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What supports and constrains the implementation of multifactorial falls risk assessment and tailored multifactorial falls prevention interventions in acute hospitals? Protocol for a realist review

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1   **What supports and constrains the implementation of multifactorial falls risk assessment**

2   **and tailored multifactorial falls prevention interventions in acute hospitals? Protocol for a**

3   **realist review**

4

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3   48   **Abstract**
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6   49   **Introduction:** Falls are the most common type of safety incident reported by acute hospitals
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8   50   and can cause both physical (e.g. hip fractures) and non-physical harm (e.g. reduced
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10
11   51   confidence) to patients. It is recommended that, in order to prevent falls in hospital, patients
12
13   52   should receive a multifactorial falls risk assessment and be provided with a multifactorial
14
15   53   intervention, tailored to address the patient's identified individual risk factors. It is estimated
16
17
18   54   that such an approach could reduce the incidence of inpatient falls by 25-30% and reduce the
19
20   55   annual cost of falls by up to 25%. However, there is substantial unexplained variation between
21
22
23   56   hospitals in the number and type of assessments undertaken and interventions implemented.
24
25   57   **Methods and analysis:** A realist review will be undertaken to construct and test programme
26
27   58   theories regarding (1) what supports and constrains the implementation of multifactorial falls
28
29   59   risk assessment and tailored multifactorial falls prevention interventions in acute hospitals;
30
31
32   60   and (2) how, why, in what contexts, and for whom tailored multifactorial falls prevention
33
34   61   interventions lead to a reduction in patients' falls risk. We will first identify stakeholders'
35
36   62   theories concerning these two topics. We will then test these theories systematically, using
37
38
39   63   primary studies to determine whether empirical evidence supports, refutes, or suggests a
40
41   64   revision or addition to the identified theories.
42
43
44   65   **Ethics and dissemination:** The study does not require ethical approval. The review will
45
46
47   66   provide evidence for how to implement multifactorial falls risk assessment and prevention
48
49   67   strategies in acute hospital settings. This will be disseminated to academic and clinical
50
51   68   audiences and will provide the basis for a future multi-site study through which the theories
52
53
54   69   will be further refined.
55
56   70   **Systematic review registration:** PROSPERO CRD42020184458.
57
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59   71
60

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72   **Keywords:** Realist review, falls, risk assessment, hospitals, implementation

73

74   **Word count:** 3,334

75

76   **ARTICLE SUMMARY**

77   **Strengths and limitations of this study**

78   •   Our review will provide a programme theory that explains what supports and

79   constrains implementation of multifactorial falls risk assessment and tailored

80   multifactorial falls prevention interventions in acute hospitals and how, why, in what

81   contexts, and for whom tailored multifactorial falls prevention interventions leads to

82   a reduction in patients' falls risk.

83   •   It will provide evidence that healthcare providers can use to inform their own

84   multifactorial falls risk assessment and prevention strategies, with the potential to

85   reduce frequency of inpatient falls and thereby reduce the impact of both human

86   suffering and healthcare costs.

87   •   We will integrate literature from other settings and concerning interventions with the

88   same mechanisms and use citation searching to identify clusters of related studies, to

89   ensure we have adequate evidence to provide confidence in our findings.

90   •   The possibility of drawing on literature from other settings or concerning

91   interventions with the same mechanism could make the review unwieldy; to mitigate

92   against this, we will consult our lay researchers and Study Steering Committee

93   regarding which CMO configurations to test.

94

95   **INTRODUCTION**

5

96 Inpatient falls in acute hospitals are an international patient safety concern. Approximately

97 30-40% of reported safety incidents in acute hospitals are falls (1), and in England falls are the

98 most common type of safety incident reported in acute hospitals (2). Injuries occur in 15-50%

99 of hospital falls and up to 10% of these are serious (1). The proportion of falls resulting in any

100 fracture ranges from 1% to 3%, with reports of hip fracture ranging from 1.1% to 2.0% (3).

101 Outcomes for patients who acquire hip fractures in hospital are far worse than for those who

102 acquire them in the community, with significant differences in mortality, discharge to long-

103 term high-level nursing care facilities, and return to preadmission activity of daily living status

104 (4).

105 The human cost of falling also includes fear of falling again and associated loss of confidence

106 (1, 5), loss of independence (6), and social isolation (2). It can result in slower recovery (5),

107 even when physical harm is minimal, and can have longer term consequences for the patient's

108 health, as fear of falling may lead to restriction of activity and associated loss of muscle and

109 balance function, thereby increasing further the risk of falling (1). Falls can also be a cause of

110 significant distress for families and staff (3, 5). Falls in hospital are a common cause of

111 complaints (7) and can be a source of litigation (8). Falls in hospital are also associated with

112 increased length of stay and greater amounts of health resource use (3).

113 The traditional approach to managing falls in acute hospitals was to complete a falls risk

114 prediction tool (such as STRATIFY (9)). Such tools typically stratify patients according to their

115 perceived risk of falling (high, medium, low) with interventions targeting individuals at high

116 risk. There are, however, issues with this approach to risk evaluation for falls, in particular the

117 issue of discrimination, where all patients on the unit are identified as high risk, and that

118 having a score provides reassurance that action is being taken when actually it is not (10).

6

119   Given the limitations of risk prediction tools, in the United Kingdom, the National Institute

120   for Health and Care Excellence (NICE) guideline on falls in older people states that falls risk

121   prediction tools should not be used and instead a multifactorial falls risk assessment should

122   be undertaken (11). Rather than categorising a patient according to their perceived risk of

123   falling, this approach to assessment identifies individual risk factors for each patient which

124   may make them at risk of falling and that can be treated, improved or managed during their

125   stay. This may include: cognitive impairment; continence problems; falls history, including

126   causes and consequences (e.g. injury and fear of falling); footwear that is unsuitable or

127   missing; health problems that may increase their risk of falling; medication; postural

128   instability, mobility problems and/or balance problems; syncope syndrome; and visual

129   impairment. The NICE guideline states that a multifactorial falls risk assessment should be

130   undertaken for all inpatients 65 years or older and inpatients aged 50 to 64 years judged to

131   be at higher risk of falling due to an underlying condition. On the basis of this assessment, a

132   multifactorial intervention should be provided, tailored to address the patient's identified

133   individual risk factors. It is estimated that such an approach could reduce the incidence of

134   inpatient falls by 25-30% and reduce the significant annual cost of falls – estimated at £630

135   million – by up to 25% (2).

136   Even though the NICE guideline has included these recommendations since 2013, there is

137   substantial unexplained variation between National Health Service (NHS) hospitals in England

138   and Wales, in terms of the number and type of assessments and interventions undertaken

139   (5). In assessment, 32% of healthcare providers are still using risk screening tools to identify

140   those at risk of falls (12). Improvement was found between 2015 and 2017 in the proportion

141   of older patients receiving these assessment and interventions but for some of these

142   remained concerningly low. These include cognitive impairment assessment (58.5%), delirium

7

143 assessment (39.7%), medications assessment (47.8%), and vision assessment (46.2%). In

144 interventions, there was improvement in the presence of interventions where required for

145 cognitive impairment and delirium, although rates remained low (43.7% and 48.7%

146 respectively), but no overall significant change in the presence of tailored continence care

147 plans (66.9%) or mobility interventions (78.8%) for those patients who required them.

