Title: Establishing components of programmes to reduce restrictive practices: an evidence synthesis

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Abstract

Background: Incidents involving violence and aggression are a frequent occurrence in adult mental health inpatient settings. They are managed by use of restrictive interventions such as restraint, seclusion, injection of sedating drugs and constant observation. Use of these interventions carries significant risks, including physical and psychological harms to both patients and staff. Interventions are costly in terms of staff sickness and litigation as well as extra staffing resources required to implement them. As such, numerous staff training programmes have been developed to try to reduce the use of restrictive interventions. These seek to modify practice using a variety of behaviour change techniques (BCTs). Although some programmes have been evaluated, research into their effectiveness is hampered by a lack of attention to their specific components. Over recent years the MRC has supported work to develop a taxonomy of BCTs to standardise and improve the reporting of such non-pharmacological interventions. It provides a common language with which to specify the content and mechanisms by which behaviour is changed.

Aim and objectives: The aim of this study is to identify effective components of programmes that seek to reduce restrictive interventions in adult mental health inpatient settings using the BCT taxonomy.

The study objectives are to:

i) Provide an overview of programmes aimed at reducing restrictive interventions.

ii) Classify components of those programmes implemented in adult mental health inpatient settings in terms of behaviour change techniques and determine their frequency of use.

iii) Explore the evidence of effectiveness by examining behaviour change techniques and programme outcomes.

iv) Identify and prioritise behaviour change techniques showing most promise of effectiveness and that require testing in future high quality evaluations and that require testing in future high quality evaluations.

Design: An evidence synthesis of published and unpublished literature, including detailed coding of programme content using the BCT Taxonomy.

Data review:

i) Identify all manualised programmes. Data will be extracted about the characteristics of each programme including participants, setting, programme type, costs, outcome measures, fidelity, acceptability, recommendations and quality (Objective i).

ii) The content of programmes will be extracted to allow their components to be coded using the BCT taxonomy (Objective ii).

iii) Programmes that have been coded for BCTs will have information about their outcomes extracted in order to relate this back to these components (Objectives iii & iv).

Analysis: We will analyse the evidence to produce a synthesis of:

i) Overview of programme characteristics (Objective i).

ii) Programme content components in relation to behaviour change techniques, both type and frequency (Objective ii).

iii) Description of programme outcomes where BCTs have been identified and comparison of outcomes between programmes that contain a BCT or type of BCT with those that don't contain them to examine the efficacy of specific techniques or clusters thereof (Objective iii).

iv) Acceptability (Objective i).

v) Recommendations for future trials (Objective iv).

Impact: The study will generate the first synthesis of the evidence on the content and effectiveness of programmes to reduce restrictive interventions. This new knowledge will inform NHS managers' decision making about staff training, highlight gaps in the evidence and enable NIHR to commission further specific research in this area. We intend to use the findings to inform the development and testing of different models to reduce restrictive interventions.

1. Background and Rationale

Events that threaten patient and staff safety, such as violence, aggression and self harm, are not uncommon in mental health inpatient settings(1). The Royal College of Psychiatrists survey of violence in inpatient mental health settings in 2007 found violence and aggression to be commonplace, experienced by approximately three quarters of all staff and one third of patients(2). Although no large scale UK prevalence studies have been conducted since 2007, the problem is likely to have worsened, with tightening of resources coinciding with increased demand for services(3). A recent review commissioned by the Royal College of Psychiatrists into the provision of acute inpatient psychiatric care for adults found that, in many areas, staff are *'trapped in a constant process of crisis management'* (p13)(3). The costs of such prevalent violence are significant, with the NHS, as of 2010, spending £60.5 million pounds on violence-related sickness and litigation payments to staff alone(4). Use of containment measures to manage risk of violence such as seclusion, physical restraint and constant observations are also associated with substantial costs (estimated by NICE at £20.5 million per year for damage and injury, £88 million per year for observations, £6.1 million for restraint)(5). Evidence based interventions to reduce violence and the measures used to contain it, therefore, clearly have the potential to result in significant cost savings for the NHS.

Staff responses to these incidents frequently involve the use of practices which physically contain or restrict the patient and can cause serious and even lethal harm(6) as well as adverse psychological effects(7). This study will use the Department of Health definition of restrictive interventions: *'deliberate acts on the part of other person(s) that restrict an individual's movement, liberty and/or freedom to act independently in order to: take immediate control of a dangerous situation where there is a real possibility of harm to the person or others if no action is undertaken'* (4). This study will focus on the most coercive forms of such restrictive interventions: restraint (manual or mechanical holding of the patient); seclusion (isolating the patient in a locked room); coerced intramuscular injection of sedating drugs; and constant observation (patient within eyesight or arm's reach of one or more supervising nurses at all times).

