

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.

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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.

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Abstract

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

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

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

Strengths and Limitation

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

Introduction

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

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

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

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

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

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

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

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

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

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

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

Research question, aim and objectives

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

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

Objectives:

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

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

Methods

Realist Synthesis

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

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

Mechanisms can be classified as resource or response mechanisms:

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

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

Table 1.*Contexts*

Level	Socio-ecological framework	Examples
Micro	Individual	• Diagnosis
		• PA history
		• Age
		• Severity of symptoms
Meso	Relationships	• Therapeutic relationships
		• Staff
		• Peers
	Socio-environmental	• Physical environment – access to outdoor / exercise space
		• Ward culture
		• Resources
Macro	Institution and policies	• Access to healthy lifestyle choices e.g. food, movement, activities
		• Policies
		• Funding
		• Leadership

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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

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

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

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

Patient and Public Involvement

No patient involved.

The six stages of this realist synthesis

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

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

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

Search strategy (step 1)

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

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

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

Synthesis

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

Stakeholder consultations

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

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

Development of IPTs

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

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

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

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

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

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

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

Search strategy (step 2)

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

Table 2.

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 behavior* OR engagement OR adherence)

Note. Each CIMO column is connected with AND.

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.

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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.

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

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

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

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

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

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

Step 4 – data extraction

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

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

Step 5 – synthesis of the data

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

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

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

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

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

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

Ethics and Dissemination

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

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

Anticipated Impact

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

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

Patient consent for publication: Not required

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Author contributions

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

Competing Interests

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