

Physical activity interventions for inpatients in secure mental health settings: what works, for whom, in what circumstances and why? A protocol for a realist synthesis.

KEEL, Toby, MACHACZEK, Katarzyna <<http://orcid.org/0000-0001-5308-2407>>, KING, James, BREEN, Kieran, STUBBS, Brendon and KINNAFICK, Florence

Available from Sheffield Hallam University Research Archive (SHURA) at:

<http://shura.shu.ac.uk/32428/>

This document is the author deposited version. You are advised to consult the publisher's version if you wish to cite from it.

Published version

KEEL, Toby, MACHACZEK, Katarzyna, KING, James, BREEN, Kieran, STUBBS, Brendon and KINNAFICK, Florence (2023). Physical activity interventions for inpatients in secure mental health settings: what works, for whom, in what circumstances and why? A protocol for a realist synthesis. *BMJ Open*, 13: e073453.

Copyright and re-use policy

See <http://shura.shu.ac.uk/information.html>

1 **Physical activity interventions for inpatients in secure mental health settings: what works, for**
2 **whom, in what circumstances and why? A protocol for a realist synthesis.**

3 **Corresponding Author**

4 Toby Keel

5 National centre for Sport and Exercise Medicine, School of Sport, Exercise and Health Sciences,
6 Loughborough University, Loughborough, United Kingdom; St Andrews Healthcare, United
7 Kingdom

8 J.T.Keel@lboro.ac.uk

9 +441509226364

10 Orcid: 0000-0003-1284-7447

11

12 **Authors**

13 Katarzyna Machaczek

14 Centre for Applied Health and Social Care Research (CARE), Sheffield Hallam University, UK

15 k.machaczek@shu.ac.uk

16 Orcid: 0000-0001-5308-2407

17

18 James S King

19 National centre for Sport and Exercise Medicine, School of Sport, Exercise and Health Sciences,
20 Loughborough University, Loughborough, United Kingdom

21 j.a.king@lboro.ac.uk

22 Orcid: 0000-0002-8174-9173

23

24 Kieran Breen

25 St Andrews Healthcare, United Kingdom

26 j.a.king@lboro.ac.uk

27 Orcid: 0000-0003-3974-4237

28

29 Brendon Stubbs

30 Department of Psychological Medicine, Institute of Psychiatry, Psychology and Neuroscience
31 (IoPPN), King's College London, London, UK

32 brendon.stubbs@kcl.ac.uk

33 Orcid: 0000-0001-7387-3791

34

35 Florence Kinnafick

36 f.e.kinnafick@lboro.ac.uk

37 National centre for Sport and Exercise Medicine, School of Sport, Exercise and Health Sciences,
38 Loughborough University, Loughborough, United Kingdom

39 Orcid: 0000-0002-3095-7116

40

41 Key Words: Severe Mental Ill Health, Physical Activity, Secure Inpatient Settings, Realist Synthesis,
42 Engagement.

43

44 Word Count: 3739

45

46

47

48

49

50

51

52

53

54

55

56

Abstract

57 **Introduction** - The physical health of individuals with severe mental ill health (SMI) is a cause for
58 concern. Whilst the purpose of inpatient mental health settings is rehabilitation and treatment, the
59 physical health of hospitalised patients commonly deteriorates. Physical activity (PA) has been
60 identified as an appropriate intervention to help improve the psychological and physical health of
61 inpatients. To address the gaps in the current literature by exploring how, why, for whom, and in what
62 contexts physical activity (PA) interventions help patients with Severe Mental Illness (SMI), who
63 receive inpatient treatment, to increase their PA engagement.

64 **Methods and Analysis** – Realist Synthesis. Six steps will be followed: 1) identification of the review
65 question and scope of the review; 2) searching for evidence; 3) screening and appraisal; 4) extraction
66 of data; 5) synthesis of the data; and 6) dissemination. Five databases will be searched: Web of Science,
67 PubMed, PsychInfo, PsychArticles and EmBase. 10 to 15 stakeholders made up of academics and
68 people living with SMI, sport and exercise therapists, psychiatrists, physiotherapists of low, medium
69 and highly secure inpatient settings, will form an expert advisory group. They will provide their insight
70 and knowledge of the secure setting contexts and perceived principles of how PA initiatives being
71 undertaken in their hospitals for patients with SMI work, or not. The results will be published in
72 accordance with the Realist And Meta-narrative Evidence Syntheses – Evolving Standards
73 (RAMESES) publication standards.

74 **Ethics and Dissemination** - Ethical approval has been granted. The review will produce context-
75 specific guidance for Clinical Commissioning Groups and practitioners on how to optimise the
76 provision of PA interventions for people with SMI in inpatient settings.

77

78

79

80

81 **Strengths and Limitation**

- 82 • The realist approach will facilitate a novel understanding of the conditions and caveats
83 required for the successful outcomes of PA interventions for inpatients in secure mental
84 health settings.
- 85 • The advantage of using realist synthesis is that it allows for the use of a wider variety of
86 evidence sources, both formal and informal, which might not have been included in a typical
87 systematic review.
- 88 • Since the synthesis is executed at the programme theory level (the mechanisms by which
89 interventions work), rather than focusing on the interventions themselves, this study will
90 facilitate an understanding of the conditions and caveats for successful outcomes in other
91 areas with similar programme theories, such as PA interventions for people with SMI in
92 community settings.
- 93 • A significant strength of the realist approach is the inclusion of key stakeholders, comprising
94 recipients of interventions, providers, subject experts and policymakers.
- 95 • However, studies published in languages other than English will be excluded due to resource
96 constraints.

