this clear.
	Pg 8, Line 28: Do you have a reference for this?	This information was given to us via email directly from Jo McKenzie, who said it was a pre-print of Chapter 25 in the 2019 edition of the Cochrane Handbook. Not sure if it is publicly available yet, but we are sure it is the latest advice.
	Pg 17, Lines 55-59: This is confusing, I thought there WAS a significant difference from pre to post intervention??	It was confusing as written. The statistically significant difference was between the pre-intervention period and the post-intervention period for patients in the brain injury unit. The nonsignificant difference was within the brain injury unit post-intervention, comparing patients who were

		placed in the video monitored rooms as compared to other patients. Changes made to the text to clarify.
	Pg 18, Lines 19-21: Is this decrease for the video group vs. the non-video group for all groups over time?	Yes, that is correct—it is 9 months of pre-intervention data across all 3 units compared with 9 months of post-intervention data. Text added to clarify this.
	Pg 19, Line 37: I'm not sure where these other studies are discussed - you mean you have already discussed them or they will be discussed below?	They were presented earlier in the "Adding Sitters to Prevent Falls" section. Text added to guide readers to this.
	Pg 27, Line 48-49: We can only speculate as to the applicability of these finding to VA populations.	Thank you for your comment. We have now made this change to the text.
	Appendix E: Evidence Table - this table is very hard to read, can you present the data in another way e.g. as a bulleted paragraph with sub-headings?	It's a challenge, for sure. We tried some other formats, none of which seemed ideal, and this format is what we thought was the best balance between detail and presentation.
	Data items: A full description of measures seems limited/lacking—what is the "outcome" they are looking to see change/improve?	We're not sure what part of text this is referring to. Almost all the studies were seeking to decrease the number of hours sitters were ordered to prevent falls, so the outcomes were sitter use, measured in hours or money, and falls, either falls in general or falls with injury.
	Risk of bias in individual studies: Additional use of GRADE seems fine, though a bit confusing because all they had was a narrative synthesis. Could the authors be more clear about what they mean about effect estimate when they didn't do a meta-analysis? Need to be clear on how they were collating the data so the reviewer understands how they were comparing studies across one another to determine "improvement" "worsening" or "no change"	The only GRADE criteria that is different across the interventions and outcomes assessed is that video monitoring reduced sitter use while not adversely influencing falls, which was judged as having consistent evidence, because all studies reported these outcomes, whether statistically tested or not.

	The search for articles (if the authors are attempting to comment as strongly as they are on publication bias) is insufficient. There appears to be handwaving when referring to publication bias as the authors do not provide quantitative evidence. They do not mention reviewing the references of included studies or searching a formal trial registry such as clinicaltrials.gov or looking at conference abstracts. They also did not search a more comprehensive database such as EMBASE or SCOPUS. There is no mention on involving a reference librarian. It is unclear whether they limited to English only studies. That being said, their searches were reasonable but given that they only found 16 references. To be thorough suggests the authors should consider searching SCOPUS or EMBASE and make some attempt to find grey literature.	We understand the reviewer's desire for more or different databases to be searched, but this type of critique can be applied to every review of every topic – there are far more databases that can be searched than there is time and money to search them. Choices have to be made. We made our choices based on the input of our reference librarian, Roberta Shanman, MLS, who is listed in the acknowledgement (but we will now include this information in the Methods, too, since it may be overlooked in the acknowledgments). We did not search SCOPUS because it is our experience that SCOPUS has content similar to Web of Science, which we did search. We did not search EMBASE because this is not the type of intervention for which EMBASE has a known added benefit to searching PubMed (for example, EMBASE lists RCTs of drug interventions that are not found in PubMed). Instead, given this intervention, we searched CINAHL, with its focus on nurses and other health professionals. We did search the references of included studies (see next comment). We did not search clinicaltrials.gov, as we did not find a single included study that reported it to have been prospectively registered, indicating to us that studies of these interventions are not viewed by their investigators as something needing or requiring prospective registration. The gray literature search suggestion is a good one, and for this revision we did a gray literature search. We found 3 additional studies, which are now included – but the addition of these studies does not change any conclusion. We disagree with our presentation of the possibility of publication bias as handwaving. Firstly, we are not able to do statistical testing for unexplained heterogeneity, due to the nature of the data. Secondly, we are describing the real world of quality improvement initiatives, in that most – both successful and unsuccessful – almost certainly never get written up for publication. Virtually every

		US hospital is engaged each year in 1 or more QI initiatives, and there are nowhere near that number of QI publications from US hospitals each year.
	Please explain “Ref mine:10.” Is this a review of reference lists?	Ref mine is a review of reference lists.
	It might be better to have Table 1 present study characteristics for which data were extracted (e.g., study size, PICOS, follow-up period)/provide the citations and make the Robins table a later table.	The evidence table with the PICOS, study design, sample size, etc., is by ESP format something that is placed in the Appendix, so we did not move it into the body of the report (it is 40+ pages long).

APPENDIX D. CITATIONS FOR EXCLUDED STUDIES

Background, n=15

1. Patient sitters' disturbing, firsthand encounters. Hospital Employee Health. 2016;35(4):41-41.

2. Report: Train sitters upon hire, and annually. Hospital Employee Health. 2016;35(4):42.

3. Bailey M, Amato S, Mouhlas C. A creative alternative for providing constant observation on an acute-brain-injury unit. Rehabilitation nursing : the official journal of the Association of Rehabilitation Nurses. 2009;34(1):11-16, 23.

4. Boswell DJ, Ramsey J, Smith MA, Wagers B. The cost-effectiveness of a patient-sitter program in an acute care hospital: a test of the impact of sitters on the incidence of falls and patient satisfaction. Quality management in health care. 2001;10(1):10-16.

5. Feil M, Wallace SC. The Use of Patient Sitters to Reduce Falls: Best Practices. Pennsylvania Patient Safety Advisory. 2014;11(1):8-14.

6. Green JS, Grindel CG. Supervision of suicidal patients in adult inpatient psychiatric units in general hospitals. Psychiatric services (Washington, DC). 1996;47(1075-2730 (Print)):859-863.

7. Laws D, Crawford CL. Alternative strategies to constant patient observation and sitters: a proactive approach. The Journal of nursing administration. 2013;43(1539-0721 (Electronic)):497-501.

8. Lee EA, Gibbs NE, Fahey L, Whiffen TL. Making hospitals safer for older adults: updating quality metrics by understanding hospital-acquired delirium and its link to falls. The Permanente journal. 2013;17(1552-5775 (Electronic)):32-36.

