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Short-Term PsychoEducation for Carers to Help Reduce the Over Medication of People with Intellectual Disabilities Programme Development Project (SPECTROM PDP): A Feasibility Randomized Controlled Trial Protocol

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ABSTRACT

Background: We coproduced SPECTROM (Short-term Psycho-Education for Carers To Help Reduce the OverMedication of people with intellectual disabilities) (https://spectrom.wixsite.com/project) training for support staff (direct care workers) to help reduce the overmedication of people with intellectual disabilities, particularly the off-license use of psychotropics for behaviors that challenge in the absence of psychiatric disorders, which is a major public health concern. We hope that providing the support staff with the knowledge/skills about psychotropic medicines and non-pharmacological alternatives to address behaviors that challenge in people with intellectual disabilities through SPECTROM training will reduce staff demands for psychotropic medicines to address behaviors that challenge and improve their confidence to ask the prescribers to reduce or stop unnecessary off-license prescribing when appropriate. This should indirectly lead to the reduction of overmedication of people with intellectual disabilities. In this paper, we presented a protocol for a study that will explore (a) the scope of SPECTROM implementation by evaluating the barriers and facilitators of SPECTROM implementation and (b) the feasibility of a future large-scale cluster RCT to assess the cost and clinical effectiveness of SPECTROM training by evaluating the impact of the training and the feasibility of key processes such as recruitment, randomization, train-the-trainer, and the collection of anonymized data.

Methods: A multisite feasibility 2:1 (for every participant in the control arm there will be two in the SPECTROM training arm) cluster randomized controlled trial will randomly allocate community homes (clusters) providing support for adults with intellectual disabilities to either the SPECTROM arm where staff will

KEYWORDS

Cluster RCT; psychoeducation; behaviours that challenge; STOMP; SPECTROM; staff training

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receive SPECTROM training or control arm where staff will not receive SPECTROM training. Staff in both arms will receive the standard training programme provided by their organizations. Trainee's knowledge of psychiatric medicine will be assessed using the Psychotropic Knowledge Questionnaire-Revised (PKQ-R). The trainees' attitudes to addressing behaviors that challenge with or without using medicine will be assessed using the Management of Aggression and Violence Attitude Scale-Revised-Intellectual Disabilities (MAVAS-R-ID). Both questionnaires will be completed by the trainees before, two weeks, three months, and six months after training. A mixed methods process evaluation will include focus groups with a purposive sample of trainees, interviews with capacitated adults with intellectual disabilities and their families, and an online questionnaire survey. The process evaluation aims to receive feedback on the training, including the facilitators and barriers to implementing SPECTROM training. A focus group with staff in the control group will also be conducted to assess contamination. We will collect data on psychotropic prescribing in adults within the randomized community homes.

Results: Wilcoxon signed-rank paired test or ANOVA will be used to analyze pre- and post-training PKQ-R and MAVAS-R-ID scores, and qualitative data will be analyzed using the Framework Approach. The anonymized prescription data will help calculate the sample size for a future large-scale RCT involving SPECTROM training.

Conclusions: This scoping study will provide information on the facilitators of and barriers to the implementation of SPECTROM and the feasibility of conducting a future large-scale RCT for SPECTROM's clinical and cost-effectiveness.

Introduction

Individuals with intellectual (learning) disabilities (ID) are at a higher risk of displaying behaviors that challenge (18–62%) (Deb et al., 2016; Lundqvist, 2013). Behaviors that challenge impact individuals' quality of life (QoL) and those who support and care for them. Behaviors that challenge pose a major management problem and are an obstacle to social integration, may lead to carer stress, community placement breakdown and hospitalization, and the use of restrictive practices such as physical restraint and inappropriate use of medication.

Both pharmacological (Deb et al., 2022) and non-pharmacological psychosocial interventions, such as Positive Behavior Support (PBS) (Didden et al., 2016; Gore et al., 2022), are used for behaviors that challenge. PBS is a way of understanding Behaviors that challenge using a person-centered approach, assessing the broad social and physical context in which the behavior occurs, and planning and implementing ways of supporting the person, which enhances the QoL for themselves and their carers/caregivers. A recent meta-analysis found that non-pharmacological interventions have a significant,

long-lasting, moderate overall effect on behaviors that challenge (effect size = 0.573) (Bruinsma et al., 2020). Interventions combining mindfulness and behavioral techniques, such as a PBS approach, showed greater impact than other interventions.