97

98

99

100

101

102

103

104

105

106

107 **Introduction**

108 There is no consistent definition of SMI; however, diagnoses that are considered to come under this
109 umbrella term include schizophrenia, bipolar disorder and major depressive disorder (1). In the United
110 Kingdom, those with complex SMI are detained and referred through the Mental Health Act (1983)
111 and/or via the criminal justice system to be treated within secure psychiatric hospitals. These settings
112 encompass forensic services, psychiatric intensive care and acute inpatient wards (2). The security
113 levels can be categorised as follows (3):

- 114 • Low Secure – Patients whose escape from the hospital must be impeded because they present
115 a significant risk of harm to others.
- 116 • Medium Secure – Patients whose escape from hospital should be prevented because they
117 present a serious risk of harm to others.
- 118 • High secure – Those who should not be able to escape from the hospital because they present
119 an immediate and grave danger to the public and cannot be managed in lower levels of
120 security.

121 The purpose of these services is to assess, treat and rehabilitate patients in secure and safe residential
122 environments (4,5).

123 The physical health of people with SMI is a cause for concern within mental health care (6)
124 with patient inactivity and poor physical health exacerbated in secure settings (5,7). The aetiology of
125 these physical health disparities is multifactorial (8). These include contextual barriers (social,
126 environmental and institutional), such as obesogenic cultures on the wards (9) that, for instance, can
127 take the form of unrestricted access to highly calorific foods (10); patients' limited autonomy and their
128 opinion of the wards as 'prisons' (2); inconsistent staff attitudes towards and a lack of prioritisation of
129 exercise (2,11); modifiable lifestyle factors (such as smoking, poor diet, sedentary behaviour and low
130 levels of PA); and the iatrogenic effects of psychotropic medication (for example, weight gain and
131 increased hunger) (12). To address these physical health disparities, consideration of the socio-

132 ecological complexities of the social context, staffing and lived experiences of the patients, is critical
133 in the design and implementation of interventions for the treatment and recovery of SMI inpatients.

134 Physical Activity (PA) is defined as “any bodily movement produced by skeletal muscles that
135 requires energy expenditure (13). It includes all forms of activity, such as playing active games, work-
136 related activities, everyday walking, gardening, competitive sports and others (14). PA is recommended
137 by the European Psychiatric Association (15) and the Lancet Psychiatry Commission (8) with a
138 significant body of literature highlighting the importance of PA to improve the physiological and
139 psychological health of people with SMI (16). However, the majority of research on SMI PA
140 interventions has been conducted on outpatients or short-term inpatients (6). Therefore, there are
141 numerous unanswered questions concerning the use of such interventions in psychiatric secure care (5).

142 PA inpatient interventions that have been conducted in secure settings are diverse in terms of
143 study design, the sub-clinical populations that are included and resultant increases in PA levels.
144 Findings from a small number of relevant PA studies illustrate that interventions that have utilised
145 psychological and behavioural theories (5) have been largely successful in terms of increasing PA levels
146 in people with SMI in inpatient settings. Similarly, motivational theory-based interventions have been
147 effective in increasing PA levels among inpatients with SMI (17).

148 Despite the knowledge that PA improves the health of all people, the low levels of PA, high
149 levels of sedentary behaviour and worsening physical health of patients with SMI who are receiving
150 psychiatric care in secure settings remain major concerns. It remains unknown how, for whom, why
151 and in what circumstances interventions for people with SMI that are delivered in secure psychiatric
152 care settings work to increase their engagement in PA. This understanding must be gained if PA
153 interventions in secure inpatient settings are to deliver the expected benefits.

154 A realist synthesis is the appropriate methodology to be used to fill the gaps in the literature
155 and to understand complex interventions, such as those that are designed to increase engagement in PA
156 among people with SMI in secure inpatient settings. It can be used to explore the mechanisms of action
157 within interventions and to provide a list of caveats and conditions under which they operate, and for

158 whom, to achieve the desired outcomes. Our choice of this methodology is in part a reflection of the
159 importance of accounting not only for outcomes but also for the contexts of complex health
160 interventions.

161 Hence, the findings from this synthesis will help to refine the designs and implementations of
162 effective interventions that address both individual (e.g. participant age, sex, illness, medication) and
163 contextual factors (e.g. social context, environment, institutional policy). They will also be available
164 for providers to optimise current provision through the identification of conditions and caveats that
165 should be considered to achieve successful outcomes.

166 *Research question, aim and objectives*

167 Research question: How, for whom, in what circumstances and why can interventions that are delivered
168 in secure inpatient settings increase engagement in physical activity among people with SMI?

169 Aim: To utilise a realist synthesis to develop guidance to be used in the design of inpatient interventions
170 to increase engagement in PA among people with SMI.

171 Objectives:

172 The synthesis will be conducted through the performance of several steps.

- 173 1. Stakeholder consultations and literature will be used to define the scope of the synthesis and to
174 elicit initial programme theories for how interventions that are delivered in secure inpatient
175 settings might work to increase engagement in PA among people with SMI
- 176 2. Initial programme theories (IPTs) will be tested against empirical evidence.
- 177 3. The programme theories will be synthesised, tested and refined.
- 178 4. Mid-range theories will be found and articulated.
- 179 5. Actionable recommendations will be developed for policymakers, commissioners and
180 providers.