9. Manna M. Effectiveness of formal observation in inpatient psychiatry in preventing adverse outcomes: the state of the science. Journal of psychiatric and mental health nursing. 2010;17(3):268-273.

10. McCurley, J. and J. Pittman (2014). "A new approach to fall prevention in inpatient care implementing remote audio visual monitoring of at risk patients." Patient Saf Qual Health Care 11(6): 50-53.

11. Pinkhasov A, Singh D, Chavali S, Legrand L, Calixte R. A Proactive Behavioral Health Service Model to Address Use of Constant Observation in a General Hospital. Psychiatric Services. 2018;69(3):251-253.

12. Quigley PA, Votruba L, Kaminski J. Outcomes of Patient-Engaged Video Surveillance on Falls and Other Adverse Events. Clin Geriatr Med. 2019;35(2):253-263.

13. Ray R, Perkins E, Roberts P, Fuller L. The Impact of Nursing Protocols on Continuous Special Observation. Journal of the American Psychiatric Nurses Association. 2017;23(1):19-27.

14. Schoenfisch AL, Pompeii LA, Lipscomb HJ, Smith CD, Upadhyaya M, Dement JM. An Urgent Need to Understand and Address the Safety and Well-Being of Hospital "Sitters". American journal of industrial medicine. 2015;58(12):1278-1287.

15. Torkelson DJ, Dobal MT. Constant observation in medical-surgical settings: a multihospital study. Nursing economic$. 1999;17(0746-1739 (Print)):149-155.

Condition, n= 1

1. Esserman L. Recommend Watchful Waiting with Close Observation. In. Vol 374. Waltham, Massachusetts: New England Journal of Medicine; 2016:390-391.

Duplicate, n=1

1. Burtson PL, Vento L. Sitter Reduction Through Mobile Video Monitoring. Journal of Nursing Administration. 2015;45(7/8):363-369.

Intervention, n=4

1. Chan DK, Sherrington C, Naganathan V, et al. Key issues to consider and innovative ideas on fall prevention in the geriatric department of a teaching hospital. Australasian journal on ageing. 2018;37(2):140-143.

2. Schoenfisch A, Pompeii L, Lipscomb H, Dement J. Violence perpetrated by hospital patients and visitors (type II) against 'sitters'. Occupational & Environmental Medicine. 2014;71:A53-A53.

3. Shever LL, Titler MG, Mackin ML, Kueny A. Fall prevention practices in adult medical-surgical nursing units described by nurse managers. Western journal of nursing research. 2011;33(3):385-397.

4. Zubkoff L, Neily J, Quigley P, et al. Virtual Breakthrough Series, Part 2: Improving Fall Prevention Practices in the Veterans Health Administration. Joint Commission journal on quality and patient safety. 2016;42(1553-7250 (Print)):497-ap412.

Letter, n=2

1. Melear B. Support for sitter alternatives...'A S.A.F.E. alternative to sitters', Nurs Manage, 2009 August issue. Nursing management. 2009;40(12):8-8.

2. Routh A, Sustaita L, Pamperin R, Holguin M. Cost containment detrimentally affects patient care... 'Constant observation: implications for nursing practice'. Journal of Psychosocial Nursing & Mental Health Services. 1995;33(8):3-3.

Outcome, n=12

1. Carr FM. The role of sitters in delirium: an update. Canadian geriatrics journal : CGJ. 2013;16(1):22-36.

2. DeSousa, T. L. (2011). Evaluation of the Patient Sitter Assessment Tool. Nursing, Rhode Island College. Master of Science in Nursing (MSN).

3. McNicoll L, Baumhover L, Gifford D, Inouye S. Impact Of 'Sitter' Reduction Policies On Restraint Use; The Effect Of A Targeted Multicomponent Intervention In. Providence, Rhode Island: Rhode Island Hospital; 2018.

4. Moghabghab R. Constant Observation for Older Adults in Acute Care: A Mixed Methods Study. Constant Observation for Older Adults in Acute Care: Mixed Methods Study. 2017:1-1.

5. Moore V, Allen L, Nash MG, Buck J, Chipps E. Exploring Nurses' Perception of Dynamic Patient Events. The Journal of nursing administration. 2016;46(2):57-60.

6. Moyle W, Borbasi S, Wallis M, Olorenshaw R, Gracia N. Acute care management of older people with dementia: a qualitative perspective. Journal of clinical nursing. 2011;20(3-4):420-428.

7. Nadler-Moodie M, Burnell L, Fries J, Agan DL. A S.A.F.E. alternative to sitters...Specialized Adult-Focused Environment. Nursing management. 2009;40(8):43-50.

8. Richman C, Sarnese P. Patient Sitter Use Within Hospitals: A Cross-Sectional Study. International Healthcare Security and Safety Foundation;2014.

9. Riddell K. A comparative study of the constant observation model of care, Master of Nursing thesis: School of Nursing and Midwifery, Deakin University; 2012.

10. Siddharthan K, Nelson A, Tiesman H, Chen FF. Advances in Patient Safety Cost-effectiveness of a Multifaceted Program for Safe Patient Handling. In: Henriksen K, Battles JB, Marks ES, Lewin DI, eds. Advances in Patient Safety: From Research to Implementation (Volume 3: Implementation Issues). Rockville (MD): Agency for Healthcare Research and Quality (US); 2005.

11. Tzeng H, Yin C. International perspectives. Using family visitors, sitters, or volunteers to prevent inpatient falls. Journal of Nursing Administration. 2007;37(7/8):329-334.

12. Wilkes L, Jackson D, Mohan S, Wallis M. Close observation by 'specials' to promote the safety of the older person with behavioural disturbances in the acute care setting. Contemporary nurse. 2010;36(1037-6178 (Print)):131-142.

Systematic Review, n=4

1. Lang CE. Do sitters prevent falls? A review of the literature. Journal of gerontological nursing. 2014;40(5):24-33; quiz 34-25.

2. Nienaber A, Schulz M, Hemkendreis B, Lohr M. Special Observation in Inpatient Treatment of People with Mental Illness A Systematic Review of the Literature. Psychiatr Prax. 2013;40(1):14-20.

3. Wood VJ, Vindrola-Padros C, Swart N, et al. One to one specialling and sitters in acute care hospitals: A scoping review. International journal of nursing studies. 2018;84:61-77.

4. Xu C, Audrey TX, Shi SL, et al. Effectiveness of interventions for the assessment and prevention of falls in adult psychiatric patients: A systematic review. JBI library of systematic reviews. 2012;10(9):513-573.