Other PBS-based non-pharmacological interventions have also been shown to effectively reduce behaviors that challenge (McGill et al., 2018). In contrast, the evidence for the effectiveness of medication in addressing behaviors that challenge is, at best, equivocal, but the harm caused by these medications' side effects is obvious (Deb et al., 2023). Nevertheless, psychotropic (psychiatric) medications are used widely among people with ID (50–63%), mostly for behaviors that challenge rather than a psychiatric disorder for which they are licensed (see Deb, 2024). However, national (National Institute for Health and Care Excellence NICE, 2015) and international (Deb et al., 2009) guidelines on the management of Behaviors that challenge among people with intellectual disabilities recommend psychosocial intervention first and the use of medication only when psychosocial interventions have failed and there are serious risks of harm to self or others.

National Health Service England (NHSE) embarked on a major campaign in 2016 called "STopping Over-Medication of People with a learning disability, autism or both (STOMP)" (Branford et al., 2019), which was recently supplemented by STAMP (supporting treatment and appropriate medication in pediatrics). Although many organizations in the UK have signed up for the STOMP pledge, there is no real mechanism in practice to deliver the pledge. Therefore, even more than seven years after launching this initiative, the goal of stopping overmedication has not been achieved (Deb, Aimola, et al., 2020c, 2020a; Henderson et al., 2020). Using co-production, we recently developed the SPECTROM (Short-term Psycho-Education for Carers To Help Reduce the OverMedication of people with intellectual disabilities) (https://spectrom.wixsite.com/project) training programme through a UK NIHR (National Institute for Care and Health Research) -funded project to help implement STOMP pledge and help reduce the overuse of psychotropic medication among adults with intellectual disabilities (Deb, Limbu, et al., 2020b).

In our previous study, only a few care staff explicitly reflected on the fact that their own behavior may influence aggressive behavior (Unwin, 2013). Furthermore, only 16% of staff mentioned issues around communication despite much aggressive behavior being considered to be communicative (Bowring et al., 2017; Deb et al., 2022). Staff felt they would benefit from training and information about potential triggers to help them think more about environmental conditions and their role in precipitating behaviors that challenge. Many other researchers have highlighted support staff's frustration for not having the right training and desire to gather more knowledge and training on (a) mental health issues, (b) medication prescribing – when to use them and why, and when not to use them and why, (c) medication side effects,

(d) and when and how medication could safely be withdrawn (Lalor & Poulson, 2013). All the issues staff expressed are addressed in SPECTROM training, including staff's own attitude to Behaviors that challenge and how to address these reactions, including management of their own stress.

The ultimate aim of SPECTROM is to empower, inform and equip support staff with knowledge and skills to understand the person they support, handle their own psychological responses to behavior and negotiate the care pathway, advocating on behalf of the person they care for, and taking the views of adults with intellectual disabilities fully into account. Therefore, following SPECTROM training, a lesser demand from staff for initiating medication to manage behaviors that challenge and demand for withdrawal of medication where appropriate should indirectly lead to a reduction in inappropriate medication use and an increase in non-pharmacological psychosocial intervention for behaviors that challenge.

Two field tests of SPECTROM involving 60 trainees in the UK and Australia found significant post-training improvement in psychotropic knowledge and staff attitude in the medication management domain of attitude to manage behaviors that challenge (Barratt et al., 2023; Deb et al., 2023; Wilson et al., 2023). The current study will provide information on care service provider organizations' views and needs on SPECTROM, the facilitators and barriers of implementing SPECTROM within care service provider organizations, and assess the feasibility of conducting a future large-scale clinical and cost-effectiveness study of SPECTROM using an RCT.

Methods

The current study is a scoping exercise and a feasibility cluster RCT.

The study will use the following five work packages (WPs). Figure 1 shows a study flow diagram.

WP 1 (months: 1–4): A stakeholder scoping workshop.
WP 2 (months: 5–6): A feasibility cluster RCT.
WP 3 (months: 7–12): Outcome data collection over six months.
WP 4 (months: 13–15): A mixed methods process evaluation.
WP 5 (months: 16–18): Dissemination workshop.

WP 1: Stakeholder scoping workshop

Recruitment

At first, we will run a scoping workshop to which we will invite participants from several organizations that provide services for adults with intellectual disabilities (a mixture of independent sector, social service and voluntary sector providers) (also a mixture of big and small organizations) to a one-