181

182 **Methods**

183 *Realist Synthesis*

184 Realist synthesis is an iterative process that involves the identification, testing and refinement of
185 initial programme theories to produce modified and consolidated theories, using a wide range of
186 evidence (18). It involves consulting pertinent materials/evidence such as policy documents, grey
187 literature, think pieces, editorials, etc. (a wider variety of sources, both formal and informal, than
188 those typically used in a systematic review), and stakeholders, including the recipients of
189 interventions, providers and policymakers (19).

190 At the heart of the realist synthesis is the context-mechanism-outcome (CMO) configuration and the
191 unit of analysis is the programme theory rather than the interventions themselves (18). The primary
192 objective is to explain how the mechanisms of actions within interventions operate or fail to operate,
193 and to explore contexts in which they operate that lead to desired or undesired outcomes (20).

194 Mechanisms can be classified as resource or response mechanisms:

- 195 • Resource mechanisms are the resources offered by the social programme (21); for example,
196 educational classes on the benefits of PA, or access to the gym.
- 197 • Reasoned response mechanisms are human responses to the resources offered by the
198 intervention (21).

199 Contexts are made up of a variety of psychological, organisational, economic, and technical
200 relationships, also known as micro, meso and macro forces, which influence each other (22). These
201 ‘backdrop’ conditions trigger, shape, and modify the ways in which mechanisms present themselves
202 to bring about particular outcomes (23). The consideration and exploration of contextual factors are
203 integral, as low levels of PA in this population are a product of a complex system (24). The above
204 definition of contexts befits the socio-ecological framework that this synthesis will follow (Table 1).

205

206

Table 1.

Contexts

Level	Socio-ecological framework	Examples
Micro	Individual	<ul style="list-style-type: none">• Diagnosis• PA history• Age• Severity of symptoms
	Relationships	<ul style="list-style-type: none">• Therapeutic relationships• Staff• Peers
Meso	Socio-environmental	<ul style="list-style-type: none">• Physical environment – access to outdoor / exercise space• Ward culture• Resources• Access to healthy lifestyle choices e.g. food, movement, activities
	Institution and policies	<ul style="list-style-type: none">• Policies• Funding• Leadership
Macro		

207

208 *Philosophical underpinning*

209 The realist approach aims to explore causal effects, the processes underpinning change, and the
210 impact of social contexts (25). Within a realist research paradigm, reality is stratified into three
211 overlapping layers – the empirical (the observable), actual (happening below the surface) and real (the
212 unobservable entities or structures that when the right context is correct, activate causal mechanisms)
213 (20,26). Realist approaches emphasise the need to go beyond the empirical and to theorise about what
214 is happening in the different layers of reality.

215 In realist research, it is considered that, as social reality is processed in our brains, language, and
216 culture, it cannot be directly measured, but it can be indirectly interpreted (27). The development of

217 knowledge and a new theoretical position occurs through the use of processes such as observation,
218 induction, deduction and abduction. Realist enquiry therefore utilises:

- 219 • abductive logic – creative and educated inferences about the underlying causal
220 mechanisms that are drawn from an examination of the evidence and research
221 (28); and
- 222 • retroductive logic –the theorising that is necessary to understand and develop a
223 way of ‘testing’ whether or not these mechanisms exist and if so, how and why
224 they work (20,28).

225 Overall, to understand complex PA behavioural interventions in secure settings, we will
226 hypothesise, test and explain the underlying causal forces and mechanisms that make PA
227 interventions for patients with SMI work in inpatient contexts.

228 *Patient and Public Involvement*

229 No patient involved.

230 *The six stages of this realist synthesis*

231 This synthesis will follow six stages of a realist synthesis through the use of guidance outlined by
232 Hunter et al (20). The conduct of realist synthesis is an iterative process; therefore, the steps explained
233 below may be revisited. The synthesis will start in January 2023 and end approximately in April 2024.

234 *Step 1 – determining the scope of the study & identifying initial programme theories*

235 The purpose of step 1 is to scope, become familiar with and map out: i) the content of interventions,
236 ii) the context(s) of their use, iii) the policy objectives, and iv) the type/form of outcomes/impacts;
237 through informal searches of the relevant evidence (29). Mapping will be undertaken in collaboration
238 with stakeholders.

239

240

241 Search strategy (step 1)

242 We will search and review key index papers to identify exemplar PA interventions that have been
243 delivered for inpatients with SMI. This stage will also include ‘CLUSTER searching’ (30), which will
244 enable us to identify associated studies that provide insights into the conceptual and contextual
245 richness of the key interventions described in the index papers (30). We will also undertake forward
246 and backward citation searching and contact authors about contextually-linked papers (‘sibling
247 studies’) and discuss with stakeholders about additional sources of data ^{29 (p151),30 p134}. We will also
248 search kinship papers, which are those papers that have a common theoretical underpinning with
249 index studies (31).

250 Types of evidence: we will include reviews, blogs, conceptual papers, social media and professional
251 journals (32). Grey literature will also be searched (32). This will include: relevant government
252 departments and agency websites; websites of non-profit organisations; academic institute websites;
253 trial registries; and abstracts, conferences, theses and dissertations.