Unavailable, n=13

1. Patient sitters found effective in reducing falls. Healthcare Risk Management. 2014;36(6):54-55.

2. Six elements key to patient sitter program. Healthcare Risk Management. 2014;36(6):55-56.

3. Sitter inattention still can let falls happen. Healthcare Risk Management. 2014;36(6):56-56.

4. Video monitoring reduces falls as well as cutting costs for hospitals. Healthcare Risk Management. 2015;37(7):79-80.

5. Fall-risk patients monitored continuously by video. Healthcare Risk Management. 2015;37(7):80-80.

6. 'More than a sitter': a practice development project on special observation in acute general hospital care. Foundation of Nursing Studies: Improvement Insights. 2017;12(1-10):3-3.

7. Alspach G. Where are we heading in healthcare?...patients' basic needs for physical care and safety met by hired sitters rather than staff nurses. Critical care nurse. 2001;21(2):11-14.

8. Dennis S. Formal observation in the acute in-patient setting: policy, training and practice. Mental Health Care. 1998;2(1):26-28.

9. Evans G. Patient 'sitters' at high risk of violence, physical threats. Hospital Employee Health. 2016;35(4):37-40.

10. Fielden NM. Managers forum. Video monitoring of psychiatric patients. JEN: Journal of Emergency Nursing. 2003;29(3):276-277.

11. Kramer JR, Mittlestedt D. 'Geriatric sitter' provides needed attention for difficult patients. Modern Nursing Home. 1971;26:44-45.

12. Lipkis-Orlando R, Mian P, Levy G, Lussier-Cushing M. Challenge for the 90s: a safe and cost-effective sitter program... patients who are suicidal, confused, and display unpredictable behavior. MEDSURG Nursing. 1993;2(6):483-485.

13. Sandrick K. Clear policies are needed to guide the use of 'hired sitters' in acute care. COR Clinical Excellence. 2001;2(4):4-5.

APPENDIX E. EVIDENCE TABLE

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
Adams, 2013[17] USA	**Study Setting:** • Med-Surg • ICU **Setting Details:** • 4 hospitals - 2 urban tertiary teaching hospitals - Geriatric center - Orthopedic and spine hospital **Baseline Fall Rate:** 4.5 falls/1000 pt days (derived from Fig. 3 image; raw numbers not provided)	Time Series	Yes **-- to reduce sitter usage** without negatively impacting select quality indicators: falls, restraints, and pressures ulcers	1:1 sitters	• Formal criteria for sitters • Equipment like low beds • Education • Chair alarms • Increased rounding • Activity aprons • No skid socks • Color-coded blankets & chart stickers (identifying tools)	• Benchmarking • Falls Champions on each unit • Daily huddles identify patients at increased risk of falls • More frequent rounding on pts designated as high risk for falls • Monthly feedback • Staff education on indication for sitter alternative equipment and how to obtain them • Letters sent to staff, physicians, patients and families regarding changes to sitter policy • Changing sitter request form from paper to electronic	**Falls:** Falls/1,000 patient days: no change (Figure 3) **Falls with injury:** Not reported. "Severity of injury rate from a fall decreased" (anecdotal comment in the text. No supporting data provided) **Change in Sitter Use:** **"**Over a 6-month period, sitter use dropped appreciably (see Figure 1). This reduction has been maintained to date" **Costs:** $1.2 million annual savings	**FALLS:** Pre-intervention Data for fall rates: 7 quarters (Nov 2007-May 2009) 1st Intervention: June 2009 Final Intervention: Sept 2010 Most recent Data reported July 2011 **COSTS:** Baseline Pre-intervention Data for costs: Fiscal Year 2009 (Sept 2009-Aug 2010)

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							$400,000 sitter agency savings ($477, 561.86 FY09 à 491,991.27 FY10) **Other Outcomes:** Restraint use decreased from 12% à 3%	**Post-Intervention** Fiscal Year 2010 (Sept 2010 – Aug 2011
Bock, 2016[18]USA	**Study Setting:** · 48-bed adult medical specialties unit · 53-bed adult telemetry unit **Setting Details:** · 2 hospitals affiliated with a 7- hospital health system **Baseline fall data:** Unit 1: 3.14 falls/1000 pt days	Pre-post	No	1:1 Sitter	• Fall reduction best practices • New vendor equipment	• Gap analysis via a collaborative work group that reviewed current evidence and system policies to identify most effective practices. • Best practices disseminated and targeted to the two intervention units. • Active fall safety huddle at the beginning of each shift to identify all high-risk patients	**Falls:** Both units reported a small and statistically insignificant increase in fall rate Unit 1: 3.14 à 3.35 falls/1000 pt days (p=0.41) Unit 2: 3.48 à 3.80 falls/100o pt days (p=0.45) Combined performance:	**Pre-intervention** 12 months (FY 2016) **Post-intervention** 60 days (annualized)

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals

	Unit 2: 3.48 falls/1000 pt days					• Scripted safety education discussion with patients during bedside shift report
						• Staff education via staff meetings, Fall Risk Committee education, vendor best practices, handouts and emails
						• New product vendor with new equipment:
						  • Cordless chair and mobility alarms
						  • Non-restraint roll belts
						  • Improved patient mobility support equipment
							3.30 à 3.57 (p=0.42)
							Falls with injury:
							Not analyzed for statistical significance due to the extreme infrequency of such events
							Change in Sitter Use:
							Unit 1 reduced sitter use by 32.8% (p=0.83)
							1.90 FTE à 1.28 FTE
							Unit 2 reduced sitter use by 57.9% (p=0.93)
							2.12 FTE à 0.89 FTE
							Combined performance reduced sitter use by 46% (p=0.96)
							4.02 FTE à 2.17 FTE
							Costs:	

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							46 % sitter reductions produced an annualized savings of $72, 324 **Other Outcomes:** None	
Burtson, 2015[19] USA	**Study Setting:** • Med-Surg **Setting Details:** • 595 bed Magnet academic health system • 2 university-affiliated hospitals **Baseline Fall Rate:** (quarterly range) 2.16-3.41 falls/1000 pt days over 4 years **Baseline Fall with Injury Rate:** (quarterly range) 0.54-0.87 falls	Time Series	Yes – for reduction in sitter use, preventing falls, preventing elopements	1:1 sitters	• Video monitoring Guidelines	• Mobile video monitoring carts • Standardized workflows • Video monitoring technician training with competency testing • Project champions educate clinicians • Re-evaluation after 6 months with devised criteria • Elimination of sitter from physician order sets • Daily manager reviews • Elimination of high fall risk from	**Falls:** Falls per 1000 patient days: no change (Figure 3) **Falls with injury:** Decreased (per Figure 4; data not reported) **Change in Sitter Use:** Decrease in sitter and VMT staffing by 23.9% year 1, 53.6% year 2	**Pre-Intervention** 1.5 years (= 6 quarters) **Post-Intervention Data** 2 years (= 8 quarters)

