



STUDY PROTOCOL

**REVISED** Contextual factors and intentional rounding in acute hospitals: understanding what works, for whom, in what settings: a realist synthesis protocol [version 3; peer review: 3 approved, 1 not approved]

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**Abstract**

**Background**

This study aims to understand and explain the influence of contextual factors on the implementation of Intentional Rounding in acute hospitals using the realist synthesis methodology.

Falls of hospital admitted patients are one of the most frequent concerns for patient safety in the acute hospital environment. The reasons why people fall are complex. International guidelines recommend a multifactorial assessment and effective prevention and management of identified risk factors in order to reduce the number of falls. Intentional Rounding (IR) is one approach for delivering this. IR is an umbrella term, understood as a structured process whereby nurses or care staff carry out regular checks with individual patients using a standardised protocol to address such issues as positioning, pain, personal needs and placement of possessions.

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## Methods

This study will use realist synthesis to understand what works, for whom, in what circumstances, and in what settings. Realist synthesis is a theory driven interpretive approach to evidence synthesis. It is our intention to analyse IR as an intervention, which aims to enhance patient care and safety in hospital settings. The synthesis forms part of a larger implementation study examining interventions that reduce the number of falls that occur in hospitals. Search terms will include intentional rounding, purposeful rounding, comfort rounding and hourly rounding and will encompass search terms beyond IR and falls rates to avoid limiting the synthesis. This synthesis will conform to the RAMESES (realist and meta-narrative evidence synthesis group) publication and reporting quality standards.

## Conclusions

The findings will inform the next phase of an implementation study on IR in acute hospital settings, to address evidence informed enablers and barriers to IR. The results will be disseminated in a peer-reviewed journal and through presentations.

## Keywords

Intentional Rounding, Nurse rounding, Patient rounding, Acute Hospital, Intervention, Falls Prevention, Realist synthesis,

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Any reports and responses or comments on the article can be found at the end of the article.

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**REVISED Amendments from Version 2**

The realist synthesis protocol has kindly been reviewed by our colleagues in King's College, London. Professor Ruth Harris, Sarah Sims and Dr Mary Leamy have provided valuable commentary and feedback to enable improvements in this protocol.

There has been a revision of the section regarding the origins of Intentional Rounding (IR) in the USA by the Studer Group in 2007. The reference list and paper has been updated with two more references including a more recent publication by [Leamy et al. \(2023\)](#), which has been published since version 1 of this protocol.

This paper has provided greater focus for the proposed realist synthesis. The rationale for this review has been updated to reflect how this realist synthesis is intended to further refine the programme theory which was published by [Leamy et al. \(2023\)](#).

The two programme theories which were supported in the evaluation in hospital ward settings have been a starting point for the current realist synthesis and have provided valuable insight into the implementation of IR at the frontline in hospital wards.

There have been 32 more international research studies on intentional rounding in acute care settings since the literature search prior to publication of the realist evaluation in 2019 and it is intended to incorporate this research into the current synthesis to build on and refine the programme theory.

The methods section has also been updated based on the valuable commentary.

**Any further responses from the reviewers can be found at the end of the article**

**Introduction**

Falls pose a significant challenge to healthcare systems internationally, with ageing populations and increasingly higher expectations of active living, falls prevention remains at the top of the safety agenda ([Gerrish et al., 2019](#)). Falls are a leading cause of non-fatal injuries among older adults and these injuries may have adverse physical, social and psychological effects. In Ireland, hospital falls are the most commonly reported incident within the Health Service Executive (HSE). In 2021, 34,114 falls were reported and over half (n= 18,023) of these occurred in acute hospitals ([HSE, 2022](#)). Falls are costly to patients, carers and society from a physical, psychological and economic perspective. Falls lead to physical harm, prolonged hospital stays, and decreased quality of life for patients, and affects those who care for them and society in general ([WHO, 2021](#)).

A fall is defined as an event, which results in a person coming to rest inadvertently on the ground or floor or other lower level ([WHO, 2021](#)). There are different types of falls - assisted, injurious, negligible or no harm and the reasons why they occur are complex and multifactorial ([State Claims Agency, SCA, 2019](#)). Intrinsic risk factors are related to the person, including age, history of falls, physical illness, cognitive impairment, medications and movement disorders. Extrinsic risk factors include elements of the environment: lighting, flooring, clutter, unstable furniture and faulty walking aids ([NICE, 2013](#)).

The cost of falls worldwide has been estimated in excess of €400 billion each year ([WHO, 2021](#)). There is speculation of

continued rising costs across countries yet data on falls incidence with associated costs are not collated routinely in some countries. In Ireland, fall-related injuries in older people cost at least €402 million to the Irish economy ([HSE, 2008](#)). A National Fall Prevention Strategy has yet to be developed. In the US, using 2015 data, falls cost the economy an estimated \$50 billion per year ([Florence et al., 2018](#)) and falls and fall related fractures cost the National Health Service (NHS) more than £2.3 billion per year in 2013. However, these figures are not current and much has changed since these data were collected. The costs of falls in healthcare are understudied and better and routine measurement is needed to ensure that falls-prevention strategies are economically sound. The World Health Organisation ([WHO, 2021](#)) estimate that 37.3 million falls require medical attention per year (2017–2020), with an estimated 684,000 individuals dying because of a fall annually worldwide ([WHO, 2021](#)). The costs noted here include hospital and community-based falls, not in-hospital falls alone.