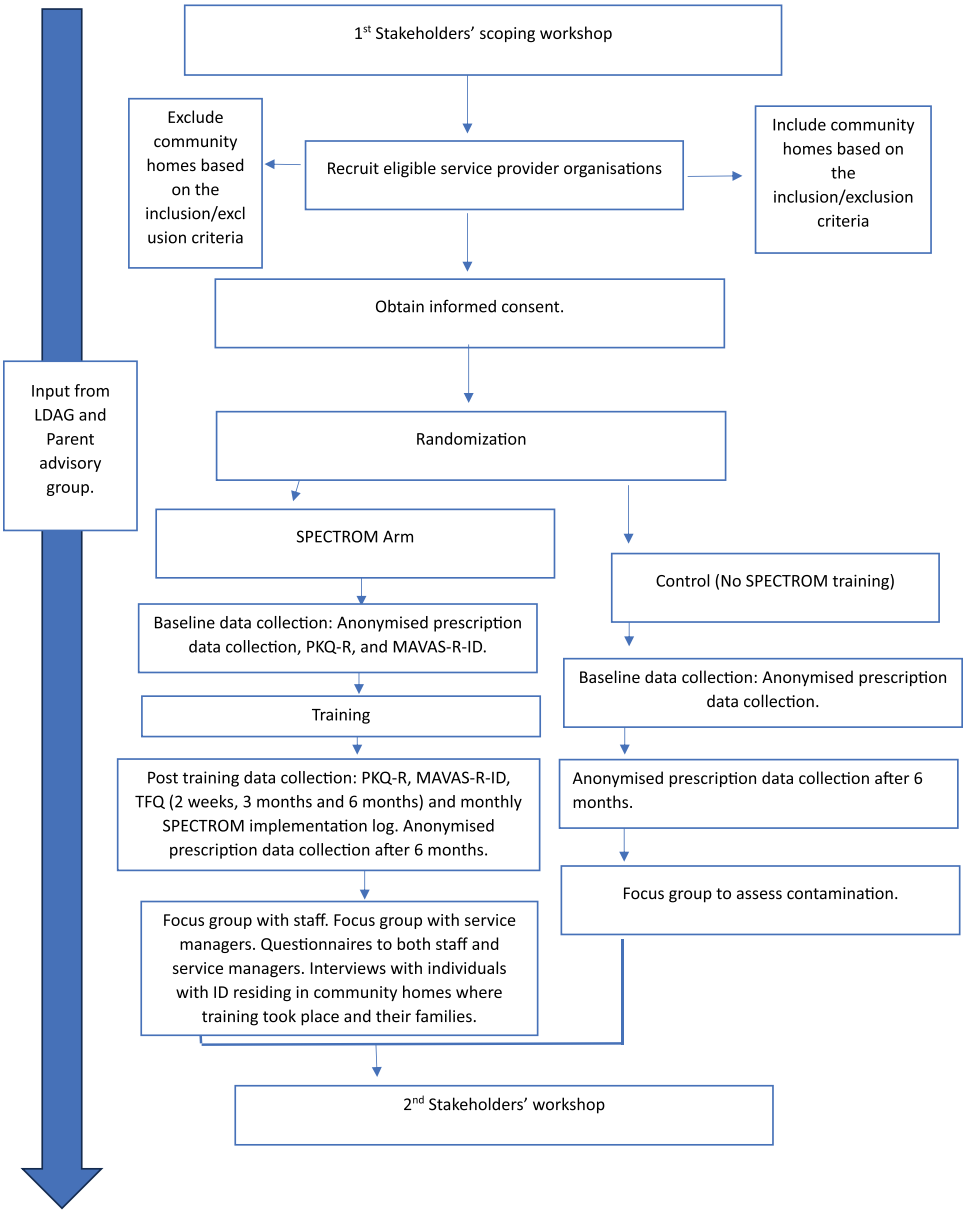


Figure 1. Flow diagram illustrating the sequence of work packages and participant flow.

day workshop to discuss the implementation of SPECTROM. We anticipate involving 15–20 organizations (we will invite around 30 organizations to allow for 30% attrition), including the seven that participated in the SPECTROM development project. The rest of the organization's contact details will be gathered online (Voluntary Organisation Disability Group has more than 30 organizations on their website). We will include a mixture of support staff, service/home managers/PBS trainers, and a Board member from each

organization. Altogether we expect to have 30–40 delegates. It is important to involve board members at the director level to ensure commitment from the organizations and also the support staff and their managers who will implement the training.

Data Collection

After the initial introduction and warm-up session, the research team will present the SPECTROM project to the group using online resources. We envisage this will last 90–120 min, followed by a 10-min coffee break. After that, we will have an open discussion and address any questions from the audience before discussing how best to implement SPECTROM, what the barriers are and how to overcome them.

After lunch, the delegates will be divided into several breakaway groups to discuss specific issues that arise from the morning session (for example, lack of time or computer at work). Flip charts will be used to help with the discussion. After a coffee break, a spokesperson from each breakaway group will present their recommendations to the whole group for further discussion and conclusions.

Data Analysis

We need to know whether the organizations are interested in participating in the training and a future large-scale RCT, what the facilitators and barriers to SPECTROM's implementation are, how they could be overcome, and what support would be needed to achieve this. This will help us determine whether SPECTROM training could be delivered at a scale.