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
	with injuries/1000 pt days					nursing protocol for sitters • Sitters requested outside of protocol were authorized by a unit manager after specific alternatives were tried and failed to meet the safety need.	**Costs:** Estimated savings $772,000 year 1, $1,720,000 year 2 **Other Outcomes:** Not reported	
Cournan, 2018[20] USA	**Study Setting:** • Rehab Unit *(authors describe unique rehab unit, more similar to inpatient hospital setting in terms of patient acuity and facility resources. Have included in this study to be comparable to Med-Surg)* **Setting Details:**	Pre/Post	No	1:1 and close observation	• Video monitoring • bed • alarms • chair alarms • low beds • fall mats • sitters	• Video Monitor Tech monitors up to 15 patients at one time • Mobile units had speakers. All units able to zoom and move 360 degrees • Video Monitoring exclusion criteria: patients pulling at tubes/devices, restlessness and agitation requiring undivided attention and suicidal patients • Established escalating protocol if the	**Falls:** Fall rate on Brain Injury Unit per 1,000 patient-days: 10.26 prevideo à 6.87 postvideo significant, t(18) = 2.647, p=.016 Hospital-wide fall rate per 1,000 patient-days: 6.34 falls per month (SD = 1.75) for the 21 months prevideo à 5.09 falls per month (SD	**Pre-Intervention** 21 months **Post-Intervention** 12 months

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
	• 115-bed freestanding inpatient rehabilitation facility (with focus on 31-bed brain injury unit within facility) **Sample Size:** • 15 beds monitored of total 115 beds in facility ➔ 8 mounted in brain injury unit ➔ 2 mounted in other units ➔ 5 mobile units **Baseline Fall Rate:** 6.34 falls/1000 pt days					patient does not respond to monitor technician remote • Nurse manager reviews VMT log • Patients removed from monitoring program if shows a steady decrease in need for VMT interventions • Video monitor room was separate from the nurses' station to minimize distractions • Manufacturer provided training on how to use the video system • VMTs trained to look for behaviors that might lead to unsafe action • Physician order and patient/family consent not required	= 1.52) for the 12 months postvideo significant, t (31) = 2.043, p=.0496 Brain injury Unit video vs non-video fall rate per 1000 patient-days: no difference Proportion of in-room falls increased (72.4% pre à 77% post) Number of hallway falls decreased (20 pre à 3 post) **Falls with Injury:** Not reported **Change in Sitter Use:** Not reported **Costs:**	

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							Net $40,000 savings in 21-month period for Falls and fall-related injuries. $186,120 saved on one-to-one sitters in 12 months **Other Outcomes:** Not reported	
Davis, 2017[21] USA	**Study Setting:** · Cardiology unit · Neuroscience unit **Setting Details:** · Large, not for-profit teaching facility **Baseline Fall Rates:** Unit 1: 4.25 falls/1000 pt days Unit 2: 6.50 falls/1000 pt days	Time series	No	Constant observation (1-2 pts/sitter)	• Video monitoring	• Ceiling-mounted cameras installed at the foot of selected beds • Camera was wired to a central console at the nurses station located in close proximity to the designated patient rooms • Console observed continuously by trained, unlicensed staff member for 4 hours at a time • Staff member monitoring the console would immediately go to the room if concerning	**Falls:** No statistically significant change in falls/1000 pt days Unit 1: 4.25 (baseline) à 6.25 (Year 2) à 1.25 (Year 4) Unit 2: 6.50 (baseline) à 8.25 (Year 2) à 6.00 (Year 4) **Falls with injury:**	**Pre-intervention** Baseline time interval not defined **Post-intervention** 4 years

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						behavior was noted. Another staff member would monitor the console until the responder returned.	Not reported **Change in Sitter Use:** Unit 1: Statistically significant decrease of in-room sitter days Year 2: 61.86 à 7.875 (p<0.05) Year 4: 61.86 à 1.13 (p<0.001) Unit 2: Statistically significant decrease of in-room sitter days Year 2: 45 à 1 (p<0.001) Year 4: 45 à 0.29 (p<0.001)	

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							Costs: Unit 1: statistically significant decrease in monthly expense for sitter at Year 4 Year 2: $17,255.70 à $10,632.30 (not statistically significant) Year 4: $17,255.70 à $8,749.86 (p<0.05) Unit 2: statistically significant decrease in monthly expense for sitter at Years 2 and 4 Year 2: $12,549.60 à $8,715.00 (p<0.05) Year 4: $12,549.60 à $5716.99 (p<0.05)	

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							Other Outcomes: Self-harm events were measured; however, due to the rareness of these events inferential statistics could not be performed	
Donoghue 2005,[16] Australia	**Study Setting:** • Med-Surg **Setting Details:** • Acute aged care unit with hospital in Sydney, Australia **Baseline Fall Rate:** 16.4 falls/1000 occupied bed days	Time series	Yes Falls	Nursing risk assessment Moving pts closer to nurses' station Medication review and adjustment Guidelines for physical restraints Magnetic falls risk symbols applied to beds	• Volunteers as "companion observers"	• Revised risk criteria and clinical judgement used by nursing staff to identify patients at high fall risk. • High-risk patients placed in 4 bed room near the nurses' station • CO volunteers were assigned 2-hour shifts weekdays from 08:00-20:00 • Escalating protocol of: - gentle reassurance of the patient - alerting nursing staff if unsuccessful • Other CO activities: - Conversation - playing cards	**Falls:** During 6-month pilot: 51% reduction in rate of falls (16.4 falls/1000 OBD à 8.4 falls/1000 OBD) 18 month post-pilot data: Decreased in fall rate (15.6/1000 OBD à 8.8/1000 OBD)=44% reduction in risk (p<0.000; OR 0.56, 95% CI 0.45-0.68) Average monthly reduction of 6.8 falls/1000 bed days	**Pre-Intervention** 6 month **Post-Intervention** 18 month post-pilot data collected

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						- reading out loud - playing appropriate music - providing practical assistance with finding belonging - meal set-up • Volunteer coordinator in daily contact with nursing unit manager to identify any issues	Decrease in repeated falls during CO intervention (32% à 15.5%; p<0.01; OR 0.39; 95% CI 0.20-0.77) 5 months with no repeat fallers **Falls with Injury:** Not reported **Change in Sitter Use:** Not reported **Costs:** Not reported **Other Outcomes:** Communication between nurses and volunteers was sometimes problematic (anecdotal)	