To reduce the number of falls that occur in hospital settings, international guidelines recommend a multifactorial assessment and the cost-effective prevention and management of identified risk factors ([Montero-Odasso et al., 2022](#)). Multifactorial interventions are recommended in the literature as a mechanism to prevent in-hospital falls ([Cameron et al., 2018](#)). Individualised interventions expounded from assessment include hypotension treatment, footwear assessment and mobility treatment, among others. However, these individual interventions will assist only a limited number of patients. Systematic approaches targeted at a wider group of patients will be required to reduce inpatient falls on a large scale. IR is an example of a systematic approach which aims to complement individualised interventions, including assessment, medication review, enhanced supervision, among others.

Initially known as “hourly rounding”, IR is an umbrella term, understood as a structured process whereby nurses or care staff carry out regular checks with individual patients using a standardised protocol to address such issues as positioning, pain, personal needs and placement of possessions ([Harris et al., 2017](#)). The concept was implemented initially by the Studer Group in fourteen hospitals in the USA in 2006. Published studies stemming from this project reported on the introduction of a rounding protocol and examined its effects on patient satisfaction, call bell use and patient falls ([Meade et al., 2006](#); [Studer Group, 2007](#)). There are many terms used for this process, including “comfort rounding”, “care rounding”, “purposeful rounding”, “patient rounding” and “nursing rounding” among others ([Sims et al., 2018](#)).

In Ireland, the adoption of IR has yet to be formally studied. In the UK, IR came to favour following recommendations from the Mid Staffordshire report to have systematised and regular interaction and engagement between nurses and patients on ward rounds ([Mid Staffordshire NHS Foundation Trust Public Inquiry \(2013, Vol III\)](#)). Although IR was not explicitly recommended, the concept of regular rounding on patients underpinned the recommendations made. The British Government endorsed IR in 2012 and advocated IR as a method of proactively addressing patients’ needs. There has been an extensive realist evaluation of IR in hospital wards,

across three NHS trusts in England by [Harris \*et al.\* \(2019\)](#). As the NHS introduced IR across trusts, some limitations became evident; for example, staff engagement was limited in areas where education programmes had not preceded the introduction of IR ([Sims \*et al.\*, 2018](#)).

While there are established benefits of IR, including improved nurse-patient communication and improved visibility of nursing staff, there are a number of methodological limitations in the IR studies, such as bias, weak study design and conflicts of interest ([Snelling, 2013](#)). There is also little information available on the implementation costs and value-for-money of IR, which is important to inform what IR protocol is selected and how it is implemented ([OECD, 2022](#)).

There is an information gap on the ‘how’ and ‘why’ and in ‘what context’, IR works. This realist synthesis forms the first phase of a study and will examine the existing evidence on IR and develop a programme theory of how IR works in an acute hospital setting, with whom and in what circumstances. Using the programme theory, the second phase of the study will involve the design, testing, implementation and evaluation of an IR intervention to reduce inpatient falls in a hospital setting. This publication sets out the protocol for the realist synthesis and the second phase will be set out in a future publication. Synthesis findings will inform the design and evaluation of strategies to address the barriers and enablers of implementation of IR in acute hospital settings.

### Rationale and existing reviews

Research on IR has focussed on the effectiveness of IR on call bell usage, patient satisfaction rates, falls, pressure ulcers and pain management ([Meade \*et al.\*, 2006](#)) ([Lucas, 2010](#)). Results from the landmark study ([Meade \*et al.\*, 2006](#)), found that IR reduced call bell use and falls and improved patient satisfaction rates when completed hourly. However the acknowledged use of quasi-experimental approaches may have produced more positive results than a random assignment. Based on staff reporting, [Lucas \(2010\)](#) found that IR reduced pressure ulcer incidences and improved pain management. The results of these studies suggest that further research on the implementation and potential effects of IR on patient outcomes is required. There is a dearth of research focussing on the barriers and enablers to implementation of IR. IR has been the focus of literature reviews who found that it has mixed results, and contextual factors play a part in its success or otherwise ([Harris \*et al.\*, 2017](#); [Ryan \*et al.\*, 2019](#)). A recent systematic mixed method review that included twenty-one studies, found that evidence is mixed and quality of data is not robust, due to weak methodological design of many of the studies and a large variation in sample sizes ([Christiansen \*et al.\*, 2018](#)). [Ryan \*et al.\* \(2019\)](#) conducted an integrative literature review of IR and found that overall it is a positive intervention as it encourages improved nurse patient interaction. They recommend further research around how it has been implemented, what was working well about IR, what the barriers are and in what context it is successful.

A small number of existing literature reviews demonstrate the contextual factors influencing IR ([Christiansen \*et al.\*, 2018](#);

[Sims \*et al.\*, 2018](#)). These offer explanations about how it works well in some areas where patients may need regular interaction e.g. care of the older person units, and may not be successful in other areas, e.g. a busy surgical ward where the patient is mostly independent ([Christiansen \*et al.\*, 2018](#)). There has been only one realist review completed on fall prevention programs using IR ([Sims \*et al.\*, 2018](#)). This review formed part of a larger evaluation programme in the NHS and identified eight programme theories of IR. Only two of these programme theories explained how the intervention worked in the evaluation of IR, “Consistency and Comprehensiveness” and Accountability ([Leamy \*et al.\*, 2023](#)). The present review is necessary to find up to date information regarding what it is about IR that enhances patient safety and prevents harmful outcomes for patients in order to build on existing programme theory.

The question about IR, and for whom it will work, in what circumstances and how it works, is best answered using a realist synthesis, as there is a requirement to understand more fully how and for whom IR is successful in an acute hospital setting. [Duddy and Wong \(2023\)](#) recommend that a realist approach is best suited when the outcome of an intervention is likely to be variable and context dependent. A realist synthesis will assist in the development of a programme theory about why IR works in some areas and not in others based on learning from previous studies. As this synthesis is part of a larger implementation study, searching only evidence related to IR and falls rates would limit the synthesis. Therefore, it is our intention to build on the existing theories about IR, to further analyse and refine theories about IR as an intervention, which affects patient care and safety in hospital settings.