254 The search results will be screened. The selection of evidence to inform the development of IPTs will
255 be based on its rigour and relevance (20). The method of development of IPTs is explained in a later
256 section.

257 Synthesis

258 Data will be synthesised to produce the IPTs, which will be laid out in the form of context, resource
259 and response mechanisms, and outcomes configurations (CMOs) (20). In these configurations,
260 ‘context’ describes the conditions under which the intervention is delivered (“causative factors which
261 fall outside of the parameters of the interventions”) (33), ‘mechanism’ elucidates how the intervention
262 is supposed to work (“causative factors attributable to the intervention”) (33), and ‘outcome’
263 describes the anticipated outcomes of the intervention.

264

265

266 Stakeholder consultations

267 A key feature of a realist synthesis is the involvement and consultation of key stakeholders (34). To
268 ensure the inclusion of multiple perspectives of UK SMI inpatient contexts, stakeholders will form an
269 expert advisory group (EAG) that will provide specialist advice throughout the synthesis. The EAG
270 will be made up of academics and people living with SMI, sport and exercise therapists, psychiatrists,
271 physiotherapists of low, medium and highly secure inpatient settings. Ten to fifteen stakeholders will
272 be recruited for the EAG through stratified purposive sampling.

273 During step 1, the stakeholders will provide their insight into what might constitute a programme
274 theory (20), and knowledge of the secure setting contexts and perceived principles of how PA
275 initiatives being undertaken in their hospitals for patients with SMI work, or not. They will also
276 signpost the study team towards the grey literature, which will include policy, strategic plans and
277 other relevant information. Throughout the process, stakeholders will be consulted via informal
278 meetings, focus-group discussions, emails and visits to inpatient settings. As this is an iterative
279 process, there could be more consultations. These steps will be published for transparency.

280 Development of IPTs

281 After initial consultations with stakeholders and familiarisation with the literature, IPTs will be
282 developed through the use of abductive and retroductive reasoning. The IPTs will be inferred
283 frameworks based on the most likely and plausible explanations for engagement in PA interventions
284 in inpatient settings. Pre-existing and established theories, known as substantive theories, will be used
285 to inform this process. Substantive theories which are likely to be of relevance to this synthesis
286 include:

- 287 • Health psychology, including behaviour change theories: the capability, opportunity,
288 motivation, behavioural framework for behaviour change (35); the affective-reflective theory
289 of physical inactivity and exercise (36); and the self-determination theory (37).
- 290 • Sociological theories such as unintended consequences of social action (38)
- 291 • Implementation theories (39)

292 The building of the IPTs will be an iterative process whereby the researcher will go through many
293 cycles of adapting and changing the CMOs as the researcher deepens their understanding of the
294 intervention research, following stakeholder conversations and literature mapping (20,40).

295 CMO adaptations and cycles will be recorded on an Excel spreadsheet. After each edit and CMO
296 adaptation, a new tab will be created so that all edits are logged and recorded.

297 *Steps 2 and 3 – search for primary studies, and screening and appraisal*

298 In step 2, the hypothesised IPT will be tested against empirical studies.

299 We will use the context and implementation of complex interventions (CIMO) framework to identify
300 empirical studies from different subsets of literature against which the IPTs should be tested. This
301 framework has been selected as it has been proposed to be the closest match to realist synthesis
302 terminology and questions (31,41).

303 Search strategy (step 2)

304 Table 2 below shows the draft search strategy/broad patterns of search since the search strategy in realist
305 synthesis is iterative and ongoing throughout the project (42). The searches, therefore, will be revisited
306 at predetermined stages.

307

308

309

310

311

312

313

314

315 **Table 2.**

316 *CIMO Search Strategy*

Context	Intervention / Resource Mechanism	Response Mechanism	Outcome
(Severe mental illness* OR forensic) AND (inpatient* OR secure service*)	(access* OR therapeutic relationship* OR leadership OR patient cent* OR intervention* OR fitness OR walk* OR aerobic exercise* OR aerobic training OR resistance training OR sport* OR yoga OR swim*)	(motivation OR psychological theor* OR enjoyment OR barrier* OR determinant* OR self-efficacy OR behaviour change OR evaluation OR feasib* OR affect* OR mastery OR autonom*)	(Physical Activit* OR exercis* OR sedentary behavio* OR engagement OR adherence)

317 *Note.* Each CIMO column is connected with AND.

318

319

320

321

322

323

324

325

326

Table 3.*Inclusion and Exclusion Criteria*

Criteria	Description
Inclusion	
Context (C)	Studies conducted within secure settings (low, medium and highly secure mental health services). However, if studies outside secure services have potential relevance to the CMOs, they will be included.
Intervention (I)	Any form of PA intervention, e.g., structured exercise sessions, yoga, walking, gardening, or review of such.
Mechanism (M)	The mechanisms will be formed based on step 1. They will include key substantive psychological theories and key terms, e.g. motivation, autonomy, and enjoyment.
Outcome (O)	Increased engagement in physical activity, increased levels of physical activity, reduction in the amount of time in sedentary behaviours. Where PA is measured, validated measures will be eligible for inclusion. These are based on either data from devices (e.g., pedometers, accelerometers, or inclinometers) or data from questionnaires (i.e., self-report data). Included qualitative outputs will discuss experiences of PA (e.g., barriers and facilitators).
Study design	No restriction will be applied regarding study design; all studies, including systematic and scoping reviews, will be included. This is because clinical recommendations and inferences may be drawn from the reviews.
Exclusion	
Population	Studies on non-adult populations, because different environmental and therapeutic approaches are taken in adolescent inpatient contexts compared with those of adults (42).
Publication date	Studies published before 2007, because the Mental Health Act was amended in that year and changes were made to treatments, diagnoses of certain illnesses, and patient safeguarding rules (43).
Language	Studies not written in English or with a translation.