148 Given this variation, there is a need to understand the contextual factors that support and

149 constrain the implementation of multifactorial falls risk assessment and tailored

150 multifactorial falls prevention interventions in an acute hospital setting, in order to improve

151 practice. However, even if tailored multifactorial falls prevention interventions are

152 implemented, contextual factors may constrain their use, so that they do not achieve the

153 desired impact. For example, several studies suggest patient adherence to inpatient falls

154 prevention strategies depends on a range of contextual factors including patient willingness

155 to ask for assistance, with some patients not wishing to 'bother' staff (13) or not accepting

156 that they are at risk of falling (14-17). Therefore, in this paper, we present the protocol for a

157 realist review that aims to determine:

158 1. What supports and constrains the implementation of multifactorial falls risk assessment

159 and tailored multifactorial falls prevention interventions in acute hospitals; and

160 2. How, why, in what contexts, and for whom tailored multifactorial falls prevention

161 interventions lead to a reduction in patients' falls risk.

162 This protocol has been written in accordance with PRISMA-P guidelines (Additional file 1).

163

164 **METHODS AND ANALYSIS**

165 We will undertake a realist review. Realist review is a literature review method that

166 represents a divergence from traditional systematic review methodology (18). It starts by

8

167 identifying stakeholders' theories and then uses empirical evidence to systematically evaluate

168 these, allowing us to compare how an intervention is intended to work with how it actually

169 works in practice. For realists, interventions do not produce outcomes. Rather, interventions

170 offer resources; outcomes depend on how recipients respond to those resources, which will

171 vary according to the context. Realist theories, referred to as Context-Mechanism-Outcome

172 (CMO) configurations, explain how different contexts trigger particular intervention

173 mechanisms (the reasoning and responses of recipients to intervention resources) which, in

174 turn, give rise to a particular pattern of outcomes.

175   Realist approaches can be thought of as consisting of three phases: theory elicitation, theory

176 testing, and theory refinement, and we use this structure to describe the process of the realist

177 review.

178

179 **Patient and Public Involvement**

180 The lay member of the project team (DW) contributed to the design of the study. He has

181 recruited a group of lay researchers (members of the public who will contribute to the

182 conduct of this research) who will provide input into the review, prioritising the theories to

183 be tested in Phase 2 of the review.

184

185 **Phase 1: Theory elicitation**

186 *Search strategy*

187 Searches will be designed by an information specialist with expertise in realist reviews (JW)

188 and peer reviewed by a second information specialist. A combination of free text terms,

189 synonyms and indexing terms will be used. The searches will not be limited by publication

190 date.

9

191   The databases to be searched include:

192   • Ovid Medline (1946 – present) and Medline In-Process & Other Non-Indexed Citations

193   • Ovid Health Management Information Consortium (1983 – present)

194   • EBSCO CINAHL (1981 – present)

195   We will undertake the following searches:

196   • *Practitioner theories:* Programme theories are likely to be found in editorials, comments,

197   letters, and news articles (19), so searches will be undertaken, using a filter (set of search

198   terms) to limit the search to these publication types (see Additional File 2 for an example

199   search strategy). In addition to searching the databases listed above, we will search

200   relevant professional journals and the websites of professional organisations. Given the

201   range of professional groups potentially involved in falls risk assessment and prevention,

202   a set of professional journals will be selected covering all the relevant professional groups.

203   This is likely to include, for example, the Nursing Standard, the Pharmaceutical Journal,

204   Frontline (a professional journal for physiotherapists), and Optometry Today. Websites

205   for professional organisations, including the British Geriatrics Society, the Royal College

206   of Nursing, and the Royal Pharmaceutical Society, will be searched. Searches will also be

207   run on Google for reports of quality improvement projects, such as the FallSafe quality

208   improvement project (7).

209   • *Academic theories:* The discussion sections of empirical studies often include the authors'

210   theories about why the intervention did or did not achieve the desired effect (20).

211   Therefore, studies of falls prevention interventions will be searched for, using existing

212   systematic reviews as a starting point. See Additional File 3 for an example search strategy.

213   • *Substantive theories:* We will review articles retrieved in the 'academic theories' search

214   for reference to substantive theory and, if necessary, we will undertake an additional

10

215   search for relevant substantive theories on risk assessment and guideline adherence.

216   The records identified in the searches will be saved and managed in an EndNote library.

217   Details of all search activities (databases, websites, date of search, number of records found,

218   search strategies) will be recorded in a timeline spreadsheet.

219

Screening process and inclusion/exclusion criteria

221   A 'liberal accelerated' approach to screening will be taken, where one reviewer reviews all

222   records/full text papers and a second reviewer reviews records/full text papers excluded by

223   the first reviewer (21). This approach is less time and resource intensive than having two

224   reviewers review all records/full text papers while maximising inclusion, increasing the

225   number of records/full text papers retained in comparison to a single reviewer (22). Because

226   the purpose of this phase of the review is to identify and catalogue programme theories and

227   theory fragments, rather than to assess their validity, selection will be based on relevance to

228   the topic of the review (18, 19). The inclusion criteria for the 'practitioner theories' and

229   'academic theories' searches will be:

230

231   • Multifactorial/single factor falls risk assessment or falls risk prediction tools and/or

232   multifactorial/single falls prevention interventions

233   • Adults/older people

234   • Acute hospital setting

235   • Include arguments about what supports or constrains implementation and/or in what

236   contexts and for whom they can/should be used

237   • Published in the English language

238

11

239   Exclusion criteria will be:

240

241   • Children and young people

242   • Settings other than acute hospital

243   • Published in languages other than English

244

245   We will include articles about single factor risk assessment tools on the basis that

246   understanding what supports and constrains their use will inform our understanding of what

247   supports and constrains use of multifactorial risk assessment tools. Similarly, we will include

248   articles about single falls prevention interventions on the basis that understanding what

249   supports and constrains the implementation and use of single interventions will inform our

250   understanding of what supports and constrains the implementation and use of multifactorial

251   interventions which contain those single interventions as a component. This is in line with the

252   realist approach, which seeks to link the responses to an intervention to particular resources

253   provided by the intervention. We will also include articles about falls risk prediction tools to

254   understand how and in what contexts they continue to be used instead of multifactorial falls

255   risk assessments.

256   We will exclude articles published in languages other than English because the nature of

257   realist review means that we would need to translate the full article, for which the project

258   does not have adequate resources. This is in contrast to traditional systematic reviews where

259   only defined data needs to be identified and translated (23).