[Sims \*et al.\* \(2018\)](#) carried out a realist synthesis of IR in acute hospital wards that informed an evaluation project ([Harris \*et al.\*, 2019](#)). The literature search spanned from 2006 up to and including 2016, 44 papers were reviewed spanning a variety of settings such as accident and emergency, orthopaedic, maternity, medical and surgical units, mental health and intensive care. There is a need to update this eight-year old realist review and explore if recent studies add to what is already known about IR internationally. There have been 32 additional international studies on IR since 2016. Rounding as a tool is mentioned in international guidance as a positive intervention and therefore an exploration of the recent literature after 2016 is required ([Agency for Healthcare Research and Quality, 2013](#)). In addition, [Harris \*et al.\* \(2019\)](#) discussed how previous studies failed to explain how IR works in a specific context and what drives IR to succeed or otherwise. They found that IR reduces potential harm when implemented in a comprehensive and consistent manner but that there is limited evidence of how it works in practice. They concluded that a poor understanding of how IR works poses a major challenge to learning, replication and sustainability of the intervention.

### Realist synthesis methods

Realist synthesis is a theory-driven approach to evaluation. It enables the researcher to answer the question “what works for whom under what circumstances, how and why?” ([Wong \*et al.\*, 2013b](#)). A realist synthesis may begin with an initial search of literature to illicit how an intervention is avowed to

work (the initial programme theory). It is suited to complex interventions such as IR as any intervention that is used and adapted in healthcare is prone to modification due to many variables such as staff engagement and perception, environment, education, policy and patient factors among others. IR is a good example of a complex social intervention as it is multi-component and the outcomes and resource implications may be influenced by the context in which it occurs.

A realist synthesis approach views causation as generative: mechanisms might be triggered within certain contexts resulting in one or more outcomes following an intervention (Pawson *et al.*, 2005). There is no simple ‘yes’ or ‘no’ answer to the question of the implementation and cost effectiveness of IR unless we explore what makes it successful, for what type of patient and in what circumstances. The identification and understanding of context-mechanism-outcome configurations may achieve this. The realist synthesis approach is required to help policy-makers and healthcare professionals to understand how IR may alter contexts, which then trigger hidden mechanisms that reduce falls and produce other intended or unintended outcomes.

Economic data will be purposefully incorporated into the realist synthesis, to identify the resource use and cost requirements commonly associated with implementation of IR in the hospital setting. This is necessary for the review findings to address the value and financial viability of IR and be of utility informing economic decisions. These affect its acceptance by decision-makers and practitioners Coast *et al.* (2000).

Anderson and Hardwick (2016) proposed that cost effectiveness should be articulated in realist synthesis. The relation between costs and outcomes, and in favour of selecting interventions and implementation strategies that are cost effective can inform the programme theory. To calculate costs of an initiative, the cost of harm is a factor. With in-hospital falls, there are direct costs such as longer length of stay, diagnostics, surgery, health professional wages etc. The unknown additional costs that need to be considered include follow-up care in non-acute settings, consequent hospital readmissions and outpatient appointments, loss of wages for the individual or their family carers, among others. The principles of economic evaluation, i.e. resource use and responses to resource use will form part of the criteria for this synthesis. There are no economic evaluations on the implementation of IR in an Irish hospital setting so the advancement of knowledge on IR and whether it is a viable option to consider is necessary and timely.

## Research aim and objectives

### Research aim

This study aims to understand how, when and under what circumstances IR in acute hospital settings improves patient safety and outcomes, and what are the barriers and enablers of its implementation.

### Objectives

1. Determine how IR has been implemented in hospital settings.
2. Develop a range of programme theories that describe how IR works, for what type of patients, in what setting

and with what types of staff, in what circumstances and why.

3. Identify and describe the most important mechanisms by which IR is thought to produce better outcomes for patients, healthcare staff and the service in the hospital setting.
4. Identify and describe the contextual factors that enable or block the impact of these mechanisms (enablers and barriers)
5. Identify and describe the resource use and cost requirements or impacts of the different mechanisms and contextual factors related to developing and implementing IR in a hospital ward
6. Synthesise the data using realist methodology to explain the circumstances in which IR is likely to be effective and cost effective in a hospital setting.

## Methods

This synthesis will conform to the RAMESES (realist and meta-narrative evidence synthesis group) publication and reporting quality standards for a realist synthesis (Wong *et al.*, 2013b; Wong *et al.*, 2016). Realist synthesis is a theory-driven approach designed for evaluating complex social interventions such as IR (Sims *et al.*, 2018). Realist inquiry postulates that the outcomes of an intervention are influenced by how it is implemented and in what context it is conveyed (Pawson *et al.*, 2004). A key output of a realist synthesis is a programme theory or theories and understanding the success or failure of an intervention by asking exploratory questions. These questions include: What is it about this intervention that works? For whom? In what circumstances? These questions may be answered through the identification of context-mechanism-outcome configurations (Sims *et al.*, 2018).

This synthesis will be based on the stages of a realist review put forward by Pawson *et al.* (2004) with the addition of a further stage of stakeholder involvement for theory refinement, which was added by Molnar *et al.* (2015) and used by Power *et al.* (2019). See Box 1.