Restrictive interventions are widely used internationally(8) although reliable prevalence data can be hard to find and are influenced by discrepancies in definition and recording methods(9). Cultural differences mean that across countries some forms of restrictive intervention are more acceptable than others. For example, mechanical restraint is a feature of US acute treatment but its use is forbidden in UK acute settings(10). Despite such differences, there is an emerging international consensus that restrictive interventions are used too frequently(11). They can result in unintended injury to patients and staff(12), and; there is a particular risk of positional asphyxia associated with face down restraint(12). There are substantial costs associated with staff sickness(4) and resource intensive observation of patients(13). Restrictive interventions can also have a profoundly detrimental effect on therapeutic relationships between staff and patients(14).

Restrictive interventions began to attract attention following deaths that occurred during their use(15), and this increased further when the abuse of patients at Winterbourne View hospital was documented in 2011. The government policy response to Winterbourne View(16) stipulated that all services need protocols in place to minimise the use of restrictive interventions, but ensure that when they become necessary they are used in a safe and ethical way. NHS mental health services provide training to inpatient staff on the prevention and management of violence. This training may be provided in-house or from private providers but there are no detailed guidelines on what this training should consist of or who should accredit the courses available(10). An additional tier of local quality improvement interventions has followed, involving a range of often idiosyncratic approaches that lack empirical support for their effectiveness. There is an urgent need to disentangle these overlapping policies and practices to ensure delivery of the highest standard of evidence based care.

Concerted efforts have been made over the past 20 years in the US, Australia and Europe to reduce the use of restrictive interventions with varying degrees of success. In the UK, initiatives to reduce restrictive interventions such as *Safewards*, *6 Core Strategies* and *No Force First* have been promoted and adopted by some Mental Health Trusts, some of which have been evaluated and reported in the literature(17,18). These have typically aimed to reduce violent and aggressive behaviour through changing staff behaviour to encourage use of de-escalation techniques, supported by various policy and procedural changes. Although some of these programmes have been the subject of systematic reviews in relation to their outcomes(17), their specific content has not been examined in detail and the mechanisms through which they might change behaviour are not fully understood. Furthermore, it is not known to what extent those programmes that have shown reductions in the use of restrictive interventions (or other outcomes such as increased staff confidence) have features in common.

The development of future programmes to reduce restrictive interventions is hampered by these limitations. This review is an essential first step to further intervention development. Its unique contribution to the evidence will be to identify the specific components of programmes and their relation to outcomes. This will identify the most promising programme components and permit them to be tested within a trial setting. It will lead to interventions which are better defined, more acceptable to patients and staff, more completely implemented and more cost effective.

1.1 Quality of the evidence

There have been numerous complex programmes developed and tested to promote the reduction of restrictive interventions in mental health wards although it remains unclear which components of these programmes have contributed to their effectiveness.

A Cochrane review of containment strategies for people with mental illness (19) concluded that *'current non-pharmacological approaches to violent behaviour are not supported by evidence from controlled studies'* meaning that the evidence base for current clinical practice is weak. There has been a relatively recent intensification of research in this area with *6 Core Strategies* and *Safewards* trials representing two prominent examples. The *Safewards* initiative showed a reduction in *'containment'* and *'conflict'* events in the intervention group(17) and demonstrate that innovative evidence based interventions can reduce violence and containment usage in settings that contend with the resource limitations characteristic of UK acute services. This initiative categorises violence, absconding, self harm, rule breaking and medication refusal as *'conflict'* and restraint, seclusion and sedation as *'containment'*.

A trial of the *6 Core Strategies* programme(18) demonstrated a reduction in *'restraint-seclusion and observation days'* although no differences in terms of violence.

Observational studies, although generally considered low quality, have reported the reduction of restrictive interventions and violent behaviours after the delivery of programmes(20–22) whereas others have reported no effect(23). Another study showed some evidence in favour of restraint training over de-escalation training(24). Programmes have tended to focus on a single restrictive intervention. However, it is important to examine these practices collectively because they are often used together or in sequence(25), for example, a patient may be restrained and given coerced intra-muscular medication before being placed in seclusion(26,27). There is some evidence reporting broader outcomes to suggest that staff gain in confidence and knowledge (1,28).