Data will be analyzed using a Theory of Change (ToC) map (Breuer et al., 2018). In the ToC map, the outcome pathway to achieve the ultimate impact is divided into several small steps, which, although similar but unlike the Logic Model, do not always move in a linear fashion. In each step, facilitators and barriers (assumptions) are explored, and each intermediate intervention is based on a rationale and tested to create an evidence base (indicators). The steps are interdependent on each other in a Bayesian fashion. ToC enhances the Medical Research Council's framework for complex interventions (Craig et al., 2008).

WP 2: Feasibility cluster rct

This RCT will explore the feasibility of a future large-scale RCT to assess the cost and clinical effectiveness of SPECTROM training.

Inclusion and Exclusion Criteria

Inclusion Criteria

- Support staff (direct care workers), service (home) managers, and possibly PBS trainers working with adults with intellectual disabilities within Social Care provider organizations within a community setting.
- Service providers that support adults with intellectual disabilities in a community setting.
- Service provider organizations located in England and Wales.
- Community homes with at least one adult with intellectual disabilities receiving psychotropic medicine.

Exclusion Criteria

- Support staff, service managers, and PBS trainers working solely with children with intellectual disabilities and/or within a hospital setting.
- Service providers that do not support adults with intellectual disabilities.
- Service provider organizations located outside England and Wales.
- Community homes where no one is receiving psychotropic medicine.

Recruitment

Various social care provider organizations that support individuals with intellectual disabilities in the community in the UK, including those who participated in the SPECTROM development project (Deb et al., 2021), will be approached for participation. Each organization will delegate the task of identifying potential participants (service managers, PBS trainers, and support staff) to a named organization member. The nominated member will choose at least two community homes in different parts of England and Wales. Each nominated member will approach potential participants and pass a copy of the Participant Information Sheet to those interested in participating in the research. From the chosen community homes, the service manager will discuss the project with their staff team for participating in the study. Potential participants will be given at least 24 h to consider the information. The contact details of those interested in participating in the study will be passed on to the research assistant (RA). The RA will verbally summarize the study and answer any questions before recording written consent.

Each service manager will be asked to choose one service/community home (if they oversee more than one) where, as per the inclusion criteria, at least one service user is receiving psychotropic medicine. The PBS or other trainers from the same organization will also be recruited if possible.

Randomisation

The present study will be a multisite parallel design feasibility cluster RCT with two arms and a 2:1 allocation ratio (two into the SPECTROM training arm and one into the training as usual (TAU) arm). The community homes will act as clusters and be randomly allocated to one of the arms. The 2:1 ratio will allow for more homes to receive the training. The project statistician will remotely randomize the clusters using a standardized randomization formula and software.

We will randomize at least eight community homes/services through at least four service provider organizations from England and Wales. We have not done a power calculation as this is a feasibility study, but we think the proposed number of participants would be feasible to recruit and sufficient to collect the feasibility outcome data. Service managers and their staff teams, randomized to receive SPECTROM training, will receive the training over and above their organization's training. The rest of the service manager's teams (control arm) will receive their organization's usual training but not SPECTROM. We envisage each community home to have on average, 10–15 staff and 1–3 adults with intellectual disabilities who receive psychotropic medicine. The research team will not be blinded to the randomization allocation.

Intervention

SPECTROM Training Arm

SPECTROM is a blended learning system that combines face-to-face training and online web-based resources. Depending on the circumstances, these resources are introduced through two-day in-person or online training. The face-to-face training consists of two core modules: (a) Medication/STOMP and (b) Alternatives to medication (ATM). Twelve additional modules are introduced through two core modules. More information can be found at https://spectrom.wixsite.com/project (Deb et al., 2021; Deb & Limbu, 2024). The face-to-face training will also introduce several internal resources and tools for trainees to use in their daily practice. In the current study, we plan to deliver the face-to-face training sessions online via the MS Teams platform to accommodate

participants residing across various parts of England and Wales and mitigate the logistical challenges associated with travel and, sometimes, overnight stays. This will potentially allow more trainees from a wide geographic area to participate.

Module 1 will cover Medicine/STOMP and will be delivered in two sessions. Session I will include.

- Discussion of different psychiatric (psychotropic) medicines, their indications, when they could and should not be used, their side effects, their monitoring requirements, etc.
- Why should we be concerned about the overmedication of people with intellectual disabilities? This section includes some statistics on medication use and the scientific evidence, or rather lack of it, supporting medication use for behaviors that challenge.
- Staff-led in-house STOMP action planning reviews (STAR) for psychiatric medicine in preparation for a formal clinic review by the prescriber. This section provides a structure and tools for review. However, staff do not make any decisions about medication changes. The review encourages staff to discuss with the prescribers whether psychotropics are still required and whether it is appropriate to consider a dose reduction and implement non-medicinal interventions.
- Psychiatric medicine withdrawal, the withdrawal side effects, and how to prepare for the withdrawal. This section is designed to build staff confidence to discuss the possibility of psychotropic withdrawal with prescribers where appropriate and properly prepare all stakeholders for the withdrawal.