### Box 1. Planned Stages of Realist Synthesis (Hunter *et al.*, 2022) (Pawson *et al.*, 2004)

#### 1. Identify the Review Question

- a. Map the research area
- b. Informal literature search
- c. Concept mining
- d. Develop initial rough programme theories
- e. Consult stakeholders
- f. Build hypothetical model of key initial rough programme theories to test in literature

#### 2. Searching for primary studies

- a. Database search
- b. Skimming for relevance – Citation tracking
- c. Snowballing
- d. Grey literature
- e. Contact authors



**3. Quality Appraisal**

- a. Bespoke screening and appraisal tools
- b. Consider rigour and relevance

**4. Extracting the data**

- a. Extraction templates
- b. Rich description and thick detail

**5. Synthesising the data**

- a. Juxtaposing
- b. Adjudicating
- c. Reconciling
- d. Consolidating
- e. Situating

**6. Disseminating the findings**

- a. Consult with stakeholders for widest impact
- b. Recommendations based on middle range theories around which particular aspects of programme implementation need to be considered

Publication

**Stage one: clarify scope and developing an initial programme theory**

In the initial stage of the synthesis, a literature search will be carried out to locate existing theories that explain how IR works, in what circumstances, for whom and how it generates outcomes for patients. To conduct a realist synthesis, it is important that a broad range of empirical research is included.

The exclusion/inclusion criteria are necessarily broad to ensure the theory development phase is able to take in the widest range of evidence of theories (Hardwick *et al.*, 2013). A preliminary informal search (stage one) of literature was conducted in CINAHL and PubMed in November 2022. The informal searches conducted in stage one are different from the more formal searching that will be conducted in stage two, as they are exploratory in nature. Programme theory development will necessitate iterative discussions within the research team to progress competing theories in to an initial programme theory (McConnell *et al.*, 2022).

The existing programme theories as developed and evaluated by Leamy *et al.* (2023) will be used to start the literature synthesis along with a background knowledge by the authors on IR. In line with the RAMESES realist synthesis guidance by Wong *et al.* (2013b), “all theories remain theories that can be refined or disproved as new evidence comes to light”. The realist synthesis method, as described by Pawson *et al.* (2005), highlights that a significant amount of papers will be identified through “snowballing”, that is using the reference lists of relevant articles to identify further papers for review.

Sims *et al.* (2018) conducted a realist synthesis of IR and used seven terms to describe the concept of IR for their literature search and this study will use the same strategy. This synthesis will search for new evidence to support or refute the theories in order to develop initial programme

theories (IPTs). These IPTs will inform the second stage of literature searching. Following stage two searching, the programme theory will be reviewed and rival explanations to the theory developed will be explored. The realist synthesis is part of an implementation study, testing IR in a variety of acute ward settings in hospitals to assess whether IR is an effective and cost-effective intervention in reducing falls in the acute hospital setting. To develop programme theories, an initial immersion in sources of information about the effectiveness and cost-effectiveness of IR will be completed.

**Stage two: search strategy**

The search strategy has been planned with the assistance of an Information Specialist. The major healthcare databases and repositories will be searched. See Box 2 for a list of search terms and databases that will be used for the search strategy. There will necessarily be further literature searches based on analysis of the preliminary evidence. Realist synthesis are iterative in process and there will be ongoing need for searching of databases throughout the synthesis until saturation is reached (Pawson *et al.*, 2004). The references and citations in the 2018 realist synthesis and 2019 evaluation papers on IR in the hospital setting by Sims *et al.*, and Harris *et al.*, respectively will be used as a starting point for review of the literature and theory development.

**Box 2. Search Strategy****Databases that will be utilised for search include**

CINAHL, Medline/PubMed, PsycINFO, Embase, Cochrane Library and any other relevant databases identified by the information specialist

**Search terms to be used for Intentional Rounding**

Intentional round OR hourly round OR patient round OR comfort round OR purposeful round

OR proactive nurse round AND acute hospital setting or hospital or acute ward

The inclusion and exclusion criteria will be broad to ensure that the theory development phase will take in the widest range of evidence of theories. In line with Sims *et al.* (2018) criteria, areas of general weakness in evidence and individual study weakness will be reported where appropriate.

**Inclusion criteria:**

- Studies on implementation of IR in acute hospital settings.
- Population will include hospital inpatients over 18 years of age
- Study design includes all types of design which will help to direct theory development
- Any publication deemed relevant by the researcher i.e. opinion pieces in peer-reviewed journals, health-care policy documents, studies including other interventions to reduce falls in acute hospitals that may add to theory development

- There will be no limits placed on country of origin, patient safety outcomes or dates to ensure all relevant literature is included. To include only falls as an outcome would limit the data extraction

#### Exclusion criteria:

- Studies not in the English language.
- Studies in non-acute hospital or community settings.

#### Stage three: selection and appraisal

During the initial phase of the synthesis, sources that contribute to theory development will be reviewed through a process of note taking, annotation and conceptualisation. The abstracts of all papers identified by searches will be screened for suitability by AH. Allocation of abstracts to other members and double screening of all abstracts by another member of the team will ensure rigour. The entire team will discuss conflicts until agreement is reached. Potentially relevant papers will be assessed using a structured data extraction form developed by AH. Inclusion criteria are studies (a) conducted in acute hospitals, and (b) implemented and tested a version of IR as a single intervention or allied to/bundled with other existing interventions. The relevance and contribution of documents to theory building will be part of the selection criteria.

After relevance checks, the full text of the literature will then be retrieved and independently assessed for rigour by AH. This is in line with RAMESES publication and reporting standards for realist synthesis as described by Wong *et al.* (2013a; 2016). Further searching will arise due to the iterative fashion of the review and the team will decide selection criteria based on whether the literature can further refine theory (Power *et al.*, 2019). Any disagreement over eligibility based on quality will be resolved through discussion by the team.