260   A PRISMA flow chart detailing the review decision process for Phase 1 will be developed.

261

262   ***Analysis and synthesis***

12

263   Included articles from the 'practitioner theories' and 'academic theories' searches will be

264   imported into NVivo and coded as context, mechanism, and outcome. Outcomes will include,

265   for example, fall rates, but also any other outcomes reported, to capture both intended and

266   unintended impacts. A 10% random sample of papers will be coded by a second reviewer for

267   consistency. An Excel spreadsheet will be used for recording the CMO configurations from

268   each article. Our experience of undertaking realist reviews suggests that individual articles

269   are unlikely to provide us with fully formed CMO configurations or to even contain

270   information about all three elements of context, mechanism, and outcome (20). Therefore,

271   we will also record CMO fragments in the Excel spreadsheet. Once this is complete, the list of

272   CMO configurations will be refined to combine those that are similar. Narrative summaries of

273   each of the substantive theories identified will be written and we will compare the CMO

274   configurations with the substantive theories, using the substantive theories to fill in any

275   remaining gaps in the CMO configurations. The resulting CMO configurations, explaining both

276   (1) what supports and constrains implementation of multifactorial falls risk assessment and

277   tailored multifactorial falls prevention interventions in acute hospitals, and (2) how, why, in

278   what contexts, and for whom tailored multifactorial falls prevention interventions lead to a

279   reduction in patients' falls risk, will combine to provide an initial programme theory.

280   A particular risk for realist reviews is that they can easily become unwieldy (19). We will

281   mitigate against this by taking guidance from our lay researchers and Study Steering

282   Committee regarding the CMO configurations that should be taken forward for testing in

283   Phase 2 of the review. We will first identify a sub-set of possible CMO configurations, based

284   on the feasibility of testing them, undertaking initial scoping searches to gauge the extent of

285   the available literature, and based on their potential for informing practice (e.g. if a CMO

286   configuration contains contextual factors that constrain the conduct of falls risk assessment

13

287 that are not amenable to change, it will not be taken forward for testing). We will discuss the

288 remaining sub-set of CMO configurations with our lay researchers and our Study Steering

289 Committee and ask them to rank them in order of priority; those CMO configurations which

290 have the highest ranking across both groups will be taken forward to the next stage.

291

292 **Phase 2: Theory testing**

293 ***Search strategy***

294 Searching will be purposive and iterative, driven by the prioritised CMO configurations, in

295 order to identify empirical studies relevant to testing of the initial programme theory (19).

296 Searches will be designed by an information specialist (JW) with input from the review team.

297 It will be peer reviewed by a second information specialist. Health and multidisciplinary

298 databases to be searched include:

299 • Ovid Medline and Medline In-Process & Other Non-Indexed Citations (1946 – present)

300 • EBSCO CINAHL (1981 – present)

301 • Ovid EMBASE (1947 – present)

302 • Web of Science Core Collection (1900 – present)

303 • ProQuest Applied Social Sciences Index & Abstracts (1987 – present)

304 An initial scoping search suggests there is limited empirical evidence from the hospital setting,

305 with existing research tending to focus on the community setting. However, realist reviews

306 offer particular benefits when considering interventions where there is limited primary

307 research because the key unit of analysis is the intervention mechanism; this means that

308 literature concerning the same intervention in another setting or other interventions that

309 have the same underlying mechanism are deemed relevant, so a wider breadth of evidence

310 is available (19, 24). Consequently, while initial searches will be limited to the hospital setting,

14

311   where there is an absence of literature searches will be broadened out to include literature

312   from the community setting and care homes. We may also broaden our search to include

313   literature concerning other interventions that are based on the same mechanisms as those

314   within the initial programme theory. Search techniques will include structured literature

315   searching of academic databases listed, and also complementary searching such as citation

316   searching and other CLUSTER searching techniques (25) that can identify relevant studies

317   through links in citation networks or through a focus on specific authors or projects. Grey

318   literature searching (for example websites of professional organisations) will be undertaken

319   where it likely to uncover literature relevant to the programme theories under investigation.

320

321   ***Screening process***

322   As in Phase 1, a 'liberal accelerated' approach to screening will be taken. Relevance of each

323   study to testing the initial programme theory will be assessed pragmatically against key

324   inclusion criteria concerned with the context (acute hospitals) and the intervention (falls risk

325   assessment and/or falls prevention interventions). Priority will be given to those studies that

326   meet all inclusion criteria but we will also include studies which match the intervention

327   criteria but not the context criteria (e.g. studies about falls risk assessment in care homes)

328   and studies which match the context criteria and are concerned with interventions that have

329   the same underlying mechanism (e.g. studies about pressure ulcer risk assessment in acute

330   hospitals). All study designs will be included, acknowledging that different study designs make

331   different contributions to theory testing; for example, randomised controlled trials (RCTs)

332   provide information on outcome patterns and may provide some pointers to likely contextual

333   differences, but they seldom provide information about mechanisms, information which is

334   more likely to be found in qualitative studies. A PRISMA flow chart detailing the review

15

335   decision process for Phase 2 will be developed.

336

Appraisal and analysis

338   Studies deemed to be relevant will be appraised using the Mixed Methods Appraisal Tool (26).

339   However, we will not exclude studies based on this appraisal. Additionally, following the

340   realist approach, in describing the studies, we will reflect only on the quality of those

341   elements of the studies from which *evidential fragments* for theory testing are drawn (27).

342   For example, in a mixed methods study, questionable analyses of falls data are not of concern

343   if what we are drawing on are the well conducted qualitative elements of the study. As in

344   Phase 1, included studies will be imported into NVivo and coded as context, mechanism, and

345   outcome, capturing all reported outcomes.

346   Guidelines for systematic reviews suggest that, in addition to assessing risk of bias in

347   individual studies, an assessment of the risk of bias across studies – such as publication bias

348   and selective reporting within studies – should be undertaken (28). However, this assumes a

349   traditional systematic review that relies on quantitative studies and uses approaches that are

350   not easily applicable when using the wide range of study designs that realist reviews typically

351   incorporate.

352

Phase 3: Theory refinement

354   Coded data for each individual study will be compared in turn with the initial programme

355   theory to determine whether the findings support, refute, or suggest a revision or addition to

356   the CMO configurations. The resulting programme theory will be summarised in both

357   diagrammatic and narrative form (29, 30).

358   In reporting the review, the Realist And Meta-narrative Evidence Syntheses: Evolving

16

359 Standards (RAMESES) publication standards will be followed (31). Any changes from this

360 protocol will be reported and the rationale provided.

361   For systematic reviews, it is recommended that the strength of the body of evidence is

362 assessed and reported (28), for example using the Grades of Recommendation, Assessment,

363 Development and Evaluation (GRADE) approach (32) or GRADE-CERQual (Confidence in the

364 Evidence from Reviews of Qualitative research) (33). Approaches such as GRADE are not

365 appropriate for a realist review, because they rely on hierarchies of evidence in making

366 assessments and treat inconsistency in effects across studies as a problem, whereas realist

367 reviews accept that there may be 'nuggets of wisdom' in methodologically weak studies (27)

368 and expect variation in effects because of variation in programme contexts (34). GRADE-

369 CERQual involves assessing each individual review finding based on the four components of

370 methodological limitations, coherence, adequacy of data, and relevance (33). It has been used

371 for previous realist reviews (35, 36) and fits better with the realist approach, involving

372 consideration of the theoretical contributions of studies and encouraging reviewers to be

373 sensitive to the importance of context (14). Therefore, we will use CERQual to assess each

374 CMO, rating confidence in each as either high, moderate, low, or very low. This will both

375 support decision making of those who wish to use the findings of the review to inform their

376 practice and highlight areas where further primary research is needed.