In session II, we will use case vignettes to re-iterate the good practices for using psychotropic medicine learned in session I.

Module 2 will cover alternatives to medicine (ATM) for addressing behaviors that challenge in adults with intellectual disabilities. It will be delivered in two sessions. Session I will concentrate on the following topics.

- Understand the reasons for behaviors that challenge and provide a comprehensive assessment of the behaviors that challenge.
- Understand the person behind the behavior and help them build their skills.
- Understand and manage staff's own feelings and attitudes toward behaviors that challenge and the person manifesting the behavior and how that influences the behavior of the person they support.

In session II, we will discuss how to support carers/caregivers themselves, including managing their own stress.

Like module 1, module 2 will also introduce certain tools to the trainees for use in their service.

By learning how to address behaviors that challenge without medicine and through person-centered care, the direct care workers/support staff would be expected not to ask for psychotropic medicine for behaviors that challenge in the first instance. Also, by learning how to prepare for antipsychotic withdrawal thoroughly, they will become more confident to ask the prescribers whether it is necessary to reduce the dose and discontinue medicine when appropriate. Both these approaches should reduce overmedication. However, the support staff (direct care workers) will be warned not to change or reduce medication.

The research team will train the service managers or the PBS trainers, and depending on the situation, the service managers, the PBS trainers, or the research team will train the staff teams. We envisage the research team delivering each module over 4 h. However, the service managers/PBS trainers may be able to divide the delivery of each module into two to three sessions.

Control Arm

The control will receive training as usual (TAU). They will receive any training and services currently offered by their respective organization but not SPECTROM.

WP 3: Follow-up data collection

We will collect three types of data after the randomization: a) pre- and post-training questionnaires (see Figure 2) data from the trainees in the training arm only, b) anonymous data collection of psychotropic prescriptions from all randomized community homes before and six months after the training, and c) collection of data on the SPECTROM resources implementation in the day-to-day practice of staff team including the use of tools introduced during the training. The schedule of data collection is presented in Figure 2. For the anonymous data collection, the service/home manager from each randomized community home will provide data using a proforma on psychotropic prescriptions in their respective homes with their indications (reasons for their use) (to distinguish psychotropic use on-label for psychiatric disorders from off-label for behaviors that challenge in the absence of a psychiatric disorder) to the research team. Antiepileptic medications purely used for epilepsy treatment will be excluded from this data collection.

We will assess any post-training change in trainees' knowledge of psychotropic medication, including the use of psychotropic medicines for behaviors that challenge, using the Psychotropic Knowledge Questionnaire-Revised

Assessment	Study period										
	Screening	Baseline	Week 1	Week 2	1 M (Month)	2 M	3 M	4 M	5 M	6 M	7 M
Eligibility screen	A										
Informed consent	B										
Randomization/ allocation	B										
SPECTROM Intervention			I								
Demographics		I									
PKQ-R		I		I			I			I	
MAVAS-R-ID		I		I			I			I	
TFQ				I							
SPECTROM implementation proforma					I	I	I	I	I	I	
Anonymous medication prescription data		I, C								I, C	
Interviews, focus groups, and questionnaire survey									I, C, D	I, C, D	I, C, D

Abbreviations: A = for all potential participants, B = Eligible participants, I = Participants in the SPECTROM Arm, C = Participants in the Control/TAU Arm, D = Residents with intellectual disabilities who reside in service homes where training was delivered.

Figure 2. The SPIRIT figure – schedule of enrollment, intervention, and assessment. Abbreviations: A = for all potential participants, B = Eligible participants, I = Participants in the SPECTROM Arm, C = Participants in the Control/TAU Arm, D = Residents with intellectual disabilities who reside in service homes where training was delivered.

(PKQ-R) (de Kuijper & van der Putten, 2017). We will assess any change in staff attitudes toward behaviors that challenge and the person showing behaviors that challenge using the Management of Aggression and Violence Attitude Scale-Revised-Intellectual Disabilities (MAVAS-R-ID) scale (Duxbury, 2003) before and two weeks, and six months after the training. We will also collect data through Qualtrics on the Trainee Feedback Questionnaire (TFQ) (Deb et al., 2021) 3 months after the training to receive feedback on the training and SPECTROM resources, including their acceptability, practicality, and usefulness for their practice and person-centered care.

Data Analysis

If the PKQ-R and MAVAS-R-ID data are not normally distributed, the Wilcoxon signed-rank paired test will be used, or ANOVA will be used if they are normally distributed. Descriptive statistics will be used to analyze

TFQ data and the SPECTROM implementation log. The main aim of this feasibility project is to assess the feasibility of data collection using these assessment measures.