#### Stage four: data extraction

The included data will be entered on an Excel spreadsheet to include variables summarised in the [Table 1](#) below. The Standards for Reporting Implementation Studies (StaRI) Checklist by Pinnock *et al.* (2017) has been used to guide this extraction tool. There will necessarily be information included in some studies which may not be conducive to StaRI guidance and this will be captured in the Excel spreadsheet.

Contexts, Mechanisms and Outcomes will be extracted from papers. Literature will be reviewed using the same search criteria and databases for identification of any new mechanisms of IR that may be relevant. Data from each of the studies selected will be analysed thematically to provide a comprehensive description of the purported mechanism of IR. Contexts that appear to activate or inhibit the mechanisms will be identified and outcomes when the mechanism is present or absent will be noted (Harris *et al.*, 2017). A realist causal

explanation for an outcome involves the researcher understanding the mechanism that produces the outcome and identification of what is functioning as context to activate the mechanism (Duddy & Wong, 2023). Text related to context, mechanisms and their relationship to outcomes will be coded by AH. The codes used will be inductive (created to categorise data reported in included studies), deductive (created in advance of data extraction based on the initial programme theory) and retroductive (created based on interpretation of the data to infer what the hidden causes might be for outcomes). This process is similar to that being used by Ford *et al.* (2021) in their EQUALISE study on health inequalities.

#### Stage five: data synthesis and analysis

The key analytic process in a realist synthesis involves iterative testing and refinement of theoretically based explanations (programme theories) using empirical evidence from data sources (Wong *et al.*, 2013b). Programme theories will be tested and refined. This will be achieved by drawing comparisons with the evidence, exploring, and analysing the relationships between contexts, mechanisms and outcomes. Evidence will be compared to identify recurring patterns of CMOs across the data including trends that may support, contradict or generally inform the programme theory. Iterative analysis will be carried out to refine the identified CMO configurations in order to fully explain how, why and in what circumstances IR may successfully or otherwise be implemented (Coles *et al.*, 2017; Power *et al.*, 2019).

Rayan software will assist in management of the data and a thematic analysis approach will be adopted to synthesise findings. All included studies will be analysed by AH. The process of synthesis will include: (1) comparison of findings from different studies; (2) using findings from studies to address the purpose(s) of the synthesis; (3) seeking both confirmatory and contradictory findings; (4) refining programme theories in the light of evidence; and (5) disseminating the review with findings, conclusions and recommendations. Data analysis should take a “retroductive” approach – using both inductive and deductive approaches to identify hidden or causal factors that lie beneath patterns of change. The programme theories will be tested and refined (RAMESES II project, 2017). The realist synthesis will include diverse sources of evidence and synthesis structured around the analytical activities described in Pawson *et al.* (2004), including juxtaposition, reconciliation, adjudication, consolidation and situation of evidence. These activities when clearly documented in a realist review achieve transparency of synthesis (Hardwick *et al.*, 2013).

#### Stage six: theory refinement with stakeholders

A stakeholder consultation workshop is planned following on from data synthesis, in order to refine the programme theories. The group will consist of people involved directly in patient care, hospital management, quality and safety staff, and patient or family representatives. This workshop will serve

**Table 1. Data extraction tool - adapted from the Standards for Reporting Implementation Studies (StaRI) Checklist (Pinnock *et al.*, 2017).**

Checklist Item	Variable	Details of data to be retrieved
1	Author and Year	
2	Title	
3	Rationale for study	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work.
4	Details of intervention	Including evidence about its effectiveness and how it is expected to achieve its effects
5	Country of Origin	
6	Aims and Objectives	The aims of the study, differentiating between implementation objectives and any intervention objective
7	Methods – Design and Key features	Cross referencing to any appropriate methodology reporting standards
8	Details of Intervention	Include details of intervention, frequency, who completed it, what it consists of, i.e. what needs it addressed for the patient
9	Details of implementation strategy	How was it carried out – education, role modelling, protocol,
10	Context/Setting	The context in which the intervention was implemented (consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).
11	Details of the site chosen for implementation	Location, specialty, personnel, resources – single site or multi-site
12	Sample size	Include number of patients the intervention was tested on. Rationale for sample size?
13	Duration of data collection	
14	Evaluation	Outcomes – Include Organisation, Staff, Patient, Process or implementation outcomes – what was expected and what happened
15	Results	Outcomes
		Characteristics of population
		Process Outcomes
16	Resource Use, costs, economic outcomes	Is this reported? Are they once-off costs, implementation costs, cost-outcome descriptions/relationships?
17	Implementation and Intervention Fidelity	Did the implementation strategy go as planned and was the intervention delivered as planned
18	Methods of analysis	How did they analyse the findings?
19	Context	The backdrop of programmes – triggers or modifies the behaviour of a mechanism
20	Mechanism	An underlying entity, process or structure that operates in a particular context to generate an outcome
21	Outcomes	The result of interaction between a mechanism and its triggering context
22	CMO Configuration	How a context triggers or changes the behaviour of mechanisms (enables or blocks) and produces an outcome

two purposes. It will aid the process of theory development and refinement and ensure that any research findings are clear and useful to those involved in providing and receiving IR in a hospital setting. Brennan *et al.* (2014) describe this

process as a reality check, to assist in validation of the programme theory for use in clinical practice. This process is recommended in realist synthesis as understanding what key stakeholders know about an intervention and their reasoning



for or against its implementation is essential to understanding it (Harris *et al.*, 2017).

## Dissemination of findings

Findings and results from this synthesis will be disseminated and shared with stakeholders, frontline practitioners and policy makers. They will be shared as a final report with presentations to stakeholders and practitioners. The results will be utilised to inform the next stage of a larger implementation study on the effect and cost-effectiveness of the implementation of IR in acute hospital settings on fall rates. The work will be presented at a relevant national conference, and a publication based on the review will be written up and published in a peer reviewed academic journal.