The existing restrictive interventions literature repeatedly calls for guidance to be based on robust transparent studies(29,30) and for programmes to be better described and better evaluated. Livingston and colleagues(20) reviewed training programmes to reduce restrictive interventions and highlighted the difficulty of reaching conclusions owing to the programmes evaluated comprising:

'different types of aggression management programs, which contain a variety of approaches. The focus, curriculum, and duration of the training vary substantially from one program to another.'(p. 24)(20). The recent NICE guideline on violence and aggression calls for research to be carried out into the content and nature of effective de-escalation techniques used and the most effective and efficient ways of training professionals in their use. The guideline goes on to say that research is needed to *'systematically describe current techniques for de-escalation'*(10).

The reporting of non-pharmacologic trials has historically struggled to accurately describe programmes, with a recent review finding that only 39% of programmes were *'adequately'* described when published(31). This does not necessarily mean that programmes are not described, but that there is no common language with which to describe their components (32,33). In response to this lack of consensus, the Medical Research Council (MRC) supported the development of a taxonomy of behaviour change techniques (BCTs) that can be used both prospectively in the design of programmes and retrospectively when applied to completed programmes(34). This taxonomy enables the robust synthesis of evidence that has previously been problematic to unpick and compare. It has been designed for use across all theory based programmes aimed at both patients and professionals(35). A BCT is defined as *'an observable, replicable, and irreducible component of a programme designed to alter or redirect causal processes that regulate behaviour'*. It provides a reliable method of precisely specifying components of programmes in a transparent manner using an established language. This promotes more accurate reporting and replication(36) as well as more successful implementation with proven effectiveness(35). This taxonomy is now being widely used internationally to report programmes(37), synthesise evidence(38,39) including reanalysing existing programmes to explore their components(40). It is influencing the design of programmes(41) in particular as it can lead to the identification of BCTs potentially associated with effectiveness (35).

All programmes to reduce restrictive practices use behaviour change techniques. For example, role playing verbal de-escalation strategies could be coded as *'rehearsal of relevant skills'* involving *'social comparison', 'monitoring of emotional consequences'* and*' feedback on behaviour'.* An expert delivering information about risks of restraint could involve *'information about health consequences'* delivered by a *'credible source'.* No existing reviews have looked at both the outcomes and components of programmes that aim to reduce restrictive interventions. This study will examine which behaviour change techniques are present in existing programmes and in particular, which are present in programmes reporting to reduce restrictive interventions on wards. This study will make recommendations for which BCTs should be tested for effectiveness within future programmes to reduce restrictive interventions. The research team will seek future funding to develop and test an intervention based on the results of the review. Greater understanding of the most active components and modes of action of programmes that seek to reduce violence and containment use have the potential to generate knowledge that could be used to enhance their effectiveness, resulting in greater cost savings for the NHS.

2. Aims and objectives

2.1 Aim

The aim of this study is to identify, standardise and report the effectiveness of components of programmes that seek to reduce restrictive interventions adult mental health inpatient settings.

2.2 Objectives

The study objectives are to:

2.2.1. Provide an overview of programmes aimed at reducing restrictive interventions

2.2.2. Classify components of those programmes in terms of behaviour change techniques and determine their frequency of use.

2.2.3. Explore the evidence of effectiveness by examining behaviour change techniques and programme outcomes.

2.2.4. Identify and prioritise behaviour change techniques showing most promise of effectiveness and that require testing in future high quality evaluations.

3. Research Plan

We propose to carry out an evidence synthesis of published and unpublished literature. We will adhere to accepted guidelines produced by the Centre for Reviews and Dissemination(39) and the Cochrane Collaboration(44) and will follow PRISMA guidelines(45). We will register the review protocol with PROSPERO.

The review will have five stages.

i) To perform an environmental scan to identify programmes to reduce restrictive interventions (Objective 2.2.1). Environmental scanning methods were developed to identify broader information about an area than that retrievable solely from published literature. In health care settings they have been used to inform future planning, evidence of current practice and to raise awareness of an issue(45). They can take a *'passive'* approach where existing data, both published and unpublished are collected and analysed, or the *'active'* approach where additional knowledge is generated through primary data collection(45). This study will use passive environmental scanning methods to collect descriptive or evaluative information available about programmes that aim to reduce restrictive interventions.

ii) To synthesise the features of programmes (Objective 2.2.1) reporting the context of how programmes are delivered. For example, being delivered to groups or individuals; the person delivering the programme; the setting, timing and frequency of the programmes (33). These will be recorded using Tidier(31), a 12 item checklist that prompts detailed recording of programmes based on the questions *'why, what, who, how, where, when and how much?'* It serves as an extension to both CONSORT and SPIRIT(31). Where available, fidelity and acceptability data will also be reported.

iii) Where possible, to extract the content of the programmes using the BCT Taxonomy (Objective 2.2.2) All materials available for each programme (for example, manuals, evaluation reports) will be coded, by trained coders, using the BCT Taxonomy a reliable method for extracting data regarding the content of programmes (35). This will identify the individual BCTs detected in each programme and their frequency of use.

iv) To extract outcomes of coded programmes and relate them to BCT content (Objective 2.2.3). When a programme has been coded for BCTs any outcome data will then be extracted.

v) Analysis of potential relationships between reduction of restrictive interventions and BCTs will be carried out with the aim of generate hypotheses for future testing and to develop potential causal models for future trials (Objective 2.2.4).

