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SPECTROM training for carers to help reduce the overmedication of people with learning disabilities: feasibility of implementation

Submission date	**Recruitment status**	[_] Prospectively registered
15/01/2024	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/01/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/03/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Backgrounds and study aims

People with learning or intellectual disabilities (LD) and autism are more likely to be given psychiatric medicines than others, often for behaviours that challenge (BtC). Many also take these medicines for a long time without proper review. These medicines can cause serious side effects. These medicines are licensed for psychiatric illnesses like schizophrenia and depression, not for BtC without a psychiatric illness. The many reasons for BtC needs a thorough assessment before a treatment is given. Support staff play a pivotal role in this process. Therefore, training staff properly is crucial to achieving the best outcome for BtC. The study team worked with people with LD, support staff, family carers, and doctors to develop SPECTROM training for staff. SPECTROM aims to empower, inform, and equip staff with skills to understand BtC and the person behind BtC and manage their psychological responses to BtC. The training should increase the staff's knowledge on the assessment of and the treatments for BtC in people with LD. Staff are warned not to reduce medicine or provide any treatment themselves. The study will investigate whether SPECTROM training can be delivered in organisations that support adults with LD. It will also see whether the training will empower staff, make them more knowledgeable about the pharmacological and non-pharmacological interventions for BtC, and improve their interactions with professionals, family members and the person they support.

Who can participate?

Only organisations that support adults with LD in the community located in England and Wales are eligible for the free training. Service managers and support staff (possibly Positive Behaviour Support trainers) within these organisations can participate and receive the training. Residents who are adults (18 years or older) and residing within these organisations and their families will also be recruited for interviews as part of the process evaluation (See WP4).

What does the study involve?

The study team plans to discuss with organisations how SPECTROM training can be rolled out. Eight or more community homes will be randomly selected through at least four or more different social care service provider organisations. Staff (Service managers and support staff) from some of the homes will be trained in SPECTROM and others not. Both will receive their

usual training. Information on psychiatric prescriptions will also collected anonymously from these homes. Staff who participated in the training will be asked to complete some questionnaires to measure their knowledge of psychiatric medicines, attitude towards BtC and feedback on the training. Focus groups and questionnaires will also be carried out with staff who received the training to explore the impact of SPECTROM training. A focus group will be conducted with staff who did not receive the training to see if they knew about the training and if they visited the website or used any SPECTROM resources. In addition, adults with LD who reside in the community homes where SPECTROM training was delivered and their families will be interviewed to explore the impact of SPECTROM training from their perspectives.

What are the possible benefits and risks of participating?
Staff may benefit from the training and learn about different types of psychiatric medicines, how to be prepared for medicine reviews or clinic reviews by doctors and other prescribers such as specialist pharmacists and nurses, what questions to ask the prescribers, and also how to effectively liaise with different professionals including doctors and the family caregivers. The training will also teach staff how to handle their stress, assess the causes of BtC and what alternatives to medications are available for BtC. There are no major risks from participating. If the participants feel unwell or exhausted during the training, they can leave and return later. Similarly, if any participant feels unwell or uncomfortable during the focus groups, they can leave and return later if they want to.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
July 2023 to March 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR), Programme Development Grants (Reference NIHR204577)

Who is the main contact?
1. Prof Shoumitro (Shoumi) Deb, s.deb@imperial.ac.uk
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Study website
https://spectrom.wixsite.com/spectrompdp

Contact information

Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
334044

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 60738, IRAS 334044, D-2417

Study information

Scientific Title
Short-term Psycho-Education for Carers To help Reduce the Over Medication of people with intellectual disabilities (ID): Programme Development Project (SPECTROM PDP)

Acronym
SPECTROM PDP

Study objectives

The overall aim of this study is to assess the feasibility of implementing SPECTROM training for support staff to help reduce overmedication of people with intellectual disabilities at a scale and a future definitive RCT.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/10/2023, The West Midlands-Coventry & Warwickshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048211; coventryandwarwick.rec@hra.nhs.uk), ref: 23/WM/0211

Study design
Mixed method quantitative and qualitative design

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Care home, Community, Internet/virtual

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Reduction of overmedication in people with intellectual (learning) disabilities.

Interventions
The methodology of this study involves randomisation of community homes to provide SPECTROM training to staff and mixed methods process evaluation.

There are five work packages (WPs).

WP1: Workshop: Pre-study administrative preparatory work WP 1 will include a one-day workshop involving 30-40 social care service provider organisations' senior managers, service /home/locality managers from 15-20 service provider organisations to determine the desire to participate in SPECTROM training and its implementation, including a future RCT to assess the scalability of SPECTROM. We will invite participants from several organisations that provide services for people with ID (a mixture of independent sector, social service and voluntary sector providers, and a mixture of big and small organisations). We will invite the seven service provider organisations that participated in the SPECTROM development project and identify other service provider organisations from the internet, including Voluntary Organisation Disability Group, which has more than 30 organisations on its website.

After the initial introduction and warm-up session, the research team will present the SPECTROM project to the group using online resources (SPECTROM website https://spectrom.wixsite.com/project). 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. We will conduct this workshop online to facilitate the participation of as many delegates as possible from different parts of the country by eliminating the need for travel and overnight stays for many.