327

328 Inclusion and exclusion criteria are shown in Table 3

329 Search sources: five key databases: Web of Science, PubMed, PsychInfo, PsychArticles and EmBase.

330 These were chosen due to their use in reviews of a similar nature (5,43). Covidence software will be

331 used to record the steps and remove duplicates. Based on the inclusion and exclusion criteria, a search

332 strategy has been developed with an experienced librarian.

333 The primary reviewer will screen the titles and abstracts initially for inclusion or exclusion in
334 accordance with their ‘relevance’ to the IPTs. Relevance will be determined according to whether or
335 not they develop, refute, refine, or endorse the IPTs (19). If deemed relevant, the full texts will be
336 reviewed. Due to the iterative nature of the synthesis and the potential changes to programme
337 theories, no paper will be fully discarded but will be held in reserve, as it may become useful at a later
338 stage (20,34). In addition to the systematic search, papers will be added in by the researcher during
339 the use of search techniques such as forward and backward citation searches and hand searches.

340 Grey literature will be integrated into the review process. Grey literature is defined as “a range of
341 documents not controlled by commercial publishing organisations” (44). It may include a variety of
342 documents ranging from government and NHS policy statements, unpublished studies, reviews from
343 within organisations, blogs such as those produced by charity organisations, the content of key
344 websites such as that of the World Health Organisation, and conferences. These documents will be
345 found through the use of hand searches through search engines (such as Google scholar) or they will
346 have been signposted by stakeholders or colleagues. The inclusion of grey literature will be
347 determined according to its relevance to the IPTs.

348 These steps may be revisited and updated throughout the research process and will be recorded and
349 published transparently in accordance with the RAMESES II reporting standards (18). The literature
350 search will be presented as a flow chart of study selection according to the preferred reporting items
351 for systematic reviews and meta-analyses system.

352 All included citations and grey literature will be screened and appraised in terms of its rigour. This is
353 to judge whether the data collection methods used in each publication are scientifically robust and
354 therefore, whether the publication can be included. Rigour will be determined through consideration
355 of the points highlighted by Hunter et al (20):

356 “Is a piece of literature good enough to be included? Were the methods used to generate the data
357 credible, plausible, and trustworthy?”

358 However, if the information is useful from a study that is deemed to show poor rigour, due to its
359 relevance and insight into the programme theories, the study may be included (45).

360 *Step 4 – data extraction*

361 A data extraction spreadsheet will be created, in which the descriptive details and characteristics of
362 each identified study will be elicited. These details include the study aims, design, methods used,
363 participants, and setting. The data extraction sheet also will record the key information regarding the
364 CIMOs of the studies and the IPTs they refine, support or refute. The details of the context,
365 mechanisms or psychological theory may not be explicitly stated, yet they can be inferred abductively
366 by the researcher. For example, self-selected exercise intensity and positive feelings of effect can be
367 inferred to be part of the psychological theory of affective and reflective theory of inactivity.

368 The data analysis process will be revisited and, if necessary, refined, throughout the synthesis. The
369 results of this process will be presented as a flow diagram (27).

370 *Step 5 – synthesis of the data*

371 The synthesis stage aims to test and refine the IPTs and hypothetical CMO configurations that the
372 researcher proposes as useful to show how, why, and in what circumstances, PA interventions are
373 successful at increasing PA levels of patients with SMI.

374 To find patterns across the data spreadsheet, the researcher will be guided by five synthesis
375 techniques, as outlined by Hunter et al (20) and explained below.

- 376 • Juxtaposition of sources of evidence – “where evidence about implementation in one source
377 enables insights into evidence about outcomes in another source” (46)
- 378 • Reconciliation of sources of evidence – developing possible reasons why differences in
379 outcomes occur despite similar contexts.
- 380 • Adjudication of sources of evidence – methodological strengths and weaknesses of sources of
381 evidence.

- 382 • Consolidation of sources of evidence – when studies provide similar or the same causal
383 evidence about mechanisms and outcomes.
- 384 • Situating – the development of possible explanations as to why differences occur within the
385 evidence.

386 The data will be synthesised and incorporated into the CMOs and discussed with the research team
387 and the EAG to further test programme theories. Stakeholder knowledge and experience will be
388 combined with the research and grey literature evidence to gain real-world insight to bridge the gap
389 between research and professional practice. By doing this, we aim to provide novel insight into the
390 contexts and mechanisms that underpin PA interventions that are delivered in inpatient mental health
391 settings.

392 As an outcome, a revised and refined model, of the most salient CMO configurations, will be
393 presented as ‘middle-range theories’ that provide transferable insight and lessons to other clinical
394 populations, contexts and interventions with comparable programme theories (27).