3.1 Health technologies being assessed

Multi-faceted programmes aimed at mental health care professionals to reduce restrictive interventions in adult mental health inpatient settings.

3.2 Design and theoretical/conceptual framework

The study is an evidence review. A programme will be any manualised, multi-faceted, theory based approach that seeks to reduce the use of restrictive interventions through behaviour change techniques.

3.3 Target population and setting

Care staff working in adult mental health inpatient settings (including acute, forensic and PICU services).

3.4 Inclusion/Exclusion Criteria

3.4.1 Inclusion criteria

Population: Care staff working in adult mental health inpatient settings (including acute, forensic and PICU services).

Dated between: 1999-2015

Programmes: Manualised programmes aimed at changing the behaviour of inpatient adult mental health service staff to reduce restrictive interventions.

3.4.2 Exclusion criteria

Evaluations of pharmacological or environment modification programmes without any behaviour change component.

Non English language programmes.

3.5 Search strategy

Research literature, policy and grey literature including training manuals will be identified using comprehensive search strategies developed in collaboration with the Information Specialist. Evaluative and descriptive studies of manualised programmes to reduce restrictive interventions will be sought from databases including MEDLINE; CINAHL; BNI; EMBASE; PsycInfo. Training manuals, policies, guidance and other grey literature will be sought from NHS Evidence, Google search (limited to nhs.uk domain), ProQuest Dissertations and Abstracts, voluntary organisation websites (e.g. MIND, Rethink, Mental Health Foundation) and professional bodies (e.g. Royal College of Psychiatrists). Search terms will be identified by the Information Specialist in collaboration with the

project team, and from consulting the known literature and database thesauri (e.g. MeSH). Searches will include the concepts '*restrictive interventions'* and *'mental health inpatients'* and will be limited to publications since 1999 (the introduction of National Service Framework for Mental Health). Scoping searches based on a draft MEDLINE search (Appendix 1) indicate 15,000 – 20,000 records will be found. The scoping search guides our plans for searching and screening, and provides an initial *'draft'* search. This draft search will go through several iterations before a *'final'* search is conducted. The reviewers will screen some sample search results and feedback the relevancy of the studies. Search strategies will be adapted with the aim of producing fewer and more relevant results without missing relevant studies. Additional studies will be identified via bibliographies of reviews and retrieved articles, targeted author searches and forward citation searching. The project management group will be asked for details of any known programmes and authors of current and recently completed research projects will be contacted directly.

3.6 Review Strategy

All potentially eligible records will be stored and managed in reference management software (Endnote(46)). Two reviewers will screen titles and abstracts for potential relevance in accordance with the inclusion criteria. When both reviewers agree to exclude, the reason for exclusion will be recorded. Where there is disagreement, full text articles will be reviewed and any unresolved disagreement will be subject to third party review. Where there is agreement between the two reviewers on inclusion, the full text article will be retrieved and be independently assessed against the inclusion criteria by the two reviewers and again, any disagreement subject to third party review

3.7 Data extraction

Data extraction will follow a three stage process:

i) Identify all manualised programmes. Data extraction will be governed by a pro forma that will allow systematic collection of data relating to the programmes. Data will be extracted about the characteristics of each programme including participants, setting, programme type, outcome measures, fidelity, acceptability, recommendations and quality. Where information is forthcoming, we will describe the associated costs in terms of training materials, delivery and staff time.

ii) The content of programmes will be extracted to allow their components to be coded using the BCT taxonomy. The MRC BCT Taxonomy consists of 93 items, each one an individual behaviour change technique. e.g. *'social comparison'* or *'problem solving'*. Individual BCTs are also grouped into clusters, e.g. *'Goals and planning'*. The taxonomy provides examples of these items, often related to patient behaviour, although recent studies have provided examples of healthcare professionals behaviour to inform studies such as this that seek to code healthcare professional behaviours(42). Using the taxonomy and supporting examples, researchers will independently code the selected interventions. (Researchers will be fully trained in the application of the taxonomy, training in identifying and coding BCTs is provided by an online, free, interactive, self-directed course.) Coding will be done by importing all intervention materials (published papers, manuals, powerpoint slides, handbooks) into NVivo (a flexible qualitative software package that facilitates the coding of multimedia materials for analysis. Each of the 93 items of the BCT taxonomy will be turned into a code in NVivo and be considered for each intervention, the codes will be applied where there is evidence of the BCT being used. E.g. Where a professional is delivered information about the potentially harmful effects of restraint during a training session, this will be coded as *'BCT 5.1 Information about health consequences'*. Any assumptions made by the coder will be recorded, also within NVivo, in order that discrepancies can be discussed.