377

378 **ETHICS AND DISSEMINATION**

379 Ethical approval is not required for this review.

380

381 This review will provide evidence that healthcare providers can use to inform their own

382 multifactorial falls risk assessment and prevention strategies, with the potential to reduce

17

383   frequency of inpatient falls and thereby reduce the impact of both human suffering and

384   healthcare costs. Therefore, the results will be published in an academic journal that has a

385   clinical readership. We will also present the findings at other venues where we will reach

386   clinical staff, including the Royal College of Nursing International Nursing Research

387   Conference, local Falls Collaboratives, and Nursing, Midwifery and AHP Research conferences

388   at local Trusts. We will engage with the wider public via a project website, where links to

389   publications will be provided, and social media, e.g. Twitter.

390

396

Author Contributions

398   RR is Principal Investigator and guarantor for the review. She conceived, designed, and

399   secured funding for the review in collaboration with JW, NA, FH, DD, HS, NH, PG, SW, CT, and

400   DW. All authors provided input into various aspects of the design of the review and revised

401   drafts of the protocol. RR led the writing of this protocol manuscript. All authors read and

402   approved the final manuscript.

403

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407

Competing interests statement

409   The authors declare that they have no competing interests.

410

Additional files

412   Additional file 1: Checklist of PRISMA-P reporting standards

413   Additional file 2: Practitioner theories example search strategy

414   Additional file 3: Academic theories example search strategy

415

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PRISMA-P 2015 Checklist

What supports and constrains the implementation of multifactorial falls risk assessment and tailored multifactorial falls prevention interventions in acute hospitals? Protocol for a realist review (Randell et al.)

Section/topic	#	Checklist item	Information reported Yes	No	Line number(s)
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	Not applicable
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☒	☐	70
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	5-28
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	399-403
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☒	☐	360-361
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒	☐	406-407
Sponsor	5b	Provide name for the review funder and/or sponsor	☒	☐	406-407
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☒	☐	394-396
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	96-156
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	157-161

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Section/topic	#	Checklist item	Information reported Yes	No	Line number(s)
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	229-260, 323-335
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	191-208, 298-320
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	Provided as additional files
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	217-219, 264-265, 268-272, 344-346
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	222-224, 323
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	264-269, 344-346
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☒	☐	264-267, 344-346
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☒	☐	265-267, 344-346
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	339-344
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☐	☒	Not appropriate for realist review
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☐	☒	Not appropriate for realist review

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Section/topic	#	Checklist item	Information reported Yes	Information reported No	Line number(s)
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☐	☒	Not appropriate for realist review
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	272-280, 355-358
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☒	☐	347-352
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	362-377

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What supports and constrains the implementation of multifactorial falls risk assessment and tailored multifactorial falls prevention interventions in acute hospitals? Protocol for a realist review (Randell et al.)

Additional file 2: Practitioner Theories Search Strategy Example

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to July 22, 2020>

1   Accidental Falls/ or exp Hip Fractures/pc (25502)
2   (fall or falls or faller*).tw,kw. (147405)
3   or/1-2 [falls] (155967)
4   Risk Assessment/ (265290)
5   risk assess*.tw,kw. (69279)
6   (fall* adj3 (assess* or screen* or prevent* or predict*)).tw,kw. (10727)
7   exp Accident Prevention/ (86820)
8   or/4-7 [assessment or prevention] (391878)
9   nursing time*.jn. (39139)
10   3 and 8 and 9 (26)
11   nursing standard.jn. (35276)
12   3 and 8 and 11 (33)
13   health service* journal.jn. (10933)
14   3 and 8 and 13 (3)
15   10 or 12 or 14 (62)

What supports and constrains the implementation of multifactorial falls risk assessment and tailored multifactorial falls prevention interventions in acute hospitals? Protocol for a realist review (Randell et al.)

Additional file 2: Academic Theories Search Strategy Example

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to July 21, 2020>

1   Accidental Falls/ or exp Hip Fractures/pc (25500)
2   (fall or falls or faller*).tw,kw. (147448)
3   or/1-2 [falls] (156010)
4   Risk Assessment/ (265251)
5   risk assess*.tw,kw. (69315)
6   (fall* adj3 (assess* or screen* or prevent* or predict*)).tw,kw. (10733)
7   exp Accident Prevention/ (86806)
8   or/4-7 [assessment or prevention] (391875)
9   Hospitalization/ (107412)
10   Subacute Care/ (1049)
11   Hospital Units/ (10146)
12   exp Hospitals/ (274581)
13   Rehabilitation Centers/ (8183)
14   Inpatients/ (21949)
15   ((acute or sub-acute or subacute) adj3 (care or ward?)).tw,kw. (31737)
16   ((rehabilitation or geriatric) adj (ward? or unit? or department?)).tw,kw. (6423)
17   inpatient?.tw,kw. (107879)
18   hospital*.tw,kw. (1294309)
19   or/9-18 [hospital] (1485504)
20   3 and 8 and 19 [Fall assmt & prevention in hospitals] (3313)
21   meta-analysis/ or "systematic review"/ (194072)
22   (Literature review* or (systematic adj2 review*) or (narrative adj2 review*) or (critical adj2 review*) or scoping review* or synthesis or meta-analys* or "meta analysis" or (realist adj2 review*)).ti. (551543)
23   ("Search filter*" or "search strateg*" or "literature search*").ab. (66610)
24   or/21-23 [Systematic reviews] (635237)
25   20 and 24 (139)

BMJ Open

What supports and constrains the implementation of multifactorial falls risk assessment and tailored multifactorial falls prevention interventions in acute hospitals? Protocol for a realist review

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Primary Subject Heading:	Geriatric medicine
Secondary Subject Heading:	Health services research, Nursing
Keywords:	GERIATRIC MEDICINE, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Risk management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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3   **What supports and constrains the implementation of multifactorial falls risk assessment**

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5   **and tailored multifactorial falls prevention interventions in acute hospitals? Protocol for a**

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7   **realist review**

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3

48 **Abstract**

49 **Introduction:** Falls are the most common type of safety incident reported by acute hospitals

50 and can cause both physical (e.g. hip fractures) and non-physical harm (e.g. reduced

51 confidence) to patients. It is recommended that, in order to prevent falls in hospital, patients

52 should receive a multifactorial falls risk assessment and be provided with a multifactorial

53 intervention, tailored to address the patient's identified individual risk factors. It is estimated

54 that such an approach could reduce the incidence of inpatient falls by 25-30% and reduce the

55 annual cost of falls by up to 25%. However, there is substantial unexplained variation between

56 hospitals in the number and type of assessments undertaken and interventions implemented.