395 **Ethics and Dissemination**

396 Ethical approval was granted by the Loughborough University Research Ethics Committee (2021-
397 6220-5431). All stakeholders’ identities were anonymised, and data stored on password protected
398 university computers.

399 The results of this synthesis, which will follow the Realist And Meta-narrative Evidence Syntheses:
400 Evolving Standards quality and publication standards (27), will be submitted to a peer-reviewed
401 journal. Key stakeholders will receive a short summary of the findings. Also, the results will be
402 presented at conferences and in blog posts, using the National Centre for Sport and Exercise Medicine
403 platform and social media sources.

404 **Anticipated Impact**

405 The synthesis will produce context-specific guidance for Clinical Commissioning Groups, NHS
406 practitioners on how to optimise the provision of PA interventions for people with SMI in inpatient

407 settings. The findings will enable effective tailoring of PA interventions in different types of setting
408 (context) and for different groups and individuals. They will improve the provision of interventions as
409 well as patient experience and outcomes.

410

411 Patient consent for publication: Not required

412 Correspondence concerning the article should be addressed to Toby Keel, National Centre of Sport
413 and Exercise Medicine, School of Sport, Exercise and Health Sciences, Loughborough University,
414 United Kingdom. Email: J.T.Keel@lboro.ac.uk

415 **Author contributions**

416 Author TK wrote the first draft of the manuscript. Authors KM, JK, KB and FK reviewed the first
417 draft of the paper and provided critical revisions, KM significantly contributed to methodology, and
418 authors (TK, KM, JK, KB, BS, FK) contributed to the final manuscript.

419 **Competing Interests**

420 None declared.

421 **Funding**

422 This research received no specific grant from any funding agency in the public, commercial or not-
423 for-profit sectors.

424

425

426

427

428

429

- 431 1. Vancampfort D, Firth J, Schuch FB, Rosenbaum S, Mugisha J, Hallgren M, et al. Sedentary
432 behavior and physical activity levels in people with schizophrenia, bipolar disorder and major
433 depressive disorder: a global systematic review and meta-analysis. *World Psychiatry*.
434 2017;16(3):308–15.
- 435 2. Rogers E, Papathomas A, Kinnafick FE. Inpatient perspectives on physical activity in a secure
436 mental health setting. *Psychol Sport Exerc* [Internet]. 2021;52(April 2020):101827. Available
437 from: <https://doi.org/10.1016/j.psychsport.2020.101827>
- 438 3. National Health Service (NHS) England. Adult High Secure Services - Service Specification
439 [Internet]. 2021. Available from: [https://www.england.nhs.uk/wp-](https://www.england.nhs.uk/wp-content/uploads/2021/02/service-specification-high-secure-mental-health-services-adult.pdf)
440 [content/uploads/2021/02/service-specification-high-secure-mental-health-services-adult.pdf](https://www.england.nhs.uk/wp-content/uploads/2021/02/service-specification-high-secure-mental-health-services-adult.pdf)
- 441 4. Galappathie N, Khan ST, Hussain A. Civil and forensic patients in secure psychiatric settings:
442 A comparison. *BJPsych Bull*. 2017;41(3):156–9.
- 443 5. Rogers E, Kinnafick FE, Papathomas A. Physical activity in secure settings: A scoping review
444 of methods, theory and practise. *Ment Health Phys Act* [Internet]. 2019;16(September
445 2018):80–95. Available from: <https://doi.org/10.1016/j.mhpa.2018.11.004>
- 446 6. Deenik J, Tenback DE, Tak ECPM, Rutters F, Hendriksen IJM, van Harten PN. Changes in
447 physical and psychiatric health after a multidisciplinary lifestyle enhancing treatment for
448 inpatients with severe mental illness: The MULTI study I. *Schizophr Res* [Internet].
449 2019;204:360–7. Available from: <https://doi.org/10.1016/j.schres.2018.07.033>
- 450 7. Lawrence D, Kisely S. Inequalities in healthcare provision for people with severe mental
451 illness. *J Psychopharmacol*. 2010;24(4 Suppl):61–8.
- 452 8. Firth J, Siddiqi N, Koyanagi A, Siskind D, Rosenbaum S, Galletly C, et al. The Lancet
453 Psychiatry Commission: a blueprint for protecting physical health in people with mental
454 illness. *The Lancet Psychiatry*. 2019;6(8):675–712.