Once the coding is complete NVivo will be used to generate individual study reports which will reveal discrepancies between coders. Each discrepancy will be discussed and resolved by the coders, if necessary further discussion will take place with other expert members of the team to achieve resolution. This discussion will consist of the coder explaining their reasoning as to why they have assigned the code. Formal agreement kappa statistics will also be used to measure consensus.

The individual study reports will be compiled to produce a summary of how many of the possible 93 BCTs are found in interventions, how often they occur and whether they are from particular clusters. Study outcome data will be extracted and this used to explore whether there are potential relationships between study outcomes and particular BCTs.

iii) Programmes that have been coded for BCT components will have information about their outcomes extracted in order to examine the efficacy of these techniques.

Extraction will be carried out by two reviewers and any discrepancies will be subject to third party review.

3.8 Quality

Study quality will be assessed based on the Cochrane Collaboration Risk of Bias Assessment Tool for RCTs(43), or the Cochrane guidance for non-randomised designs(47). The quality of qualitative evidence will be assessed using the CASP tool(48). Quality appraisals will not be used to exclude papers but to inform the synthesis.

3.9 Data Synthesis

We will analyse the research evidence to produce a synthesis of:

i) Overview of programme characteristics.

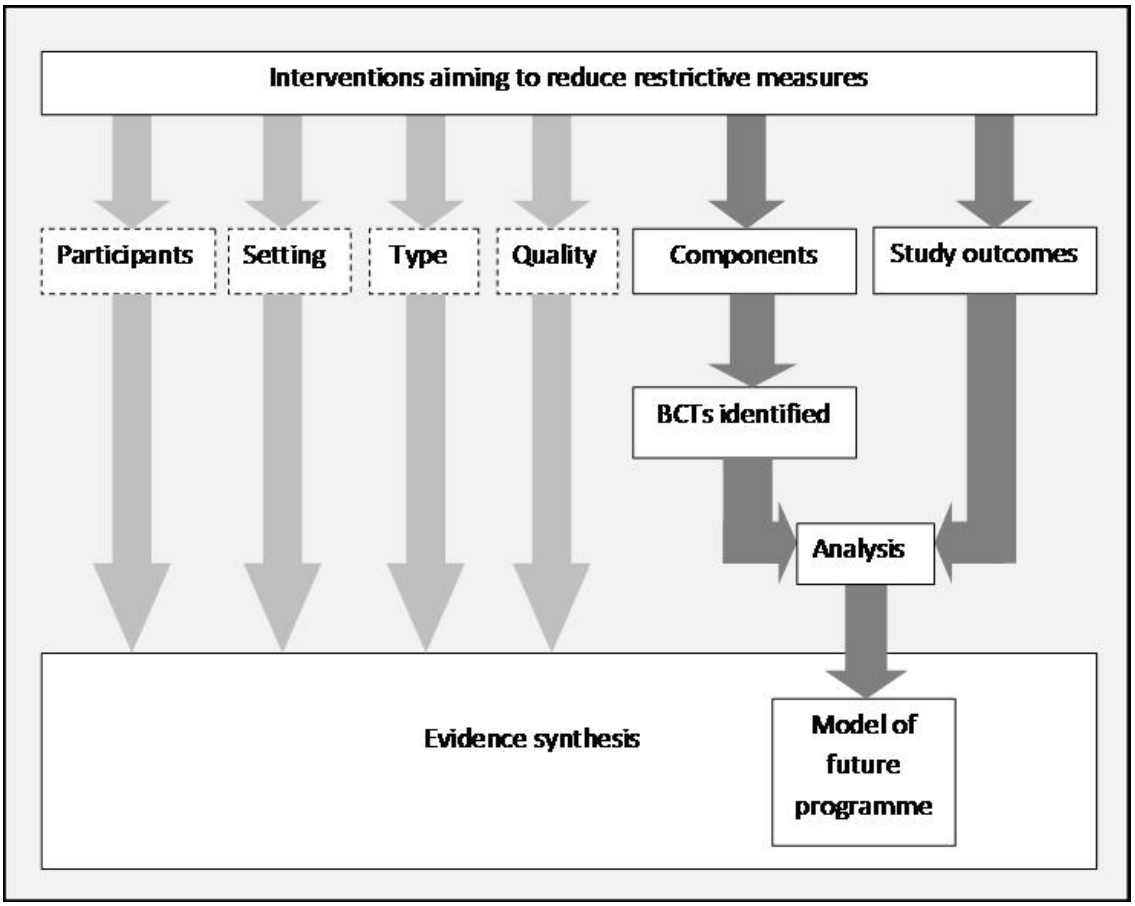
ii) Programme content components in relation to behaviour change techniques, both type and frequency.