57 **Methods and analysis:** A realist review will be undertaken to construct and test programme

58 theories regarding (1) what supports and constrains the implementation of multifactorial falls

59 risk assessment and tailored multifactorial falls prevention interventions in acute hospitals;

60 and (2) how, why, in what contexts, and for whom tailored multifactorial falls prevention

61 interventions lead to a reduction in patients' falls risk. We will first identify stakeholders'

62 theories concerning these two topics, searching Medline (1946 – present) and Medline In-

63 Process & Other Non-Indexed Citations, Health Management Information Consortium (1983

64 – present), and CINAHL (1981 – present). We will then test these theories systematically, using

65 primary studies to determine whether empirical evidence supports, refutes, or suggests a

66 revision or addition to the identified theories.

67 **Ethics and dissemination:** The study does not require ethical approval. The review will

68 provide evidence for how to implement multifactorial falls risk assessment and prevention

69 strategies in acute hospital settings. This will be disseminated to academic and clinical

70 audiences and will provide the basis for a future multi-site study through which the theories

71 will be further refined.

4

72   **Systematic review registration:** PROSPERO CRD42020184458.

73

74   **Keywords:** Realist review, falls, risk assessment, hospitals, implementation

75

76   **Word count:** 3,456

77

78   **ARTICLE SUMMARY**

79   **Strengths and limitations of this study**

80   • The use of realist review will allow us to go beyond the question of whether tailored

81   multifactorial falls prevention interventions lead to a reduction in patients' falls risk,

82   to answer questions of how, why, in what contexts, and for whom.

83   • By integrating literature from other settings and concerning interventions with the

84   same mechanisms and using citation searching to identify clusters of related studies,

85   we will ensure we have adequate evidence to provide confidence in our findings.

86   • We will consult our lay researchers and Study Steering Committee to prioritise the

87   CMO configurations for testing to mitigate against the possibility of the review

88   becoming unwieldy.

89   • Drawing on a broader range of literature will increase the time required for testing

90   each CMO configuration and may mean that we do not have time to test all the CMO

91   configurations identified.

92

93   **INTRODUCTION**

94   Inpatient falls in acute hospitals are an international patient safety concern. Approximately

95   30-40% of reported safety incidents in acute hospitals are falls (1), and in England falls are the

5

96   most common type of safety incident reported in acute hospitals (2). Injuries occur in 15-50%

97   of hospital falls and up to 10% of these are serious (1). The proportion of falls resulting in any

98   fracture ranges from 1% to 3%, with reports of hip fracture ranging from 1.1% to 2.0% (3).

99   Outcomes for patients who acquire hip fractures in hospital are far worse than for those who

100   acquire them in the community, with significant differences in mortality, discharge to long-

101   term high-level nursing care facilities, and return to preadmission activity of daily living status

102   (4).

103   The human cost of falling also includes fear of falling again and associated loss of confidence

104   (1, 5), loss of independence (6), and social isolation (2). It can result in slower recovery (5),

105   even when physical harm is minimal, and can have longer term consequences for the patient's

106   health, as fear of falling may lead to restriction of activity and associated loss of muscle and

107   balance function, thereby increasing further the risk of falling (1). Falls can also be a cause of

108   significant distress for families and staff (3, 5). Falls in hospital are a common cause of

109   complaints (7) and can be a source of litigation (8). Falls in hospital are also associated with

110   increased length of stay and greater amounts of health resource use (3).

111   The traditional approach to managing falls in acute hospitals was to complete a falls risk

112   prediction tool (such as STRATIFY (9)). Such tools typically stratify patients according to their

113   perceived risk of falling (high, medium, low) with interventions targeting individuals at high

114   risk. There are, however, issues with this approach to risk evaluation for falls, in particular the

115   issue of discrimination, where all patients on the unit are identified as high risk, and that

116   having a score provides reassurance that action is being taken when actually it is not (10).

117   Given the limitations of risk prediction tools, in the United Kingdom, the National Institute

118   for Health and Care Excellence (NICE) guideline on falls in older people states that falls risk

119   prediction tools should not be used and instead a multifactorial falls risk assessment should

6

120   be undertaken (11). Rather than categorising a patient according to their perceived risk of

121   falling, this approach to assessment identifies individual risk factors for each patient which

122   may make them at risk of falling and that can be treated, improved or managed during their

123   stay. This may include: cognitive impairment; continence problems; falls history, including

124   causes and consequences (e.g. injury and fear of falling); footwear that is unsuitable or

125   missing; health problems that may increase their risk of falling; medication; postural

126   instability, mobility problems and/or balance problems; syncope syndrome; and visual

127   impairment. The NICE guideline states that a multifactorial falls risk assessment should be

128   undertaken for all inpatients 65 years or older and inpatients aged 50 to 64 years judged to

129   be at higher risk of falling due to an underlying condition. On the basis of this assessment, a

130   multifactorial intervention should be provided, tailored to address the patient's identified

131   individual risk factors. It is estimated that such an approach could reduce the incidence of

132   inpatient falls by 25-30% and reduce the significant annual cost of falls – estimated at £630

133   million – by up to 25% (2).

134   Even though the NICE guideline has included these recommendations since 2013, there is

135   substantial unexplained variation between National Health Service (NHS) hospitals in England

136   and Wales, in terms of the number and type of assessments and interventions undertaken

137   (5). In assessment, 32% of healthcare providers are still using risk screening tools to identify

138   those at risk of falls (12). Improvement was found between 2015 and 2017 in the proportion

139   of older patients receiving these assessment and interventions but for some of these

140   remained concerningly low. These include cognitive impairment assessment (58.5%), delirium

141   assessment (39.7%), medications assessment (47.8%), and vision assessment (46.2%). In

142   interventions, there was improvement in the presence of interventions where required for

143   cognitive impairment and delirium, although rates remained low (43.7% and 48.7%

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144   respectively), but no overall significant change in the presence of tailored continence care

145   plans (66.9%) or mobility interventions (78.8%) for those patients who required them.

146   Given this variation, there is a need to understand the contextual factors that support and

147   constrain the implementation of multifactorial falls risk assessment and tailored

148   multifactorial falls prevention interventions in an acute hospital setting, in order to improve

149   practice. However, even if tailored multifactorial falls prevention interventions are

150   implemented, contextual factors may constrain their use, so that they do not achieve the

151   desired impact. For example, several studies suggest patient adherence to inpatient falls

152   prevention strategies depends on a range of contextual factors including patient willingness

153   to ask for assistance, with some patients not wishing to 'bother' staff (13) or not accepting

154   that they are at risk of falling (14-17). Therefore, in this paper, we present the protocol for a

155   realist review that aims to determine:

156   1. What supports and constrains the implementation of multifactorial falls risk assessment

157   and tailored multifactorial falls prevention interventions in acute hospitals; and

158   2. How, why, in what contexts, and for whom tailored multifactorial falls prevention

159   interventions lead to a reduction in patients' falls risk.