- 455 9. Faulkner GE, Gorczynski P, Cohn T. Psychiatric illness and obesity: recognizing the"
456 obesogenic" nature of an inpatient psychiatric setting. *Psychiatr Serv.* 2009;60(4):538–41.
- 457 10. Long CG, Brillon AM, Schell D, Webster P. The nutrition and eating habits of women in
458 secure psychiatric conditions: A survey with implications for practice and action. *Br J Forensic*
459 *Pract.* 2009;11(3):28–34.
- 460 11. Stanton R, Happell B, Reaburn P. Investigating the exercise-prescription practices of nurses
461 working in inpatient mental health settings. *Int J Ment Health Nurs.* 2015;24(2):112–20.
- 462 12. Public Health England. Severe mental illness (SMI) and physical health inequalities: briefing
463 [Internet]. 2018. Available from: [https://www.gov.uk/government/publications/severe-mental-](https://www.gov.uk/government/publications/severe-mental-illness-smi-physical-health-inequalities/severe-mental-illness-and-physical-health-inequalities-briefing)
464 [illness-smi-physical-health-inequalities/severe-mental-illness-and-physical-health-inequalities-](https://www.gov.uk/government/publications/severe-mental-illness-smi-physical-health-inequalities/severe-mental-illness-and-physical-health-inequalities-briefing)
465 [briefing](https://www.gov.uk/government/publications/severe-mental-illness-smi-physical-health-inequalities/severe-mental-illness-and-physical-health-inequalities-briefing)
- 466 13. Organization WH. WHO guidelines: Management of physical health conditions in adults with
467 severe mental disorders [Internet]. Who. 2018. 34–37 p. Available from:
468 [https://www.who.int/mental_health/evidence/guidelines_severe_mental_disorders_web_note_](https://www.who.int/mental_health/evidence/guidelines_severe_mental_disorders_web_note_2018/en/%0Ahttp://apps.who.int/iris/bitstream/handle/10665/275718/9789241550383-eng.pdf)
469 [2018/en/%0Ahttp://apps.who.int/iris/bitstream/handle/10665/275718/9789241550383-eng.pdf](https://www.who.int/mental_health/evidence/guidelines_severe_mental_disorders_web_note_2018/en/%0Ahttp://apps.who.int/iris/bitstream/handle/10665/275718/9789241550383-eng.pdf)
- 470 14. Department of Health. Stay Active, Stay Active [Internet]. 2011. Available from:
471 https://sportengland-production-files.s3.eu-west-2.amazonaws.com/s3fs-public/dh_128210.pdf
- 472 15. Stubbs B, Vancampfort D, Hallgren M, Firth J, Veronese N, Solmi M, et al. EPA guidance on
473 physical activity as a treatment for severe mental illness: a meta-review of the evidence and
474 Position Statement from the European Psychiatric Association (EPA), supported by the
475 International Organization of Physical Therapists in Mental . *Eur Psychiatry.* 2018;54:124–44.
- 476 16. Mckeon, G., Curtis, J., & Rosenbaum S. Promoting physical activity for mental health: An
477 updated evidence review and practical guide. *Curr Opin Psychiatry.* 2022;35(4):270–6.
- 478 17. Romain AJ, Bernard P, Akrass Z, St-Amour S, Lachance JP, Hains-Monfette G, et al.
479 Motivational theory-based interventions on health of people with several mental illness: A

- 480 systematic review and meta-analysis. *Schizophr Res* [Internet]. 2020;222:31–41. Available
481 from: <https://doi.org/10.1016/j.schres.2020.05.049>
- 482 18. Wong G, Westthorp G, Manzano A, Greenhalgh J, Jagosh J, Greenhalgh T. RAMESES II
483 reporting standards for realist evaluations. *BMC Med* [Internet]. 2016;14(1):1–18. Available
484 from: <http://dx.doi.org/10.1186/s12916-016-0643-1>
- 485 19. Wong G. Data gathering in realist reviews: Looking for needles in haystacks. Sage; 2018.
486 131–145 p.
- 487 20. Hunter R, Gorely T, Beattie M, Harris K, Hunter R, Gorely T, et al. Realist review. *Int Rev*
488 *Sport Exerc Psychol* [Internet]. 2022;0(0):1–24. Available from:
489 <https://doi.org/10.1080/1750984X.2021.1969674>
- 490 21. Pawson R, Tilley N. *Realist Evaluation*. Sage; 2007.
- 491 22. Greenhalgh J, Manzano A. Understanding ‘context’ in realist evaluation and synthesis. *Int J*
492 *Soc Res Methodol* [Internet]. 2022;25(5):583–95. Available from:
493 <https://doi.org/10.1080/13645579.2021.1918484>
- 494 23. Jagosh J, Macaulay A, Pluye P, Salsberg J, Bush P, Henderson J, et al. Uncovering the benefits
495 of participatory research: implications of a realist review for health research and practice.
496 *Milbank Q* [Internet]. 2012;90(2):311–46. Available from:
497 <http://www.ncbi.nlm.nih.gov/pubmed/19120978>
498 <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=PMC2690371>
- 499 24. Machaczek KK, Quirk H, Firth J, Carney R, Copeland RJ, Pollard N, et al. A whole systems
500 approach to integrating physical activity to aid mental health recovery – Translating theory
501 into practice. *Ment Health Phys Act* [Internet]. 2022;23(June):100480. Available from:
502 <https://doi.org/10.1016/j.mhpa.2022.100480>
- 503 25. Blackwood B, O’Halloran P, Porter S. On the problems of mixing RCTs with qualitative
504 research: The case of the MRC framework for the evaluation of complex healthcare