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							CO volunteers asked to perform tasks outside of their limits (*ie*, walk or feed patients)	
Giles 2006,[15] Australia	**Study Setting:** • Med-Surg **Setting Details:** • 2 Hospitals in Australia with 370 beds total • 2 four bed "safety bays" - 1 general medical unit - 1 dementia & behavioral unit **Baseline Fall Rate:** 14.5/1000 OBD (occupied bed days)	Time series	Yes Falls	No sitter	• Volunteer companion program • Four-bed "safety bay"	• Creation of a 4-bed "safety bay" on each unit • Patients at high risk for falls identified with the STRATIFY risk screening tool at 1 hospital and "clinical judgement" at the second hospital • Patients observed by volunteers 9am-5pm M-F and 4hr morning shift on Saturday • 4-hour volunteer shifts • General medicine safety bay had 1 volunteer per shift • Dementia/ behavioral safety bay had 2 volunteers/shift • Volunteer training program included falls prevention • Falls recorded in the hospital's monitoring system	**Falls:** Falls increased from 14.5 falls/1000 OBD à 15.5 falls/1000 OBD) IRR=1.07 (95% CI 0.77-1.49; p=0.346) 24 % of the falls in the implementation wards occurred in the safety bays when the volunteers were not present **Falls with Injury:** Not reported **Change in Sitter Use:** Not reported. **Costs:**	**Pre-Intervention** 2/2002-5/2002 (4 months) **Implementation period (no data)** July 2002-Jan 2003 **Post-Intervention** 2/2003-5/2003 (4 months)

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						• Volunteers kept journals to document their experience • Satisfaction surveys given to volunteers, staff, patients, patients' families	2,345 donated volunteer hours=$56,866 value ($AU24.25/hr) **Other Outcomes:** Companions acted as pt advocates, provided companionship and enhanced the delivery of care	
Jeffers, 2013[22] USA	**Study Setting:** • Med-Surg • Psych Ward **Setting Details:** • 525-bed acute care facility • 8-18 patients daily from 7 acute care units, with an average daily program census of 12 patients **Baseline Fall Rate:** 4.70-4.96 falls/1000 pt days	Time series	Yes-- Fall reduction	1:1	• Video monitoring	• Collaboration of nursing administration, acute care nursing management and staff, nursing support services, biomedical services, information technology, legal, regulatory, quality, patient safety and vendor partners • Project manager assigned to coordinate and streamline implementation steps • IT selected video technology for continuous	**Falls:** The first 3 months of VMT interventions contributed to the prevention of 57 falls 75% of nursing units met or exceeded National Database of Nursing Quality Indicators (NDNQI) benchmark fall rates **Falls with Injury:** Not reported **Change in Sitter Use:**	**Pre-Intervention** 3 Quarters **Post-Intervention** 1.5 years (6 quarters)

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						monitoring without recording and patient visualization in both high- and low-light settings • Construction of a centralized monitoring room with expansion of the nurse call system to allow immediate audio contact with nursing staff and patients • Creation of flow sheets for documentation, admit and discharge logs and resource manuals • Staff education and hands on training • Competency evaluation tools • Consent for video monitoring was part of the general consent form and did not require a separate consent • 2 CNAs staff the CVM room 24/7 with 12-hr shifts	Not reported **Costs:** $2.02 million in deferred cost savings in 1.5 years (Figure 5) $24,225 in first 3 months from 57 prevented falls First quarter deferred staff savings of $392,000 exceeded original technology investment of $305,000 **Other Outcomes:** Patient elopements: video not adequate tool for assessment of this measure The first 3 months of VMT interventions contributed to the	

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						• Patients could refuse video monitoring, and opt for 1:1 CNA sitters • Documentation occurs in real-time on a video monitoring technician work log à transferred to EMR q2h. • VMT's shift begins with a formal hand-off of information from previous shift. VMT rounds on each nursing unit to collect patient census reports and communicate w/staff. Each shift, unit charge nurse report to the VMTs to confirm correct patients are on camera.	prevention of 7 oxygen therapy disruptions and 10 IV catheter pulls. Facilitated faster transfer to SNF for 2 patients. 1 case prevented sitter risk/harm. Identified patients requiring assistance with meals or replacement of oxygen cannula	
McNicoll, 2013[23] USA	**Study Setting:** • Med-Surg **Setting Details:** • 24 bed total Med-surg unit • 8 bed area of med surg unit	Time series	No	? constant observation	• Acute Care for the Elderly (ACE) Unit/ close observation unit	• Education of nurses and nurses' aides on geriatric friendly care • ABCD Algorithm for admission criteria: -Age >70	**Falls:** Fall rates unchanged **Falls with injury**: decreased by 12%	**Pre-Intervention** data collected for 2011 (1 year)

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
	allowing close observation from a central area **Baseline Fall Rate:** Data not reported. Refer to "Any Falls" figure in text **Baseline Fall with Injuries Rate:** Data not reported. Refer to "Falls with Injuries" figure in text					-Brittle bones and risk of falls and fracture -Coagulopathy and risk of bleeding -Delirium and dementia • Environmental modifications: -Low beds -Floor mats -Bed/chair alarms -Raised toilet seats -Gait belts -Walking aids -Walking paths -Hearing amplifiers -Communal area for dining and activities -Large TV and DVD for evening entertainment • Scheduled activities for increased interaction • 2 nurses' aides and 1 nurse on the unit at all	**Change in sitter use:** Monthly constant observation hours decreased by 23% (830 à 641) **Costs:** Not reported **Other outcomes:** Pressure ulcer rates decreased by 23% Press Ganey results: -Patient satisfaction improved 1.3 points (82.3 à 83.6) Communication with RN improved 3.8 points (70.5 à 74.3) -Pain satisfaction improved 2.7 points (58.6 à 61.3)	**Post-Intervention** data collected for 2012 (1 year)