160   This protocol has been written in accordance with PRISMA-P guidelines (Additional file 1).

161

162   **METHODS AND ANALYSIS**

163   We will undertake a realist review. Realist review is a literature review method that

164   represents a divergence from traditional systematic review methodology (18). It starts by

165   identifying stakeholders' theories and then uses empirical evidence to systematically evaluate

166   these, allowing us to compare how an intervention is intended to work with how it actually

167   works in practice. For realists, interventions do not produce outcomes. Rather, interventions

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168 offer resources; outcomes depend on how recipients respond to those resources, which will

169 vary according to the context. Realist theories, referred to as Context-Mechanism-Outcome

170 (CMO) configurations, explain how different contexts trigger particular intervention

171 mechanisms (the reasoning and responses of recipients to intervention resources) which, in

172 turn, give rise to a particular pattern of outcomes.

173 Realist approaches can be thought of as consisting of three phases: theory elicitation, theory

174 testing, and theory refinement, and we use this structure to describe the process of the realist

175 review.

176

Patient and Public Involvement

178 The lay member of the project team (DW) contributed to the design of the study. He has

179 recruited a group of lay researchers from different background (members of the public who

180 will contribute to the conduct of this research) who will provide input into the review,

181 prioritising the theories to be tested in Phase 2 of the review. These people (and the lay

182 member of the Study Steering Committee) will draw on their own lived experiences of falling

183 or of caring for someone who has fallen, as well as other life experiences, to ensure that the

184 theories reflect concerns of most importance for patients and carers.

185

Phase 1: Theory elicitation

187 *Search strategy*

188 Searches will be designed by an information specialist with expertise in realist reviews (JW)

189 and peer reviewed by a second information specialist. A combination of free text terms,

190 synonyms and indexing terms will be used. The searches will not be limited by publication

191 date.

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192 The databases to be searched include:

193 • Ovid Medline (1946 – present) and Medline In-Process & Other Non-Indexed Citations

194 • Ovid Health Management Information Consortium (1983 – present)

195 • EBSCO CINAHL (1981 – present)

196 We will undertake the following searches:

197 • *Practitioner theories:* Programme theories are likely to be found in editorials, comments,

198 letters, and news articles (19), so searches will be undertaken, using a filter (set of search

199 terms) to limit the search to these publication types (see Additional File 2 for an example

200 search strategy). In addition to searching the databases listed above, we will search

201 relevant professional journals and the websites of professional organisations. Given the

202 range of professional groups potentially involved in falls risk assessment and prevention,

203 a set of professional journals will be selected covering all the relevant professional groups.

204 This is likely to include, for example, the Nursing Standard, the Pharmaceutical Journal,

205 Frontline (a professional journal for physiotherapists), and Optometry Today. Websites

206 for professional organisations, including the British Geriatrics Society, the Royal College

207 of Nursing, and the Royal Pharmaceutical Society, will be searched. Searches will also be

208 run on Google for reports of quality improvement projects, such as the FallSafe quality

209 improvement project (7).

210 • *Academic theories:* The discussion sections of empirical studies often include the authors'

211 theories about why the intervention did or did not achieve the desired effect (20).

212 Therefore, studies of falls prevention interventions will be searched for, using existing

213 systematic reviews as a starting point. See Additional File 3 for an example search strategy.

214 • *Substantive theories:* We will review articles retrieved in the 'academic theories' search

215 for reference to substantive theory and, if necessary, we will undertake an additional

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216   search for relevant substantive theories on risk assessment and guideline adherence.

217   The records identified in the searches will be saved and managed in an EndNote library.

218   Details of all search activities (databases, websites, date of search, number of records found,

219   search strategies) will be recorded in a timeline spreadsheet.

220

221   ***Screening process and inclusion/exclusion criteria***

222   A 'liberal accelerated' approach to screening will be taken, where one reviewer reviews all

223   records/full text papers and a second reviewer reviews records/full text papers excluded by

224   the first reviewer (21). This approach is less time and resource intensive than having two

225   reviewers review all records/full text papers while maximising inclusion, increasing the

226   number of records/full text papers retained in comparison to a single reviewer (22). Because

227   the purpose of this phase of the review is to identify and catalogue programme theories and

228   theory fragments, rather than to assess their validity, selection will be based on relevance to

229   the topic of the review (18, 19). The inclusion criteria for the 'practitioner theories' and

230   'academic theories' searches will be:

231

232   • Multifactorial/single factor falls risk assessment or falls risk prediction tools and/or

233   multifactorial/single falls prevention interventions

234   • Adults/older people

235   • Acute hospital setting

236   • Include arguments about what supports or constrains implementation and/or in what

237   contexts and for whom they can/should be used

238   • Published in the English language

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240   Exclusion criteria will be:

241

242   • Children and young people

243   • Settings other than acute hospital

244   • Published in languages other than English

245

246   We will include articles about single factor risk assessment tools on the basis that

247   understanding what supports and constrains their use will inform our understanding of what

248   supports and constrains use of multifactorial risk assessment tools. Similarly, we will include

249   articles about single falls prevention interventions on the basis that understanding what

250   supports and constrains the implementation and use of single interventions will inform our

251   understanding of what supports and constrains the implementation and use of multifactorial

252   interventions which contain those single interventions as a component. This is in line with the

253   realist approach, which seeks to link the responses to an intervention to particular resources

254   provided by the intervention. We will also include articles about falls risk prediction tools to

255   understand how and in what contexts they continue to be used instead of multifactorial falls

256   risk assessments.

257   We will exclude articles published in languages other than English because the nature of

258   realist review means that we would need to translate the full article, for which the project

259   does not have adequate resources. This is in contrast to traditional systematic reviews where

260   only defined data needs to be identified and translated (23).

261   A PRISMA flow chart detailing the review decision process for Phase 1 will be developed.

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263   ***Analysis and synthesis***

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264   Included articles from the 'practitioner theories' and 'academic theories' searches will be

265   imported into NVivo and coded as context, mechanism, and outcome. Outcomes will include,

266   for example, fall rates, but also any other outcomes reported, to capture both intended and

267   unintended impacts. A 10% random sample of papers will be coded by a second reviewer for

268   consistency. An Excel spreadsheet will be used for recording the CMO configurations from

269   each article. Our experience of undertaking realist reviews suggests that individual articles

270   are unlikely to provide us with fully formed CMO configurations or to even contain

271   information about all three elements of context, mechanism, and outcome (20). Therefore,

272   alongside recording any complete CMO configurations that we identify, we will also record

273   CMO fragments in the Excel spreadsheet. Once this is complete, the list of CMO configurations

274   will be refined to combine those that are similar. Narrative summaries of each of the

275   substantive theories identified will be written and we will compare the CMO configurations

276   with the substantive theories, using the substantive theories to fill in any remaining gaps in

277   the CMO configurations. The resulting CMO configurations, explaining both (1) what supports

278   and constrains implementation of multifactorial falls risk assessment and tailored

279   multifactorial falls prevention interventions in acute hospitals, and (2) how, why, in what

280   contexts, and for whom tailored multifactorial falls prevention interventions lead to a

281   reduction in patients' falls risk, will combine to provide an initial programme theory.