We hope that SPECTROM training will lead to a reduction in psychotropic prescriptions for behaviors that challenge in the absence of a psychiatric disorder. However, as the study is not powered and given the short follow-up period to assess the impact of the training on the prescribing, we will not conduct any hypothesis testing. We will analyze data descriptively with mean and standard deviation in the dose change, if any, of the risperidone equivalent of antipsychotic medicine. However, we will observe the trend in psychotropic use in each randomized arm to detect any signal of SPECTROM's effect. These data should allow the statistician to calculate the sample size for future large-scale RCT involving SPECTROM training. The purpose of prescription data collection is to assess the feasibility of remote anonymized data collection for a future larger study. Data will be retained for those who leave the study and analyzed using the intention-to-treat method.

WP 4: Process evaluation

We will conduct a mixed-methods process evaluation, including a questionnaire survey, qualitative interviews, and focus groups, based on the MRC guideline for process evaluation for complex intervention (Moore et al., 2015), to provide a contextualized analysis of the intervention delivery (SPECTROM training to staff and service managers).

Inclusion and Exclusion Criteria

Inclusion Criteria

- Support staff and service managers/PBS trainers in the SPECTROM training arm.
- Support staff and service managers in the TAU arm.
- People with mild to moderate intellectual disabilities and good communication skills who resided in homes where staff received SPECTROM training, as well as their families/advocates.
- People with intellectual disabilities who can provide informed consent.
- Adults with intellectual disabilities aged 18 or over.

Exclusion Criteria

- People with intellectual disabilities and their families/advocates who were not involved in the SPECTROM project.
- People with intellectual disabilities who cannot consent.
- Individuals with intellectual disabilities under the age of 18.

Recruitment

Staff will be selected purposively to ensure a mix of demographic characteristics and a range of community homes from different parts of England and Wales. Staff in each community home will identify family carers and people with mild to moderate intellectual disabilities with good communication skills willing to participate in the interview with their family cares. Once identified, the RA will formally assess the capacity of the interested participants with intellectual disabilities to consent. An accessible version of the participant information sheet (see Appendix 1) and consent form (Appendix 2) will be used to gain informed consent from people with intellectual disabilities. Only adults with intellectual disabilities who can give informed consent will be recruited for interviews with their family carers.

Figure 2 shows the enrollment, intervention, and assessment schedule, as in the CONSORT extension (Eldridge et al., 2016) and the SPIRIT recommendation (Chan et al., 2013). The CONSORT and SPIRIT checklists are in Appendix 3 and 4.

Qualitative Study

We will run two focus groups of 6–8 participants, one involving support staff and another service/home manager/PBS trainers who received SPECTROM training. We will interview the adults with intellectual disabilities and her/his family caregivers together as a pair. We will purposively recruit 6–8 adults with mild to moderate intellectual disabilities with good communication skills with their family caregivers to understand their experience and capture the impact of training staff in SPECTROM. For example, we are particularly interested in whether the training will improve staff engagement with people with intellectual disabilities and their families in shared decision-making about their care in general and medication in particular. Similarly, we will be interested to assess whether the training has improved staff communication and interaction with the person with intellectual disabilities and their families. SPECTROM has one module on "effective engagement with people with intellectual disabilities," which teaches staff how to improve their communication and engagement with the people they support and help them to build their skills. Therefore, during the interviews, we will ask people with intellectual disabilities whether their support staff are engaging more with them since the training and helping them with their skills building. Similarly, SPECTROM has a module on "effective engagement with the families and advocates" that teaches the staff how to engage with families more effectively. During the interviews with the families, we will explore whether they have noticed any improvement in how staff engage themselves with the person they support and the families.

We will randomly select 4–6 staff from the control arm for a focus group to assess the extent of contamination, if any. For example, whether staff in the control group accessed and used SPECTROM online resources and tools. The participants will also be given the option of online interviews/focus groups via MS Teams or Zoom if needed. All focus groups and interviews will be conducted in a mutually convenient venue. All travel expenses will be reimbursed for all participants.

Data collection and analysis

We will use a similar methodology in our previous projects (Deb et al., 2007; Deb, Nancarrow, et al., 2020a; Morris et al., 2005). BL, the researcher in the project with previous experience in collecting and analyzing qualitative research data, will run the focus groups and interviews and analyze data under the supervision of the qualitative research expert co-applicant (CV, UCL). Topic guides will be developed jointly by the chief investigator, the qualitative research expert, and the researchers framed on the themes described earlier in the implementation and the process evaluation sections that can be flexibly employed and open to emergent themes. The focus groups and interviews will be audio recorded (consent sought) and managed using a data management plan. To preserve confidentiality and anonymity, the participants in the focus groups and interviews will be asked to choose a pseudonym to protect their identities. The recording will be transported using an encrypted USB stick and stored within a password-protected intranet drive of Imperial College London (not the computer). The recording on the USB stick will be deleted once the data are stored in the Imperial College password-protected intranet.