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						times with one aide providing safety monitoring • Geriatric NP rounding twice weekly to provide support • Monthly multi-disciplinary team meetings (geriatric psychiatrist, geriatrician, management and quality nursing)		
Rausch, 2010[24] USA	**Study Setting:** • Medical-surgical units (50%) • ICU (30%) • rehabilitation (18%) • women care/ obstetrics units (2%) **Setting Details:** • 800-bed hospital • Urban tertiary Magnet designated hospital **Sample Size:**	Time Series	No	1:1 constant observation ordered by MD (RN often decides to discontinue)	• Physical restraints • Pharmaco-logic restraints (*ie*, haldol) • Intentional rounding	• Psychiatric liaison nurse (PLN) to support nursing staff on all wards to provide education and support, and closely collaborate with the nursing staff (with input from attending physician and social work) on alternatives to 1:1 Constant observation • By making rounds in person or telephoning to speak with the charge nurse, the	**Falls:** Hospital-wide falls declined by 25%. NO increase of falls **Falls with injury:** Not reported **Change in Sitter Use:**	**Pre-Intervention** 4 months **early PLN implementation** = May-August 2008 (4 months) **late PLN implementation** (when PLN role well-

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
	175 patients, age 15-94 yo Delirium and confusion precipitated most CO consults (62%), followed by suicidal ideation or precautions (17%) and elopement risk (10%) **Baseline Fall Rate:** 69 falls/month (no data to calculate/1000 pt days)					PLN contacted 15 patient-care areas of the hospital each day to determine which areas were using CO and which patients had unmet psychiatric needs. • PLN tracked Constant Observation (CO) consults during regular business hours M-F • For each CO consult the PLN completed a "Daily Attendant Report" with patient demographics, reason for CO and alternative interventions/plan . • Reports sent daily to hospital directors, patient care managers and assistant patient care managers • "Open pager" policy for nursing staff to contact	Number of constant observation shifts decreased by 42%, or 400 CO shifts **Costs:** 1:1 constant observation cost savings of $97,056 over a 4-month period, a 53% reduction in CO costs (table 2) **Other Outcomes:** No increase of restraint prevalence Psychiatric consultation-liaison nurse (PCLN) psychiatric assessment recommended by PLN one-fourth of the time	established in all hospital units) = September-December 2008 (4 months) **Post-Intervention** 8 months

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						the PLN as often as needed		
Sand-Jecklin, 2016[25] USA	**Study Setting:** • Med-surg (Mixed neuroscience, medical and med-surg units) **Setting Details:** • Large academic medical center **Sample Size:** 1508 cases **Baseline Fall Rate:** 3.9 falls/1000 pt days	Pre/Post	Yes Patient falls	1:1 sitter/constant observation sitter	• Video monitoring • Wristbands etc. • Environmental Interventions • Increased rounding • Low beds • Bed alarms	• Installation of fixed video cameras (without ability to record) in 14 private rooms on each unit • Centralized monitoring room • Video Monitor Technicians (VMT) hiring and training • Algorithm used to determine high fall risk patients appropriate for video monitoring with associated education of staff on use • CVM intervention did not require a physician order • Patient and family education, however no consent for monitoring required • Signage regarding the use of CVM placed inside and outside the room	**Falls:** 28% reduction in falls from 3.9 falls/1000 pt days to 2.8 falls/1000 patient days (Z=1.85, P=.032) Majority of falls post-implementation were not video monitored **Falls with injury** in post-implementation period: monitored (0/15) v unmonitored (6/34) **Change in Sitter Use:** 23.2% reduction in sitter shifts (56.9 shifts/1000pt days --> 43.7 shifts/1000pt days; Z 5.84, p<.001)	**Pre-Intervention** 6 months **Post-Intervention** 6 months

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						• Observation and intervention log kept by the VMTs • VMT able to redirect the patient via communication into the room, telephone call to the nurse, activation of the patient call bell system or overhead paging of staff	Only 5% of the video monitored patients also required a sitter **Costs:** Initial data from CMV implementation indicate cost savings in terms of sitter hours, but the reduction in sitter shifts was not equal to the number of monitor technician shifts (282 sitter shifts vs 1092 VMT shifts) No further data provided to calculate **Other Outcomes:** Not reported	
Skowronsky, 2015[26] USA	**Study Setting:** • Med-Surg (Internal Medicine Units) **Sample Size:** • 1859 adult patients were admitted. Of patients, there	Time series (sitter use) Variant of Non-randomized interventio	No	1:1	• close observation (4:1) • use of volunteers to observe patients' behaviors • passive alarms • diversional • activities	• Created COU: 4-bed COU – 2 semi-private rooms with glass partition and 2 nursing work stations. Staffed with 1 RN and 1 unlicensed, noncertified clinical technician	**Falls:** No differences in patient falls between general IM unit (29/1878; 1.5%) and COU (3/145; 1.6%) (P=.476).	**Pre-Intervention** 61 days

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
	were 2023 admissions: 1878 admissions to the internal medicine unit. • 145 admissions to the Close Observation Unit (COU) • Some patients were admitted multiple times during study period. **Baseline Fall Rate:** Not reported	n Study (falls)			• placing patients in public areas such as the nurses' station for closer	• Staff nurses gave input on physical layout of unit and needed equipment • multidisciplinary team guided the unit's development, including psychiatrist, SW, case manager, and nurses. • staff attended an 8-hour course in avoiding physical confrontation.	On the basis of falls per 100 patient-days, fall rates were 31 of 8408 (0.369%) in the internal medicine unit and 4 of 700 (0.571%) i COU. **Falls with injury:** Not reported **Change in Sitter Use:** IM unit required 1112.75 hours of externally hired patient companion time (and 29,421 hours for all patient companion time) = more than 0.5 full-time equivalent in externally hired personnel and 14.0 full-time equivalents in all personnel. COU did not use any patient companions. Prior to COU opening, there were 480 shifts	**Post-Intervention** Data results reflect 61 days post-implementation. Text reports following for 1-year period.

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							and 3840 hours used à post-COU, there were 115 shifts and 920 hours used(P< .001) (Fig 2) **Costs:** Not reported **Other Outcomes:** Patients treated in the COU were more likely to have a longer hospital length of stay, less likely to be discharged home, and more likely to have neurologic and psychiatric diagnoses.	
Spano-Szekely, 2018[27] USA	**Study Setting:** • Med-Surg **Setting Details:** 245 bed Magnet community hospital	Time Series	Yes Falls and falls with injuries	1:1 sitters Close observation	• Nurse assessment tool • Wristbands etc. • Bed/chair alarms • Increased rounding • Video monitoring	EBPI fall prevention program: • Nurse assessment tool • Injury risk assessment tool • Medication review • Mobility assessment • Standardized bed and chair alarm settings	**Falls:** 54 % reduction in falls: 2.51 falls/1000pt days à 1.15 falls/1000 pt days	**Pre-Intervention** Unclear monitoring period to determine baseline fall rate. Presumable 12 months/4