## Discussion

This study will use a realist synthesis approach to synthesise the available evidence and enable a better understanding of what works, for whom and in what circumstances, when, how and why in relation to IR in acute hospital settings. It is intended to build on the most recent realist synthesis on IR, which was published in 2018. The use of a realist approach will allow the synthesis to describe and explain how and

why IR works in different contexts by exploring programme theories and the interactions between contexts, mechanisms of change and outcomes.

The emphasis in this synthesis on context-sensitive findings will offer broad principles that may be applied in different situations and circumstances (Gordon *et al.*, 2020). The chosen approach will ensure that current evidence of contextual enablers and barriers can be taken in to account in designing and planning the implementation phase of a larger project.

## Data availability

All data underlying the results are available as part of the article and no additional source data are required.

## Acknowledgements

The proposed realist synthesis is part of a larger PhD project currently being undertaken by the first author (AH) and funded by the Royal College of Surgeons in Ireland Hospitals Group. The authors acknowledge the support from Andrew Simpson, librarian at Royal College of Surgeons, Dublin, for supporting the development of the search strategy of the proposed synthesis.

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## Open Peer Review

Current Peer Review Status:    

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### Version 3

Reviewer Report 10 October 2024

<https://doi.org/10.21956/hrbopenres.15324.r42498>

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**Alice Hemenway** 

University of Illinois at Chicago, Chicago, USA

The article describes a planned review of intentional rounding, focusing on what works for whom, in what certain circumstances, and in what settings. They describe the plans for a realist synthesis process in 6 stages (identify the question, search, quality appraisal, data extraction, synthesizing and dissemination). The article provides a level of detail of the methodology to allow replication.

**Is the rationale for, and objectives of, the study clearly described?**

Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Internal medicine, use of theory in pharmacy services

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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### Version 2

Reviewer Report 22 July 2024

<https://doi.org/10.21956/hrbopenres.15239.r40811>

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### Ruth Harris

King's College London, London, England, UK

### Sarah Sims

: King's College London, London, London, UK

### Mary Leamy

King's College London (Ringgold ID: 4616), King's College London, London, UK

We have reviewed the revisions and it appears that the authors have not responded to our comments. Therefore, we are unable to amend our previous status of 'Not Approved.' We would be happy to review the paper when they address our comments.

#### **Is the rationale for, and objectives of, the study clearly described?**

Not applicable

#### **Is the study design appropriate for the research question?**

Not applicable

#### **Are sufficient details of the methods provided to allow replication by others?**

Not applicable

#### **Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**We confirm that we have read this submission and believe that we have an appropriate level of expertise to state that we do not consider it to be of an acceptable scientific standard, for reasons outlined above.**

Author Response 15 Aug 2024

### Aileen Hetheron

The realist synthesis protocol has kindly been reviewed by our colleagues in King's College, London. Professor Ruth Harris, Sarah Sims and Dr Mary Leamy have provided valuable commentary and feedback to enable improvements in this protocol.

There has been a revision of the section regarding the origins of Intentional Rounding (IR) in the USA by the Studer Group in 2007. The reference list and paper has been updated with

two more references including a more recent publication by Leamy et al., (2023), which has been published since version 1 of this protocol. This paper has provided greater focus for the proposed realist synthesis. The rationale for this review has been updated to reflect how this realist synthesis is intended to further refine the programme theory which was published by Leamy et al (2023). The two programme theories which were supported in the evaluation in hospital ward settings have been a starting point for the current realist synthesis and have provided valuable insight into the implementation of IR at the frontline in hospital wards. There has been 32 more international research studies on intentional rounding in acute care settings since the literature search prior to publication of the realist evaluation in 2019 and it is intended to incorporate this research into the current synthesis to build on and refine the programme theory. The methods section has also been updated based on the valuable commentary.

**Competing Interests:** No competing interest

Reviewer Report 09 July 2024

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**Amy Drahota** 

University of Portsmouth, Portsmouth, England, UK

**Leah Fullegar**

<sup>1</sup> University of Portsmouth (Ringgold ID: 6697), Portsmouth, England, UK

<sup>2</sup> University of Portsmouth (Ringgold ID: 6697), Portsmouth, England, UK

Thank you for considering our previous feedback. We have no further comments to make.

**Is the rationale for, and objectives of, the study clearly described?**

Not applicable

**Is the study design appropriate for the research question?**

Not applicable

**Are sufficient details of the methods provided to allow replication by others?**

Not applicable

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.



**Reviewer Expertise:** falls prevention; health & care of older adults; systematic reviews; realist synthesis.

**We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

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**Version 1**

Reviewer Report 12 April 2024

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**Ruth Harris**

King's College London, London, England, UK

**Sarah Sims**

: King's College London, London, London, UK

**Mary Leamy**

King's College London (Ringgold ID: 4616), King's College London, London, UK

Thank you very much for asking us to review this paper reporting the protocol for a realist synthesis of intentional rounding. First of all, we must acknowledge that we are members of the team that undertook the NIHR funded realist synthesis and evaluation that this paper refers to (Harris et al 2017, 2019, Sims et al 2018). We are very pleased that another research team is planning to build on our work and to test out and refine further the programme theories that we identified in our realist synthesis and tested in the realist evaluation of intentional rounding in hospital wards in England. We have a number of questions and comments which we hope will be helpful to authors as they develop their work:

**Introduction**

- The introduction to the proposal focuses the review on intentional rounding as a multifactorial intervention to reduce falls. Although this is an assumption made in many published papers, the research evidence for this is very weak due to serious methodological and/or reporting weaknesses. In most healthcare organisations there are several interventions which are implemented to reduce falls, e.g., falls assessments, enhanced care, bay tagging, medicine review etc., and so it would be very difficult to identify the impact of intentional rounding. Furthermore, no evidence was found to support this in our evaluation of intentional rounding. *There is a need to provide a clear rationale to focus on falls and not other outcomes (intended or unintended).*
- It would be useful to say more about the intentional rounding intervention, its origins and the reasons for adoption. For example, there is no mention of the Studer group and there is no reference for the "landmark US study in 2006" that is referred to.
- Given that there is an existing realist synthesis it would be helpful to provide an idea of how

many new papers about intentional rounding have been published since 2016 to provide a rationale for the need to repeat/update it.