A Qualitative Data Analysis Plan based on the Framework Approach (Gale et al., 2013) will be developed to document how the qualitative data of process evaluation will be managed, analyzed, and reported. The NVivo12 Plus computer software program (Lumivero, 2020) will manage qualitative data from the process evaluation and support analysis. Two project group members will code a random sample (at least 10% of the data) for triangulation to increase coding reliability.

Questionnaire survey

To gather information on the impact of training, a questionnaire will be sent to all service managers and support staff who participated in the training. The questions will be based on the focus group findings and interviews. The questionnaires will have questions with "yes," 'no, "don't know" answers and free-text boxes to write views/comments/suggestions for the facilitators and barriers for SPECTROM implementation and their solutions.

The questionnaire data will be collected and analyzed descriptively using the Qualtrics online software. However, the information in the free-text box in the returned questionnaires will be analyzed using a framework analysis method.

WP 5: Dissemination workshop

We will hold the second stakeholders' workshop, including representatives of service provider organizations, community learning disability team members, representatives of people with intellectual disabilities and their families/advocates, to discuss the study's findings and how to proceed to the full programme of research involving SPECTROM (particularly the issues that need to be addressed during the programme of research). We envisage 30–40 delegates in this workshop.

Data analysis

As in WP 1, data collected in the dissemination workshop will also be analyzed using a Theory of Change (ToC) map (Breuer et al., 2018).

Feasibility outcomes

This study will assess the following feasibility outcomes.

- The recruitment rate and attrition. The latter will be measured using the rate of six-month follow-up data collection.
- Feasibility of randomization.
- The potential number of residents in each community home receiving psychotropics for Behaviours that challenge, which will be measured using the anonymized prescription data from the participating services.
- The feasibility of remote anonymized prescription data collection will be assessed by asking service managers from community homes to provide these data.
- The success of the "train the trainer" model will be assessed from the number of successful training sessions provided by the service managers/PBS trainers at the end of the study.
- The process evaluation will assess the intervention's impact and the barriers to and facilitators of its implementation.
- The potential contamination between the two study arms will be assessed using the focus group with a purposive sample of control group participants.

Progression criteria

If more than 60% of the service provider organizations we approach are willing to participate in SPECTROM training and the future large-scale cluster RCT, we will proceed to a UK NIHR (National Institute for Care and Health Research) Programme for the Applied Research (PGfAR) application. If less than 30% agree, we will not proceed. If the agreement is between 30% and 60%, we will have further discussions with the research team and other relevant stakeholders on how to proceed.

Data management and confidentiality

Paper documents, such as completed consent forms, contact detail forms, or any identifiable data, will be kept in a locked cabinet at Imperial College London. Any personal data (names, addresses, e-mails, telephone numbers) will be kept as hard files only, which will be kept in a locked cabinet. Any electronic data will be stored on a password-protected computer. All quantitative data, such as baseline and follow-up data from the participants, will be anonymized. The completed questionnaire from the process evaluation using Qualtrics will be kept safely in a password-protected computer on the Imperial College intranet. No identifiable data will be in the questionnaire. Access to the dataset and the cabinet will be restricted to the core research team.

The focus group and interviews will be recorded using a digital recorder and a multi-directional microphone. Consent for recording will be obtained. Recordings will be transferred to a password-protected computer on the Imperial College intranet for storage and deleted from the device. This will only be accessible by the core research team and deleted after the transcriptions are complete. The transcriptions will not have identifiable data, as participants' pseudonyms will be used. Workshop data from both workshops will be collected and kept securely in a locked cabinet at Imperial College London. A combined independent steering committee will oversee data management and research governance. It will consist of a clinical psychologist, a psychiatrist (chair) and a family member or an independent advocate and will meet every six months.

Dissemination plans

We will disseminate study findings through the dissemination workshop at WP 5. Additionally, we will disseminate the findings through our project website and newsletters, including an accessible version. We will publish papers in peer-reviewed journals and present findings at relevant conferences. We will also disseminate the findings through the websites of the service provider organizations involved in the project. A summary report will also

be produced and sent to various stakeholders, including participants who consented to receive a copy.