iii) Comparisons of outcomes between trials that contain a specific BCT and those that do not.

iv) Acceptability (synthesised using methods for qualitative and mixed method evidence(49))

v) Recommendations for future trials.

Figure 1. Overview of evidence synthesis



Programmes will be placed in subgroups depending on the type of restrictive intervention they seek to reduce: clinical, physical, and seclusion. A narrative synthesis across and within each subgroup will be carried out exploring the features of the programmes including their theoretical basis, population, outcomes and conclusions. The content of the types of programme will be described in terms of the types and frequency of behaviour change techniques that can be identified, e.g. social support, skills practice, modelling (See Table 1). The outcome data from the programmes will be presented in relation to the BCTs present and hypotheses posed as to whether specific types of behaviour change techniques appear more frequently in studies reporting certain outcomes.

Table 1. Examples of BCTs known to be present in programmes to reduce restrictive interventions

Type of Behaviour change Technique	**Example of how this BCT has been used in a model reducing restrictive interventions**
Rehearsal of relevant skills	Role playing de-escalation techniques (NHS Conflict and Restraint training)
Health consequences	Information given about the potential risks of asphyxiation or cardiac events during restraint (*6 Core Strategies* (18))
Restructuring of physical environment	Displaying posters in staff office (*Safewards*(17))

4. Dissemination and projected outputs

4.1 Dissemination

Our team has considerable skills in the area of dissemination. We will use a number of known effective mechanisms for the dissemination of findings(50–52). Representatives of our Lived Experience Advisory group will be well placed to advise study members on the most suitable ways of disseminating new knowledge. Dissemination activities will occur at local, regional, national and international levels, via professional, service user and carer organisations, in health, social care and third sector services in a range of modalities.

Our dissemination plan describes how we will use conferences, reports, and journals to disseminate findings to service users, carers, mental health professionals, CLAHRCs and commissioners across our networks and beyond. We will consider the use of other dissemination methods, for example, video interviews hosted on our website and the use of visual infographics. Dissemination will be carried out alongside the research, we will use our University webpages to keep a blog on the project, link to a project twitter feed and retain legacy pages after it is completed. We will ensure that we produce a report suitable for circulation to NHS managers, commissioners and policy makers to inform decision making about future training. Our planned strategy for impact will be designed with advice from our Lived Experience Advisory Group, University of Leeds Faculty of Medicine and Health Research and Innovation service and in line with ESRC Pathways to Impact toolkit (37). We will ensure this strategy development process consultation process involves external stakeholders, particularly NHS managers and commissioners.

We will use effective mechanisms for the dissemination (33–35) and are skilled as a team to do this with all co-applicants having active national and international networks. We will disseminate via professional, service user and carer organisations, in health, social care and third sector services in a range of modalities.

4.1.1 Conferences

We will present our results at local, national and international conferences (e.g. Network for Psychiatric Nursing Research, Horatio (European Psychiatric Nursing), Violence in Clinical Psychiatry and International Violence in the Health Sector). We will devise and host a one day conference of stakeholders to disseminate our findings.

4.1.2 Reports

Our final NIHR report will be disseminated. We will devise audio/video summaries of our key findings and circulate these via a purpose build website and social media. We will use Twitter (host tweet chat with @weMHNurses/@mentalelf), YouTube, Facebook and lay summaries written by the Lived Experience Advisory Group to broaden our audiences/dissemination.

4.1.3 Journals

A publications strategy will be developed for user/carer focussed publications, professional psychiatry/mental health nursing journals e.g. British Journal of Psychiatry. We have included costs for open access publication. We will also target sector trade press such as Mental Health Today, Open Mind and Nursing Times.

4.1.4 Network dissemination

We will promote knowledge transfer across the NHS and partner organisations e.g. Kendall is National Director for Mental Health at NHS Improvement, NHS England, National Co-ordinating Centre for Mental Health and Royal College of Psychiatry. Baker and Duxbury (past chair) via Mental Health Nurse Academics UK, Restraint Reduction Network (a network of 148 education, health and social care services and training organisations) - Duxbury current chair. Thomas is the leading policy advisor at the DH supported this application. Our team and Lived Experience Advisory Group will devise lay, audio/video summaries and disseminate through their service user/carer networks.