- The realist synthesis is presented as the preparation for a realist evaluation study in acute hospital settings in Ireland. It is stated that there is an evidence gap in how, why and in what context IR works and that it is necessary to learn more about what it is about IR that enhances patient safety and prevents harmful outcomes for patients. However, although the previous realist synthesis and evaluation are frequently cited, this protocol paper doesn't report the findings of either or provide details of how this proposed realist synthesis builds on the programme theory identified in the previous review and tested in the realist evaluation study. In our realist evaluation on acute hospital wards in England we found little or no evidence that the intervention works in the way it was expected to work or had an impact on patient safety.
- It is not completely clear, but it appears that the plan is to repeat the realist review to generate a programme theory rather than update/refine the existing programme theory. We think it would be more useful to continue refining the programme theory of intentional rounding from the current empirically informed programme theory. We have a recent paper which provides more detail of the realist evaluation which may be useful (Leamy et al 2023) [Refer ref 1]

#### Methods

- Stage one: clarifying scope and developing initial programme theory – the authors state that they are undertaking a realist to identify existing theories of IR but as mentioned above they do not share the programme theories that have already identified in the previous synthesis. They state the *'the references and citations in the 2018 realist synthesis and 2019 evaluation papers on IR in the hospital setting by Sims et al., and Harris et al., respectively will be used as a starting point for review of the literature and theory development.'* This suggests that they plan to start the review from scratch rather than starting from existing realist programme theories and searching for new evidence to support or refute them.
- Use of the Joanna Briggs Institute critical appraisal tools – It would be useful to provide a rationale for the use of these tools. In realist approaches, the quality of evidence is usually assessed a different way focussing on the quality of evidence on refining understanding of the intervention's programme theory [refer Ref 2]
- It would be helpful to give a rationale for why the Standards for Reporting Implementation Studies (StaRI) Checklist was selected as a framework for data extraction. Not all the studies reviewed will be implementation studies. Will this tool support extraction of the different types of data/information that will help explain the nuances of explaining how intentional rounding works and the contexts that influence this?

We hope these comments are helpful. In summary, our main point is that it would be helpful for this proposal for a realist synthesis to report and build on what is already known about the programme theory of intentional rounding. There are existing programme theories that have been refined through empirical evaluation, these should be reported and discussed and the review protocol designed to build on these. We think these revisions are necessary for the paper to be scientifically valid and therefore have no alternative than to select the publisher's 'Not approved' status.

#### References

1. Leamy M, Sims S, Levenson R, Davies N, et al.: Intentional rounding: a realist evaluation using case studies in acute and care of older people hospital wards. *BMC Health Serv Res.* 2023; **23** (1):

1341 [PubMed Abstract](#) | [Publisher Full Text](#)

2. Pawson, R: Evidence-Based Policy:A Realist Perspective. *Sage Publications Inc., London*. 2006.

**Is the rationale for, and objectives of, the study clearly described?**

Partly

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

No

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Nursing, realist synthesis and evaluation, intentional rounding, complex interventions

**We confirm that we have read this submission and believe that we have an appropriate level of expertise to state that we do not consider it to be of an acceptable scientific standard, for reasons outlined above.**

Reviewer Report 07 March 2024

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**Sonya Kowalski**

University of Detroit Mercy, Detroit, Michigan, USA

This article is a realist synthesis research plan to investigate the contextual factors that impact the success or failure of intentional rounding (IR) strategies on inpatient fall rates. Cost factors are included in the synthesis plan.

The rationale for the study, to fill an information gap related to specific contextual factors that contribute to efficacy of IR strategies, is clear. The objectives are clearly written and included in the search and evaluation strategies.

The realist synthesis methodology is appropriate for the study.

The search strategy; inclusion/exclusion criteria; selection and appraisal; data extraction; data synthesis and analysis; theory refinement with stakeholders are clear.

The article is well written and the work is relevant to cost-effective patient safety.

**Is the rationale for, and objectives of, the study clearly described?**

Yes

**Is the study design appropriate for the research question?**

Yes

**Are sufficient details of the methods provided to allow replication by others?**

Yes

**Are the datasets clearly presented in a useable and accessible format?**

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Fall Risk Prevention Strategies

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Author Response 08 Mar 2024

**Aileen Hetherton**

Dear Professor Kowalski,

Thank you for reviewing the article [Contextual factors and intentional rounding in acute hospitals: understanding what works, for whom, in what settings: a realist synthesis protocol](#)

We are delighted to have received approval status from you and thank you for your commentary on our published work.