Discussion

Recruitment is likely to cause difficulty as the service managers and support staff are busy caring for adults with intellectual disabilities, and there are often crises with behaviors that challenge in the services, taking up more staff time. Therefore, time constraints are likely to be a major barrier to recruitment as staff will have to be released for training during their work time. This will be problematic given the shortage of staff in most services. Another problem is the high turnover among the staff team, which is likely to cause problems with recruitment and follow-up. Lack of computer access may prevent some staff from participating in training and accessing SPECTROM onsite resources after the training. However, the whole purpose of this feasibility study is to assess these barriers in implementing the training. There has to be some gain for the organization from this project. One of these is the free training given to their staff to improve their knowledge and attitude to behaviors that challenge. This will help their professional development and should lead to better person-centered care for the person they support, which is in the best interest of the adult with intellectual disabilities. However, another advantage of the training is that the organizations can count this activity as part of their STOMP implementation strategy, as most organizations in the UK have now pledged to participate in the NHS England STOMP STAMP initiative. However, unless organizations make this training almost mandatory, persuading managers and staff to participate may be difficult.

Randomization may also cause problems. Our original intention was to randomize potential participants in a 1:1 ratio. However, we have changed this to 2 in the training arm versus 1 in the control arm (2:1 ratio) to increase the number of staff receiving training. However, if there is a high dropout rate in the training arm and, in contrast, a strong interest in participating in training in some in the control arm, it may be difficult to sustain randomization. Also, as staff who are already interested in training are randomized, many in the control arm will likely be already committed to reducing overmedication and using alternatives to medicine to address behaviors that challenge, which is the ultimate aim of the SPECTROM training. As such, they will likely access SPECTROM online resources (although the modules are password-protected to prevent this). This will also reduce the difference in practice between the two arms. Part of this will be captured at the process evaluation stage when we will involve a small number of purposively sampled staff from the control group to assess the extent of contamination between the two groups.

Unlike many other staff training programs, SPECTROM is designed for lifelong learning rather than just one-off training. So, the staff will be encouraged to use SPECTROM resources as a reference point for information for them to help with person-centered care planning. We would also expect staff to use many tools/resources available in SPECTROM, such as accessible psychotropic medicine leaflets, Comprehensive Assessment of Triggers for Behaviors of concern Scale (CATS) (Limbu et al., 2021), Yellow passport, STOMP action planning review (STAR review) checklist, questions for staff to ask the prescribers in the clinic during medicine review, pain scale, staff wellness questionnaire, etc. Staff may not have time to implement these, and there may be some overlap with the tools they already use. Similarly, we expect some overlap between the ATM (alternative to medicine) core module and the PBS training that is already available within the organization. However, these will be explored during the process evaluation focus groups and interviews.

Larger social service care provider organizations in the UK are likely to have their own PBS team and PBS trainers, whereas the smaller organizations are likely to lack them. In that sense, the SPECTROM training will likely be more useful to staff in smaller organizations. However, there are practical difficulties in involving smaller organizations in any research project because of a lack of organizational capacity. In any case, contacting the service provider organizations will be challenging, which will be explored in this feasibility study.

Because of time constraints and lack of confidence, many service managers are likely to decline the train-the-trainer model in which they are asked to train their own staff team once the research team train the service managers. However, there are certain advantages to this model. For example, we plan to deliver each core module training online over half a day because of the distance involved and time constraints. Service managers will have more flexibility in delivering the training. For example, the service managers can provide the training to their staff team over a longer period or over several sessions in person, which will encourage discussions and active participation from the support staff. There is likely to be a difference in the educational level between the service managers and the support staff, making it difficult to pitch the SPECTROM training at a level that would cater for everyone. However, if the service managers train their own staff team, they can adjust the content and the speed of training delivery to accommodate different educational and knowledge levels among different staff.

The proposed project will help identify potential limitations such as those discussed above and help identify solutions to prepare for a future larger RCT involving SPECTROM.

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Disclosure statement

No potential conflict of interest was reported by the author(s).

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Author contributions

SD was involved in the study's conception and design. SD is the lead applicant and chief investigator. BL and SD are the lead authors who wrote the initial manuscript and prepared revisions. All authors contributed substantially to the preparation of the manuscript and approved the final version. All authors are accountable for all aspects of study design. All authors are part of the project management group and are co-applicants in the grant application.

Ethics approval and consent to participate

The West Midlands-Coventry & Warwickshire Research Ethics Committee, UK, provided a favorable ethical opinion on October 9, 2023 (REC reference: 23/WM/0211). All participants will provide informed consent before inclusion in the study. Please see Appendix 1.

Data availability statement

The research team, steering committee and the sponsor's research and development department will have access to data. If appropriate and legal, the data will be made available upon reasonable request and subject to approval from the sponsor and the funder.

Institutional review board statement

The West Midlands-Coventry & Warwickshire Research Ethics Committee, UK, provided a favorable ethical opinion on October 9, 2023 (REC reference: 23/WM/0211).

Informed consent statement

All participants will provide written consent before inclusion in the study. Please see Appendix 1.

Trial registration

Name of the registry: ISRCTN; Trial registration number: ISRCTN71712166; date of registration: 24.01.24; URL of trial registry: https://doi.org/10.1186/ISRCTN71712166

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