282   A particular risk for realist reviews is that they can easily become unwieldy (19). We will

283   mitigate against this by taking guidance from our lay researchers and Study Steering

284   Committee regarding the CMO configurations that should be taken forward for testing in

285   Phase 2 of the review. We will first identify a sub-set of possible CMO configurations, based

286   on the feasibility of testing them, undertaking initial scoping searches to gauge the extent of

287   the available literature, and based on their potential for informing practice (e.g. if a CMO

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288   configuration contains contextual factors that constrain the conduct of falls risk assessment

289   that are not amenable to change, it will not be taken forward for testing). We will discuss the

290   remaining sub-set of CMO configurations with our lay researchers and our Study Steering

291   Committee, which brings together clinicians and academics with expertise including falls

292   prevention, risk assessment, patient safety, and implementation science. We will ask them to

293   rank the CMO configurations in order of priority; those which have the highest ranking across

294   both groups will be taken forward to the next stage.

295

296   **Phase 2: Theory testing**

297   ***Search strategy***

298   Searching will be purposive and iterative, driven by the prioritised CMO configurations, in

299   order to identify empirical studies relevant to testing of the initial programme theory (19).

300   Searches will be designed by an information specialist (JW) with input from the review team.

301   It will be peer reviewed by a second information specialist. Health and multidisciplinary

302   databases to be searched include:

303   • Ovid Medline and Medline In-Process & Other Non-Indexed Citations (1946 – present)

304   • EBSCO CINAHL (1981 – present)

305   • Ovid EMBASE (1947 – present)

306   • Web of Science Core Collection (1900 – present)

307   • ProQuest Applied Social Sciences Index & Abstracts (1987 – present)

308   An initial scoping search suggests there is limited empirical evidence from the hospital setting,

309   with existing research tending to focus on the community setting. However, realist reviews

310   offer particular benefits when considering interventions where there is limited primary

311   research because the key unit of analysis is the intervention mechanism; this means that

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312 literature concerning the same intervention in another setting or other interventions that

313 have the same underlying mechanism are deemed relevant, so a wider breadth of evidence

314 is available (19, 24). Consequently, while initial searches will be limited to the hospital setting,

315 where there is an absence of literature searches will be broadened out to include literature

316 from the community setting and care homes. We may also broaden our search to include

317 literature concerning other interventions that are based on the same mechanisms as those

318 within the initial programme theory. Search techniques will include structured literature

319 searching of academic databases listed, and also complementary searching such as citation

320 searching and other CLUSTER searching techniques (25) that can identify relevant studies

321 through links in citation networks or through a focus on specific authors or projects. Grey

322 literature searching (for example websites of professional organisations) will be undertaken

323 where it likely to uncover literature relevant to the programme theories under investigation.

324

325 ***Screening process***

326 As in Phase 1, a 'liberal accelerated' approach to screening will be taken. Relevance of each

327 study to testing the initial programme theory will be assessed pragmatically against key

328 inclusion criteria concerned with the context (acute hospitals) and the intervention (falls risk

329 assessment and/or falls prevention interventions). Priority will be given to those studies that

330 meet all inclusion criteria but we will also include studies which match the intervention

331 criteria but not the context criteria (e.g. studies about falls risk assessment in care homes)

332 and studies which match the context criteria and are concerned with interventions that have

333 the same underlying mechanism (e.g. studies about pressure ulcer risk assessment in acute

334 hospitals). All study designs will be included, acknowledging that different study designs make

335 different contributions to theory testing; for example, randomised controlled trials (RCTs)

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336   provide information on outcome patterns and may provide some pointers to likely contextual

337   differences, but they seldom provide information about mechanisms, information which is

338   more likely to be found in qualitative studies. A PRISMA flow chart detailing the review

339   decision process for Phase 2 will be developed.

340

341   *Appraisal and analysis*

342   Studies deemed to be relevant will be appraised using the Mixed Methods Appraisal Tool (26).

343   However, we will not exclude studies based on this appraisal. Additionally, following the

344   realist approach, in describing the studies, we will reflect only on the quality of those

345   elements of the studies from which *evidential fragments* for theory testing are drawn (27).

346   For example, in a mixed methods study, questionable analyses of falls data are not of concern

347   if what we are drawing on are the well conducted qualitative elements of the study. As in

348   Phase 1, included studies will be imported into NVivo and coded as context, mechanism, and

349   outcome, capturing all reported outcomes.

350   Guidelines for systematic reviews suggest that, in addition to assessing risk of bias in

351   individual studies, an assessment of the risk of bias across studies – such as publication bias

352   and selective reporting within studies – should be undertaken (28). However, this assumes a

353   traditional systematic review that relies on quantitative studies and uses approaches that are

354   not easily applicable when using the wide range of study designs that realist reviews typically

355   incorporate.

356

357   **Phase 3: Theory refinement**

358   Coded data for each individual study will be compared in turn with the initial programme

359   theory to determine whether the findings support, refute, or suggest a revision or addition to

16

360 the CMO configurations. The resulting programme theory will be summarised in both

361 diagrammatic and narrative form (29, 30).

362 In reporting the review, the Realist And Meta-narrative Evidence Syntheses: Evolving

363 Standards (RAMESES) publication standards will be followed (31). Any changes from this

364 protocol will be reported and the rationale provided.

365 For systematic reviews, it is recommended that the strength of the body of evidence is

366 assessed and reported (28), for example using the Grades of Recommendation, Assessment,

367 Development and Evaluation (GRADE) approach (32) or GRADE-CERQual (Confidence in the

368 Evidence from Reviews of Qualitative research) (33). Approaches such as GRADE are not

369 appropriate for a realist review, because they rely on hierarchies of evidence in making

370 assessments and treat inconsistency in effects across studies as a problem, whereas realist

371 reviews accept that there may be 'nuggets of wisdom' in methodologically weak studies (27)

372 and expect variation in effects because of variation in programme contexts (34). GRADE-

373 CERQual involves assessing each individual review finding based on the four components of

374 methodological limitations, coherence, adequacy of data, and relevance (33). It has been used

375 for previous realist reviews (35, 36) and fits better with the realist approach, involving

376 consideration of the theoretical contributions of studies and encouraging reviewers to be

377 sensitive to the importance of context (14). Therefore, we will use CERQual to assess each

378 CMO, rating confidence in each as either high, moderate, low, or very low. This will both

379 support decision making of those who wish to use the findings of the review to inform their

380 practice and highlight areas where further primary research is needed.

381

382 **ETHICS AND DISSEMINATION**

383 Ethical approval is not required for this review.

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384

385   This review will provide evidence that healthcare providers can use to inform their own

386   multifactorial falls risk assessment and prevention strategies, with the potential to reduce

387   frequency of inpatient falls and thereby reduce the impact of both human suffering and

388   healthcare costs. Therefore, the results will be published in an academic journal that has a

389   clinical readership. We will also present the findings at other venues where we will reach

390   clinical staff, including the Royal College of Nursing International Nursing Research

391   Conference, local Falls Collaboratives, and Nursing, Midwifery and AHP Research conferences

392   at local Trusts. We will engage with the wider public via a project website, where links to

393   publications will be provided, and social media, e.g. Twitter.