4.2 Outputs and impact

The proposed study will generate the first synthesis of the evidence on the content and effectiveness of interventions to reduce restrictive interventions. This will be disseminated through an HTA report, journal articles, service user, carer and professional networks as well as social media. It will identify future research priorities for interventions to reduce restrictive interventions in a UK NHS context. This new knowledge will inform NHS managers' decision making about staff training and highlight gaps in the evidence and will enable NIHR to commission further specific research in this area. Our intentions are to use the findings to inform the development and testing of different models to reduce restrictive interventions. Our strategy for impact will be designed with advice from our Lived Experience Advisory Group, University of Leeds Faculty of Medicine and Health Research and Innovation service and in line with ESRC Pathways to Impact toolkit(54).

5. Study timetable

Month	
1 (Jan 18)	Project set up, Protocol development Initial meeting of Lived Experience Advisory Group 1/3 Initial full Project Management Meeting 1/3 Research Management Group Meeting (set up) 1/18
2 (Feb 18)	Refine search strategies and conduct searches. Researcher train as BCT coder Research Management Group Meeting (focus on search results) 2/18
3 (Mar 18)	Study selection and retrieval. Supplementary materials requests Research Management Group Meeting (focus on final study selection) 3/18
4 (Apr 18)	Study selection and retrieval. Data extraction, BCT coding Ongoing supplementary materials requests Research Management Group Meeting (focus on final study selection) 4/18
5 (May 18)	Ongoing supplementary materials requests. Data extraction, BCT coding Research Management Group Meeting (focus on coding) 5/18
6 (Jun 18)	Ongoing supplementary materials requests. Data extraction, BCT coding Research Management Group Meeting (focus on coding) 6/18
7 (Jul 18)	Data extraction, BCT coding Research Management Group Meeting (focus on coding) 7/18
8 (Aug 18)	Data extraction, BCT coding Research Management Group Meeting (focus on coding) 8/18
9 (Sep 18)	Data extraction, BCT coding Research Management Group Meeting (preparation for full management and Lived Experience Advisory Group meetings) 9/18 Second meeting of Lived Experience Advisory Group 2/3 Full Management Group Meeting 2/3
10 (Oct 18)	Data extraction, BCT coding Research Management Group Meeting (planning synthesis and analysis) 10/18
11 (Nov 18)	Data synthesis and analysis Research Management Group Meeting (update on synthesis and analysis) 11/18
12 (Dec 18)	Data synthesis and analysis. Research Management Group Meeting (update on synthesis and analysis) 12/18
13 (Jan 19)	Data synthesis and analysis. Research Management Group Meeting (update on synthesis and analysis) 13/18
14 (Feb 19)	Data synthesis and analysis. Research Management Group Meeting (planning report drafting) 14/18
15 (Mar 19)	Report drafting, search updates Research Management Group Meeting (review report, plan dissemination activities) 15/18
16 (Apr 19)	Research Management Group Meeting (preparation for full management and Lived Experience Advisory Group meetings) 16/18 Third meeting of Lived Experience Advisory Group 3/3 Full Management Group Meeting 3/3
17 (May 19)	Report drafting Research Management Group Meeting (review report, dissemination activities) 17/18
18 (Jun 19)	Submission of report, preparation of publications, dissemination activities. Research Management Group Meeting (review report, dissemination activities) 18/18

The design of the study means that coding can begin on retrieved studies and materials as soon as they are accessed and the process of retrieval of other materials continue concurrently. We already

have some of these materials in our possession as members of the research team have been involved directly in a number of these projects, for example, *6 Core Strategies, Safewards*, so work can begin on coding them immediately in Month 4.

6. Project management

The team have significant experience in the successful management and timely delivery of research projects. Project management will be undertaken by PI (Baker) who will have a 20% commitment to the study. The project management strategy consists of regular monitoring of the study, primarily through a monthly Research Management Group Meeting attended by all personnel who are involved at that particular stage of the study but with the PI, CA Berzins and the Research Associate always in attendance. We will use standing agenda items, including a Project Risk Register, to assess the progress of all aspects of the project and ensure that if difficulties are foreseen we can address them as early as possible. In addition to our monthly Research Management Group Meeting we will have three full Project Management Meetings during the course of the project. These meetings will involve all co-applicants and also include service user representatives. These will take place at the beginning, halfway through (when analysis will be commencing) and towards the end (in preparation for final dissemination). These meetings will review the progress of the project to date and the future plans. The Lived Experience Advisory Group will meet three times and be consulted on all stages of the study from the key questions to be answered and the range of outcomes to be examined, the findings of the developing analysis and the subsequent dissemination.