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
	Baseline Fall Rate: 3.21/1000 patient days (higher than the National Database of Nursing Quality Indicators' median of 2.91) **Baseline Fall with Injury Rate:** 0.77/1000 patient days					• Purposeful hourly rounding • Post-fall debriefing to identify causative factors • Identification arm bands • Door signage • Bed/chair alarms Video monitoring system with trained safety technicians (STs) • Verbally redirect patient • Notify care members to go in and help patient Other details • Education of all stakeholders • Staged implementation through "small tests of change" with review from subject matter experts every 2 weeks to evaluate implementation and process of each step	**Falls with injury:** Not reported **Change in Sitter Use:** 72% reduction in sitter usage reported. **Costs:** $84,000 annual savings reported **Other Outcomes:** Not reported	quarters as it is reported baseline fall rate "in 2013" **Implementation period** Varied for each stage of fall prevention program Implementation of fall prevention program Q1 2015 (data collected through Q2 2017) Video go-live April 2016 **Post video implementatio**

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						• Evaluation of understanding and adherence to the program		**n data:** collected Q3 2016 à Q2 2017
Spiva, 2012[9] USA	**Study Setting:** • Med-Surg • ICU **Setting Details:** • 633-bed community acute care hospital - 5 critical care units (ICU) - 2 step-down units - 11 medical-surgical units **Baseline Fall Rate:** 2.45	Pre/Post	Yes – decrease fall rate	1:1	• moving patient closer to the nursing station • rotating staff to provide 1:1 • placing the patient with another sitter patient • medication review • nurse assessment tool	• sitter decision tree (includes medication review and requires alternative attempts to modify pt behavior • sitter justification and evaluation form (for nurse manager to review every 12 hours) • letters to nurses/MDs (explaining new program) • scripting for nursing staff, and a letter with a listing of private home care sitters • Educational training w/ follow-up educational fact sheet to staff • Sitter evaluation tool for each sitter to be evaluated at	**Falls:** No statistically significant difference in falls: • overall total falls 199 à 197(t = −0.050, P=.961) • overall fall rates 2.45 à 2.39 (t = −0.941, P=.360) fall rates in critical care (P=.20), step-down (P=.47), and medical-surgical (P=.81) units **Falls with Injury:** Not reported **Change in Sitter Use:** Overall: decreased from 47,218 to 17,208 hours. (t = 5.59, P=.001) • critical care (t = 3.76, P=.020)	**Pre-Intervention** June 2010 to December 2010 (7 months) **Implementation period** 5 months **Post-Intervention** June 2011 to December 2011 (7 months)

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						the end of the sitter's shift • All tools are stored on the hospital's intranet Web site for staff to access	• medical-surgical (t = 4.33, P=.001). **Costs:** Overall: decreased from $536,955 to $215,132, total cost savings of $321,822. (t = 4.76, P=.001). • critical care saved $74 675 (t = 3.58, P=.023) • medical-surgical $229 947 (t = 3.76, P=.004) • cost savings of $17 199 in the step-down unit. **Other Outcomes:** Not reported	
Tzeng, 2008[28] USA	**Study Setting:** • Med-Surg **Setting Details:** • 2 acute adult 32 bed medical units in Michigan, USA **Baseline Fall Rate:**	Pre/Post	Yes Falls and falls with injuries	1:1	Nurse Assessment tool, which includes: • requesting family help • pain management • verbal and visual (signs/labels) reorientation • Music • Back rubs	• Patient Attendant Assessment Tool (PAAT) was developed by an ad hoc committee as an initiative to improve quality and cost-efficiency • 2 acute adult medical units were provided with the PAAT, instructions for use of the tool	**Falls:** Unit 1: Increased rate of injuries from falls (Pre-PAAT mean=0.25, Post-PAAT mean=0.59, t=-2.79, P=0.01)	**Pre-Intervention** 8/2005-9/2006 (5 quarters) **Post-Intervention**

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
	Reported in falls/1000 pt days: Unit 1: 4.75 Unit 2: 5.13 **Baseline Fall with Injuries Rate:** Reported in falls/1000 pt days: Unit 1: 0.25 Unit 2: 0.49				• Sleep protocol • Medication review • Lowering bed height	and a list of suggested alternatives to the use of sitters	Total falls/1000 patient days: Unit 1: Pre-PAAT mean=4.75, Post-PAAT mean=4.35 Unit 2: Pre-PAAT mean=5.13, Post-PAAT mean=4.15 **Falls with Injury:** Not reported **Change in Sitter Use:** Unit 1: Improved fill/request rate for sitters (Pre-PAAT mean=84.98%, Post-PAAT mean=93.84%, t=-2.19, P=0.04) Unit 2: Improved fill/request rate for sitters (Pre-PAAT mean=81.11%, Post-PAAT	10/2006-2/2007 (2 quarters)

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							mean=94.58%, t=-3.12, P=0.01) **Costs:** Not reported **Other Outcomes:** Decrease in the frequency of soft limb restraints (Pre-PAAT mean=3.71, Post-PAAT mean=0.20, t=2.54, P=0.02)	
Votruba, 2016[29] USA	**Study Setting:** • Med-Surg • ICU **Setting Details:** • 350 bed urban, non-for profit, Magnet designated hospital	Pre/Post	Yes Falls and falls with injuries	1:1	• Video monitoring	• 92 non-recording ceiling cameras with infrared lighting and microphone/ speakers • Number of patients actively monitored limited to 12 • Three viewing screens split into 4 quadrants	**Falls:** 35% decrease in number of falls (85 à 53 p<0.0001, 95% CI) **Falls with Injury:**	**Pre-Intervention** 9 month **Post-Intervention**

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
	- 1 critical care/ intermediate unit - 1 neuroscience unit - 1 senior adult unit **Sample Size:** 5,041 patient discharges (post-implementation data) **Baseline Fall Rate:** 1.7% Falls per patient discharge (= 85 falls/5,109 total patient discharges)					• Protocols created for telesitter to utilize • A second responder identified for telesitter to contact if primary nurse unavailable • Reason for monitoring/fall risks and communicated to telesitter at time of admission • 8 hour telesitter training	Authors estimate avoidance of 3-5 injurious falls annually (estimated with a falls with injury estimate of 9-15% per other studies and observed 35% fall decrease) **Change in Sitter Use:** Patient companion hours decreased 10% (1,930 hr/mo à 1,735 hr/mo) **Costs:** Projected fall cost avoidance of $52,000-$87,500/year (Using the CDC's (2013) estimate of $17,500 per fall, not internal data) Projected decrease in sitter cost of $25,200/year	9 month