Kind Regards

Aileen Hetherton

**Competing Interests:** None

Reviewer Report 28 February 2024

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**Amy Drahota**

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**Leah Fullegar**

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<sup>2</sup> University of Portsmouth (Ringgold ID: 6697), Portsmouth, England, UK

Overall, this was a clearly written paper outlining the protocol for a realist synthesis on the use of intentional rounding in acute hospitals. The realist synthesis methodology is well referenced in the protocol; This is an appropriate method for the research topic. The inclusion of stage 6 (theory refinement with stakeholders) is a key stage in realist methodologies and good to see in the plan. We have a few key aspects of feedback for consideration, itemised below:

### **Introduction:**

1. Paragraph 3. Maybe worth highlighting where the costs/figures being discussed are associated with all falls (including community-based falls), and the relationship of this to in-patient falls, given the focus of the review is on preventing hospital-based falls.
2. Paragraph 4. There has been updated world guidelines published in Age & Ageing (Ref [1]) that might be beneficial to cite where NICE 2013 are cited.
3. Paragraph 4. It would be worth citing the Cochrane review on preventing falls in hospitals, which is more up-to-date than the AHRQ 2013 (Ref [2]).
4. Paragraph 8. Could perhaps signpost here that this publication sets out the protocol for the realist synthesis, and the second phase will be set out in future publications. Later on in the paper (see comment 11 below) it sometimes becomes confusing when the second phase is discussed within the realist synthesis methods.

### **Rationale and existing reviews:**

5. The rationale for the review could be further strengthened to explain how this review relates to Sims et al (2018) and explicitly indicate the gap in knowledge that necessitates the proposed review. By the end of the report it becomes clearer that this is an update of Sims (2018), however the paper would benefit from explaining this earlier on (and why there's a need for an update), and to explain any ways in which this realist synthesis differs.
6. Where it is stated that there has been no study in Ireland, is that in reference to primary evidence or to a realist synthesis having not yet been conducted in Ireland? Does that mean that this review is only going to focus on Irish primary research evidence, or that having the review undertaken in Ireland is going to shape the findings in some way that's important? It's currently a bit tricky to follow the line of argument as to why no study having yet been conducted in Ireland justifies this new review. It feels like perhaps this is a justification for the planned realist evaluation that is to follow in phase 2, rather than a justification for the synthesis, but it's currently unclear.

### **Realist synthesis methods:**

7. The line of argument around assessing resources and cost is a bit difficult to follow in this section. Some of the writing and referencing appears to be more related to phase 2 (the realist evaluation) rather than this realist synthesis. We suggest this is reviewed to focus more specifically on the incorporation of economic data into the realist synthesis.



**Research aim and objectives:**

8. The part of the aim on “promote stakeholder engagement in IR” comes as a bit of a surprise, having read the introduction/rationale, as stakeholder engagement isn’t explicitly mentioned up until this point, so it’s unclear what is being referred to here.

9. The objectives appear clear, however objective 5 does not seem to relate to the aim; would it be worth revising the aim to incorporate the issue of resource use/costs?

**Stage one: clarifying scope and developing an initial programme theory**

10. The stages of the review seem logical and fit with realist synthesis theory, however some clarity and reorganisation may be helpful in the protocol. Much of the information under the stage one heading describes the search strategy (snowballing) rather than explaining how the IPT will be developed and used. This section also states that the authors will be using the same search strategy as the existing realist synthesis on this topic, indicating they are aiming to update the existing review. This could do with clarifying earlier (see feedback point 5).

11. It’s slightly confusing to discuss the two stages in this section. Does the *synthesis* have two phases (as stated) or is it that the overall project has two phases (i.e. a realist synthesis and realist evaluation)? It might be clearer simply to focus on stage one (the synthesis) here in this methods section, rather than referring to later stages of the project.

12. Reference is made here to the inclusion/exclusion criteria being necessarily broad, however it is not yet clearly articulated what those eligibility criteria are. Consider where best to present the information on eligibility criteria (see comment 10 above).

13. Will the initial programme theory be adapted from Sims et al (2018) or developed from scratch?

**Stage 2: search strategy**

14. The inclusion and exclusion criteria do not include any mention of stakeholder engagement, patient safety outcomes, falls, or cost effectiveness – all of which have been discussed as focal points for this review. It would be helpful to clarify what is being investigated. Are there any limits placed on country, and dates?

**Stage 4: data extraction**

15. The data extraction section states that the programme theories established in the existing realist review will be used but does not state how, this might fit better under Stage 1.

16. This section also states only studies from 2016 to 2022 will be included, this information should be with the inclusion and exclusion criteria. The justification for this should also be clarified. Is it necessary to state 2022 as the upper date? What if newer research is discovered during the review process – will this not be eligible?

To summarise, this was an enjoyable protocol to read. We suggest it could be improved further by strengthening the rationale, looking at the organisation of where content is being presented and enhancing the clarity around the eligibility criteria. We wish you well with this interesting and important research.

### References

1. Montero-Odasso M, van der Velde N, Martin FC, Petrovic M, et al.: World guidelines for falls prevention and management for older adults: a global initiative. *Age Ageing*. 2022; **51** (9). [PubMed Abstract](#) | [Publisher Full Text](#)
2. Cameron ID, Dyer SM, Panagoda CE, Murray GR, et al.: Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database Syst Rev*. 2018; **9** (9): CD005465 [PubMed Abstract](#) | [Publisher Full Text](#)

### Is the rationale for, and objectives of, the study clearly described?

Partly

### Is the study design appropriate for the research question?

Yes

### Are sufficient details of the methods provided to allow replication by others?

Partly

### Are the datasets clearly presented in a useable and accessible format?

Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** falls prevention; health & care of older adults; systematic reviews; realist synthesis.

**We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.**

Author Response 24 Apr 2024

#### Aileen Hetherton

We wish to thank you for your very thorough and insightful feedback on this protocol paper.

We have taken your sixteen points in to consideration and made amendments accordingly. Your feedback and suggestions have been greatly appreciated and we hope the second version has addressed the concerns that you have highlighted.

We welcome any further feedback on this paper to ensure it is valid and will inform a scientifically sound realist synthesis study.

Once again thank you

**Competing Interests:** None to disclose