The University of Leeds will act as study sponsor. This study will be conducted in compliance with the study protocol, Good Clinical Practice guidelines and University regulatory and monitoring requirements.

7. Patient and public involvement

Service users and carers are integral to this management of this study including co-applicant representation. We have engaged with service users in the development of this application via social media in the form of twitter discussions with leading service users and careers in the area. We have discussed our ideas with the Positive and Safe Champions network, and the Restraint Reduction Network both of which include service user and carer representatives. Co-applicant Fiona Edgar is a service user research at UCLAN who has provided considerable expert by experience input. She will provide an important perspective on the interventions we are coding and the evidence we synthesise. She will participate in and contribute to the Project Management Meetings and monthly Research Management Group Meetings when work she is directly involved in is on the agenda. This will be at the beginning of the study and later as findings begin to emerge. In terms of dissemination she will contribute to the project blog and social media based dissemination through her networks. She will contribute to the writing of journal articles and other written dissemination material. She will advise on the dissemination targeted at service users and professionals and lead on the writing of lay summaries. She will participate in the presentation of findings in person by speaking at conferences or other meetings.

A Lived Experience Advisory Group of around eight people will be established and populated from established groups at the University of Leeds, LYPFT, and from a forthcoming group that will recruit service users with an interest in patient safety. This group will be chaired by a Fiona Edgar who will act as the conduit between the Lived Experience Advisory Group and the Project Management Meetings and the monthly Research Management Group meetings. Members of the group will be paid for their participation following Involve guidelines. The group will meet three times and be consulted on all stages of the study from initial protocol through to the dissemination of findings.

We will consult on the key questions to be answered by the research and the range of outcomes to be examined. Later in the study the group will assist in the presentation of the review for lay audiences.

PI Baker's previous PPI work has been cited by NICE, MHRN and Involve (55–57)as exemplars of good practice and he has previously held a senior leadership role in the Faculty of Medical and Human Science, University of Manchester developing Public Involvement and Engagement strategy for both research and teaching and learning.

8. Expertise and justification of support required

The research team is well qualified to deliver the proposed research. Members have significant clinical and methodological expertise. We have a national and international reputation for our work with mental health services and in the reduction of restrictive measures. We are involved in or have completed externally funded primary research into interventions for serious mental illness. We have successfully undertaken and published externally funded systematic reviews and have prior experience of applying the MRC BCT Taxonomy to complex interventions.

BAKER (PI) specialises in reducing coercive practices in acute mental health care. He is collaborating on SPICES (HS&DR: 11/1024/02) with STEWART, and *'ResTRAIN yourself'* with DUXBURY (PI),and EDGAR. He has both clinical and methodological expertise to manage this project.

BERZINS has expertise on the MRC BCT Taxonomy. She is an experienced mental health researcher and project manager and has experience of a range of methods including systematic reviews.

DUXBURY's research focuses on staff and patient perspectives on aggression and relational experiences in inpatient services. She is Chair of the European Research Group on Violence in Psychiatry and the Restraint Reduction Network in the UK. She co-wrote the DH on minimising restrictive practices in 2014 and was a member of the NICE guidelines Group on Violence 2015.

EDGAR is a service user researcher based at UCLAN. She has lived experience of coercive interventions, and has been involved in numerous research projects on this topic

KELLAR IK has a track record in designing and undertaking systematic reviews that examine behaviour change interventions and techniques in a variety of contexts. He is an expert panel member for the MRC Behaviour Change Technique Taxonomy project. He has subsequently undertaken a series of systematic reviews that utilise the BCT taxonomy.

KENDALL is a highly regarded Consultant Psychiatrist, he has led the development of more than 30 NICE guidelines on mental health, and has recently been appointed the National Clinical Director for Mental Health.

STEWART has published several reviews of restrictive practices which are widely cited, including in the current NICE guideline on violence and aggression. He is an author of the SAFEWARDS trial.

WRIGHT is an Information Specialist with expertise in mental health systematic reviews e.g.Cochrane Schizophrenia group reviews (2002-2007), Peer Interventions in Prisons (HS&DR: 10/2002/13)(58), plus methods expertise(59).

9. Carbon reduction

This study has taken the NIHR Carbon Reduction Guidelines into consideration. As a literature review it involves little travel. Study personnel have the technology to facilitate remote working so unnecessary journeys to University offices are avoided and teleconferencing will be used for meetings wherever possible. We will ensure that our findings are rapidly and appropriately disseminated.

10. Declaration of interest

None.

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