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							(extrapolated from CDC data rather than internal institution costs) 24/7 telesitter cost ($120,000) almost completely offset by combined fall cost avoidance and sitter reduction savings ($77,200-$112,700) -- (unclear where this data is extrapolated from) **Other Outcomes:** Video monitors also used to prevent elopement, protect patients from interfering with their medical devices and to monitor seizure activity.	
Weeks, 2011[30] USA	**Study Setting:** • Med-Surg **Setting Details:**	Pre/Post	No	Constant observation	• "No sitter order" • Bed alarms • Fall precaution magnet and stickers • Slip resistant socks	• Physicians no longer allowed to write orders for sitters • Sitters provided only by policy (patients on involuntary commitment,	**Falls:** A decrease in falls (0.00543 falls/pt day à 0.00436 falls/pt day) OR 250 falls/46,004 patient days	**Pre-Intervention** 21 months

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
	222 acute care bed not-for-profit hospital North Carolina, USA **Baseline Fall Rate:** 0.00543 falls/pt day **Baseline Fall-related Fracture Rate:** 0.0000652/pt day				• Encouraging family to stay with patient	suicide ideation/ attempt precautions or in behavioral restraints) or nursing assessment • Nursing annual competency testing on suicide precautions • Sitter education and suicide precaution exam	à 375 falls/86,003 patient days **Falls with Injury:** Fall-related fracture rates (0.0000652 fractures/pt day à 0.0000581 fractures/pt day) OR 3 fractures/46,004 patient days à 5 fractures/86,003 patient days OR 3 fractures/250 falls à 5 fractures/375 falls **Change in Sitter Use:** Fewer sitters used (no data reported) **Costs:** Not reported	**Post-Intervention** 42 months

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							Other Outcomes: Nurses reporting appreciation for not losing essential coworkers to a sitter assignment (anecdotal)	
Westle, 2019[31]USA	**Study Setting:** · Neuroscience (NS) · Med-surg · Cardiovascular **Setting Details:** · 815-bed hospital · 34-bed neuroscience unit · 32-bed med-surg unit · 32-bed cardiovascular unit	Time Series	No Falls Falls with injuries	1:1 Standard fall-prevention interventions: · Bed locked in low position · Bed rails up · Assistive devices, call lights and personal items within reach · Non-slip footwear	• Video monitoring with "virtual sitter" infrared camera (all pts received standard fall-prevention interventions)	• Infrared camera with depth sensors to visualize full-body 3-D movement • Open software program to define and draw virtual zones, tip wires and other trigger points • Two-way audio interface • "Virtual sitter" patient fall risk algorithm • Pts at risk for suicide/homicide, overdose or under legal restrictions excluded	**Falls:** Pilot: Neuroscience unit falls/1000 pt days: 4.77 pre "virtual sitter" à 3.45 post "virtual sitter" P<0.001 0 falls during the first three months of the pilot Post-scale falls/1000 pt days:	**Pre-intervention** 12 months for neuroscience and med-surg units 5 months for cardiovascular care unit **Post-intervention**

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
	Sample size: **Pilot:** 348 patient care days (98 pts monitored with "virtual sitter") **Baseline Fall Rate:** Neuroscience: 4.77 falls/1000 pt days 0.91 injuries/1000 pt days Med-surg: 4.30 falls/1000 pt days 0.76 injuries/1000 pt days Cardiovascular: 2.87 falls/1000 pt days 0.70 injuries/1000 pt days			· Clutter-free rooms · Dry floors and adequate lighting · Hourly clinical rounds · Patient and family education · Bed and chair alarms		• Creation of a central monitoring technician workstation for the pilot and subsequent off site central monitoring unit (CMU) • Training of monitor technicians with escalation pathway when a virtual sitter alert was generated	Neuroscience 4.77 à 3.90 Med-Surg 4.30 à 2.43 Cardiovascular 2.87 à 1.01 Aggregated data demonstrated 44% reduction in unassisted falls (p<0.001) **Falls with Injury:** Pilot: Neuroscience unit falls with injuries/1000 pt days: 0.91 pre "virtual sitter" à 0.74 post "virtual sitter" P<0.001 0 falls with injuries during the first 3 months of the pilot Post-scale falls with injuries/1000 pt days:	12 months pilot data 14 months post-scale data for all three units

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							Neuroscience 0.91 à 0.74 Med-Surg 0.76 à 0.34 Cardiovascular 0.70 à 0.38 Aggregated data demonstrated 40% reduction in fall-related injuries (p=0.065) **Change in Sitter Use:** 145,000 hours of patient monitoring done by 8.4 FTE monitor technicians which would have required 60 FTEs for 1:1 sitters **Cost:** Cost avoidance of $196,000 for the 14 fewer injuries from falls	

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
							(average cost of $14,000/fall with injury) **Other Outcomes:** None	
Wray, 2014[32] USA	**Study Setting:** • Med-Surg **Setting Details:** 751 bed Magnet-designated academic medical center - USA **Baseline Fall Rate:** 3.2 falls/1000 pt days	Time series	Yes Falls	1:1 (Constant Observation – CO)	• Nurse assessment tool • Increased frequency of rounding • Intentional rounding	• Constant observation practice changed from a physician-driven to a nurse-driven intervention • Nurses were provided with a variety of tools to maintain the safety of confused patients • Framework for nurses to increase the level of observation and assessment - 15-30 minute rounding - 2:1 observation - 1:1 observation • Reporting of unit CO utilization data to increase accountability and transparency	**Falls:** 10.1% improvement in fall rates (3.2 falls/1000 patient days à 2.9 falls/1000 patient days) **Falls with Injury:** Not reported **Change in Sitter Use:** 42.6% decreased in total CO hours (75,328.7 à 43,253.7)	**Pre-Intervention** FY 2011 (7/2010-6/2011) **Post-Intervention** FY 2012 (7/2011-6/2012)

Author Year Country	Setting Sample Size	Study Design	Use of Existing Theory/Logic Model	Control/Pre-Intervention Sitter Practice	Alternative(s) to Sitters	Implementation Details	Outcomes	Data Collection Intervals
						• Nurses discouraged to call physician for CO orders except in cases of suicidal patients • Engagement of family members to personally observe loved ones • Daily rounding with clinical nurse specialist to better manage confused patients	45.3% decrease in CO hours/100 patient days (115,769 à 163,622) **Costs:** 41.3% ($533,917) decrease in CO expenditures ($1,292,228—> $758,311) **Other Outcomes:** Elimination of 15.4 FTEs (36.2 à 20.8) 30.8% reduction in physical restraints (4.93% of patients in restraints à 3.41%)	