394

Acknowledgements

400

Author Contributions

402   RR is Principal Investigator and guarantor for the review. She conceived, designed, and

403   secured funding for the review in collaboration with JW, NA, FH, DD, HS, NH, PG, SW, CT, and

404   DW. All authors provided input into various aspects of the design of the review. In particular,

405   JW developed search strategies and advised on methods for assessing strength of evidence,

406   NA advised on realist methods, FH and CT advised on literature on falls, HS and SW advised

407   on current practices for falls risk assessment in the NHS, FH, DD, HS, NH, PG, CT, HZ, and CD

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408　advised on appropriate journals to search, DW, RR, NA, and LM developed the plan for lay

409　researcher involvement in the study, and all authors contributed to clarifying and refining

410　inclusion and exclusion criteria. RR led the writing of this protocol manuscript and all authors

411　have revised drafts and read and approved the final manuscript.

412

416

417　**Competing interests statement**

418　The authors declare that they have no competing interests.

419

420　**Additional files**

421　Additional file 1: Checklist of PRISMA-P reporting standards

422　Additional file 2: Practitioner theories example search strategy

423　Additional file 3: Academic theories example search strategy

424

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1

PRISMA-P 2015 Checklist

What supports and constrains the implementation of multifactorial falls risk assessment and tailored multifactorial falls prevention interventions in acute hospitals? Protocol for a realist review (Randell et al.)

Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
ADMINISTRATIVE INFORMATION					
Title					
Identification	1a	Identify the report as a protocol of a systematic review	☒	☐	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	☐	☒	Not applicable
Registration	2	If registered, provide the name of the registry (e.g., PROSPERO) and registration number in the Abstract	☒	☐	70
Authors					
Contact	3a	Provide name, institutional affiliation, and e-mail address of all protocol authors; provide physical mailing address of corresponding author	☒	☐	5-28
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	☒	☐	399-403
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	☒	☐	360-361
Support					
Sources	5a	Indicate sources of financial or other support for the review	☒	☐	406-407
Sponsor	5b	Provide name for the review funder and/or sponsor	☒	☐	406-407
Role of sponsor/funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	☒	☐	394-396
INTRODUCTION					
Rationale	6	Describe the rationale for the review in the context of what is already known	☒	☐	96-156
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	☒	☐	157-161

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Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
METHODS					
Eligibility criteria	8	Specify the study characteristics (e.g., PICO, study design, setting, time frame) and report characteristics (e.g., years considered, language, publication status) to be used as criteria for eligibility for the review	☒	☐	229-260, 323-335
Information sources	9	Describe all intended information sources (e.g., electronic databases, contact with study authors, trial registers, or other grey literature sources) with planned dates of coverage	☒	☐	191-208, 298-320
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	☒	☐	Provided as additional files
STUDY RECORDS					
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	☒	☐	217-219, 264-265, 268-272, 344-346
Selection process	11b	State the process that will be used for selecting studies (e.g., two independent reviewers) through each phase of the review (i.e., screening, eligibility, and inclusion in meta-analysis)	☒	☐	222-224, 323
Data collection process	11c	Describe planned method of extracting data from reports (e.g., piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	☒	☐	264-269, 344-346
Data items	12	List and define all variables for which data will be sought (e.g., PICO items, funding sources), any pre-planned data assumptions and simplifications	☒	☐	264-267, 344-346
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	☒	☐	265-267, 344-346
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	☒	☐	339-344
DATA					
Synthesis	15a	Describe criteria under which study data will be quantitatively synthesized	☐	☒	Not appropriate for realist review
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data, and methods of combining data from studies, including any planned exploration of consistency (e.g., I^2, Kendall's tau)	☐	☒	Not appropriate for realist review

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Section/topic	#	Checklist item	Information reported		Line number(s)
			Yes	No	
	15c	Describe any proposed additional analyses (e.g., sensitivity or subgroup analyses, meta-regression)	☐	☒	Not appropriate for realist review
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	☒	☐	272-280, 355-358
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (e.g., publication bias across studies, selective reporting within studies)	☒	☐	347-352
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (e.g., GRADE)	☒	☐	362-377

What supports and constrains the implementation of multifactorial falls risk assessment and tailored multifactorial falls prevention interventions in acute hospitals? Protocol for a realist review (Randell et al.)

Additional file 2: Practitioner Theories Search Strategy Example

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to July 22, 2020>

1   Accidental Falls/ or exp Hip Fractures/pc (25502)
2   (fall or falls or faller*).tw,kw. (147405)
3   or/1-2 [falls] (155967)
4   Risk Assessment/ (265290)
5   risk assess*.tw,kw. (69279)
6   (fall* adj3 (assess* or screen* or prevent* or predict*)).tw,kw. (10727)
7   exp Accident Prevention/ (86820)
8   or/4-7 [assessment or prevention] (391878)
9   nursing time*.jn. (39139)
10   3 and 8 and 9 (26)
11   nursing standard.jn. (35276)
12   3 and 8 and 11 (33)
13   health service* journal.jn. (10933)
14   3 and 8 and 13 (3)
15   10 or 12 or 14 (62)

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What supports and constrains the implementation of multifactorial falls risk assessment and tailored multifactorial falls prevention interventions in acute hospitals? Protocol for a realist review (Randell et al.)

Additional file 3: Academic Theories Search Strategy Example

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 to July 21, 2020>

1   Accidental Falls/ or exp Hip Fractures/pc (25500)
2   (fall or falls or faller*).tw,kw. (147448)
3   or/1-2 [falls] (156010)
4   Risk Assessment/ (265251)
5   risk assess*.tw,kw. (69315)
6   (fall* adj3 (assess* or screen* or prevent* or predict*)).tw,kw. (10733)
7   exp Accident Prevention/ (86806)
8   or/4-7 [assessment or prevention] (391875)
9   Hospitalization/ (107412)
10   Subacute Care/ (1049)
11   Hospital Units/ (10146)
12   exp Hospitals/ (274581)
13   Rehabilitation Centers/ (8183)
14   Inpatients/ (21949)
15   ((acute or sub-acute or subacute) adj3 (care or ward?)).tw,kw. (31737)
16   ((rehabilitation or geriatric) adj (ward? or unit? or department?)).tw,kw. (6423)
17   inpatient?.tw,kw. (107879)
18   hospital*.tw,kw. (1294309)
19   or/9-18 [hospital] (1485504)
20   3 and 8 and 19 [Fall assmt & prevention in hospitals] (3313)
21   meta-analysis/ or "systematic review"/ (194072)
22   (Literature review* or (systematic adj2 review*) or (narrative adj2 review*) or (critical adj2 review*) or scoping review* or synthesis or meta-analys* or "meta analysis" or (realist adj2 review*)).ti. (551543)
23   ("Search filter*" or "search strateg*" or "literature search*").ab. (66610)
24   or/21-23 [Systematic reviews] (635237)
25   20 and 24 (139)