- 505 interventions. *J Res Nurs*. 2010;15(6):511–21.
- 506 26. Haigh F, Kemp L, Bazeley P, Haigh N. Developing a critical realist informed framework to
507 explain how the human rights and social determinants of health relationship works. *BMC*
508 *Public Health*. 2019;19(1):1–12.
- 509 27. Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication
510 standards: Meta-narrative reviews. *J Adv Nurs*. 2013;69(5):987–1004.
- 511 28. Jagosh J. Retroductive theorizing in Pawson and Tilley’s applied scientific realism. *J Crit*
512 *Realis* [Internet]. 2020;19(2):121–30. Available from:
513 <https://doi.org/10.1080/14767430.2020.1723301>
- 514 29. Pawson R. *Evidence-based Policy: A realist perspective*. a. Sage; 2006.
- 515 30. Booth A, Harris J, Croot E, Springett J, Campbell F, Wilkins E. Towards a methodology for
516 cluster searching to provide conceptual and contextual “richness” for systematic reviews of
517 complex interventions: Case study (CLUSTER). *BMC Med Res Methodol*. 2013;13(1):1–14.
- 518 31. Tsang A, Maden M. CLUSTER searching approach to inform evidence syntheses: A
519 methodological review. *Res Synth Methods*. 2021;12(5):576–89.
- 520 32. Booth A, Wright, J, Briscoe S. Scoping and searching to support realist approaches. In: *Doing*
521 *Realist Research*. Sage; 2018. p. 147–66.
- 522 33. Jagosh J. The ‘Context + Mechanism’ Association: a Key Heuristic in Realist Evaluation for
523 *Innovating Complex Programmes and Policy*. In: CECAN [Internet]. CECAN; 2017.
524 Available from: [https://www.cecan.ac.uk/events/the-contextmechanism-association-mastering-](https://www.cecan.ac.uk/events/the-contextmechanism-association-mastering-a-key-heuristic-in-realist-evaluation-for-innovating-complex-programmes-and-policy-2/)
525 [a-key-heuristic-in-realist-evaluation-for-innovating-complex-programmes-and-policy-2/](https://www.cecan.ac.uk/events/the-contextmechanism-association-mastering-a-key-heuristic-in-realist-evaluation-for-innovating-complex-programmes-and-policy-2/)
- 526 34. Rycroft-Malone J, McCormack B, Hutchinson AM, DeCorby K, Bucknall TK, Kent B, et al.
527 *Realist synthesis: illustrating the method for implementation research*. *Implement Sci*.
528 2012;7(1):1–10.

- 529 35. Michie, Stralen MM van, West R. The COM-B Model of Behaviour. *Soc Chang UK*. 2019;7.
- 530 36. Brand R, Ekkekakis P. Affective–Reflective Theory of physical inactivity and exercise:
531 Foundations and preliminary evidence. *Ger J Exerc Sport Res*. 2018;48(1):48–58.
- 532 37. Ryan R. M., Deci E. L. Overview of Self-Determination Theory: An Organismic Dialectical
533 Perspective. *Handb Self-Determination Res*. 2002;3–33.
- 534 38. Merton RK. The Unanticipated Consequences of Purposive Social Action Author (s): Robert
535 K . Merton Source : *American Sociological Review* , Vol . 1 , No . 6 (Dec . , 1936), pp . 894-
536 904 Published by : American Sociological Association Stable URL : <http://www.jstor.org>. *Am*
537 *Sociol Rev*. 1936;1(6):894–904.
- 538 39. Ridde V, Pérez D, Robert E. Using implementation science theories and frameworks in global
539 health. *BMJ Glob Heal*. 2020;5(4):1–8.
- 540 40. Wong G, Greenhalgh T, Westhorp G, Pawson R. Development of methodological guidance,
541 publication standards and training materials for realist and meta-narrative reviews: the
542 RAMESES (Realist And Meta-narrative Evidence Syntheses – Evolving Standards) project.
543 *Heal Serv Deliv Res [Internet]*. 2014;2(30):1–252. Available from:
544 <http://dx.doi.org/10.3310/hsdr02300>
- 545 41. Booth A, Briscoe S, Wright JM. The “realist search”: A systematic scoping review of current
546 practice and reporting. *Res Synth Methods*. 2020;11(1):14–35.
- 547 42. Jackson L, Langille L, Lyons R, Hughes J, Martin D, Winstanley V. Does moving from a
548 high-poverty to lower-poverty neighborhood improve mental health? A realist review of
549 “Moving to Opportunity.” *Heal Place [Internet]*. 2009;15(4):961–70. Available from:
550 <http://dx.doi.org/10.1016/j.healthplace.2009.03.003>
- 551 43. Anthony J, Kinnafick FE, Papatomas A, Breen K. Physical activity for adolescents with
552 severe mental illness: a systematic scoping review. *Int Rev Sport Exerc Psychol [Internet]*.
553 2020;0(0):1–34. Available from: <https://doi.org/10.1080/1750984X.2020.1833360>

- 554 44. Adams J, Hillier-Brown FC, Moore HJ, Lake AA, Araujo-Soares V, White M, et al. Searching
555 and synthesising “grey literature” and “grey information” in public health: Critical reflections
556 on three case studies. *Syst Rev* [Internet]. 2016;5(1):1–11. Available from:
557 <http://dx.doi.org/10.1186/s13643-016-0337-y>
- 558 45. Pawson R. Digging for nuggets: How “bad” research can yield “good” evidence. *Int J Soc Res*
559 *Methodol Theory Pract.* 2006;9(2):127–42.
- 560 46. Husk K, Blockley K, Lovell R, Bethel A, Bloomfield D, Warber S, et al. What approaches to
561 social prescribing work, for whom, and in what circumstances? A protocol for a realist review.
562 *Syst Rev* [Internet]. 2016;5(1):1–7. Available from: [http://dx.doi.org/10.1186/s13643-016-](http://dx.doi.org/10.1186/s13643-016-0269-6)
563 [0269-6](http://dx.doi.org/10.1186/s13643-016-0269-6)
- 564
- 565