This will help provide information on the organisation's level of interest in participating in the training, a future RCT, and what support would be needed to achieve these. This will help us to know whether SPECTROM training could be delivered at a scale and where the overlap is with the current training and practice in each organisation.
This workshop is part of the pre-study preparatory work and is mostly administrative and not part of the main study. Attendees of the two workshops are not study participants. They have a similar role to the research team and will help with recruitment (WP1). Study participants are those who will take part in WP2-4. We will prepare an agenda for this workshop but no patient information sheet. Attendance at the workshop will be counted as their consent for participation.

WP2: Randomisation We will randomise eight or more community homes through at least four or more different social care service provider organisations and from different parts of England and Wales in a 2:1 ratio to SPECTROM training or TAU. Information on SPECTROM training can be found in the protocol. Each home will act as a cluster. Once consent is obtained, the home managers and possibly the PBS trainers in the intervention arm will be trained together by the research team over two days of online SPECTROM training. The home manager/PBS trainer will then roll out the training among the staff team managed by the home manager. SPECTROM training will be incorporated within the organisation's current training programme. Those who receive SPECTROM training will also be asked to complete questionnaires before and after the training (see WP3). The exact procedure for rolling out the training among the support staff team in the intervention arm will vary from community home to home and organisation to organisation, depending on the set-up and resources available. In the WP1 workshop we will discuss with the recruited home managers and the organisational leads how to train the home managers and possibly the PBS trainers and how they will subsequently roll out the training among the respective staff team. If the train the train-the-trainer model does not work, the research team will train the staff teams along with the service managers. We will ask the home managers to select support staff for training from only one of the homes/services they manage. On average, each home will likely have 10-12 support staff. We will also determine the number of residents with ID in each home and how many are receiving psychotropic medications and for Behaviours that challenge (BtC).

WP3: Follow-up data collection We will collect three types of data after the randomisation: a) pre- and post-questionnaire data collection from the trainees, b) anonymous data collection of psychotropic prescriptions from all randomised community homes and c) collection of data on the SPECTROM resources implementation in the day-to-day practice of staff team.

a) Participants who attended the SPECTROM training will be given three questionnaires to complete before and after the training. We will assess pre- and post-training staff knowledge of psychotropic medication and attitude toward managing BtC. As per our field-testing study, the 'Psychotropic Knowledge Questionnaire-Revised (PKQ-R)' will be used to assess staff knowledge of psychotropic medications and the 'Management of Aggression and Violence Attitude Scale-Revised-ID (MAVAS-R-ID)' to assess staff attitude toward the management of BtC. We will also

collect post-training data using the Trainee Feedback Questionnaire (TFQ) to determine the acceptability, applicability, practicality, and relevance of SPECTROM resources to trainees' practice. TFQ was successfully used in two previous pilot studies involving SPECTROM training. These questionnaires will be completed by participants who received SPECTROM training immediately before the training, within two weeks, three and six months after training to make sure that the early gains are not lost over time.

b) We will also anonymously collect data on psychotropic prescriptions for the residents in the randomised homes over six months. The service manager will be nominated from each participating community home to provide data on psychotropic prescriptions in their respective homes including PRN medication with their indications (to distinguish psychotropic use on-label for psychiatric disorders from off-label for BtC in the absence of a psychiatric disorder) to the research team. Those who are receiving antiepileptic medications purely for epilepsy treatment will be excluded from this data collection. These data will be collected at the beginning of the study (on the week before the training) and the end of the six-month follow-up. The service managers will remove all identifiable data and no key code will be kept so no one will have access to the identity of the person whose psychotropic prescription data are supplied to the research team. Therefore, these data will remain strictly anonymous. The prescription data will be collected only on those receiving psychotropic medications.

c) The staff team will keep a log of the implementation of SPECTROM using a proforma, which will ask how often staff carried out an in-house informal medication review (and how often these reviews led to a formal medical review of prescriptions), accessed SPECTROM resources for information, and used SPECTROM resources such as accessible medication leaflets (and how often this led to shared decision making), CATS and the Yellow passport. The staff team will be asked to complete this every month.

WP4: Mixed-methods process evaluation We will run two focus groups of 6-8 participants in each, one involving support staff and another service/home manager who received SPECTROM training. We will interview the adult with intellectual disabilities and her/his family carer together as a pair. We will purposively recruit 6-8 adults with mild to moderate ID who have good communication skills with their family carers to understand their experience and capture the impact of training staff in SPECTROM. For example, we are particularly interested to know whether the training will improve staff involvement with the person with ID and their families in shared decision-making about their care in general but medication. Similarly, we will be interested to assess whether the training has improved staff communication and interaction with the person with ID and their families. The participants will also be given the option of online interviews/focus groups via MS Teams or Zoom if needed. The number of participants mentioned here is the total number from the SPECTROM training arm. We will only recruit adults with mild to moderate ID and good communication skills who can attend the interview with a family carer as we will interview both together to get feedback on their experience. Any travel expenses will be reimbursed.

We will randomly select 4-6 staff from the control arm for a focus group to assess the extent of contamination, if any. A comparatively smaller number of participants are chosen from the control arm as the purpose of this focus group is to determine any contamination. For example, whether staff in the control group accessed SPECTROM online resources and used them. Whereas a relatively larger number of participants will be chosen from the training arm as we will explore the impact of various aspects of training. All focus groups and interviews will be conducted in a mutually convenient venue. All travel expenses will be reimbursed for all participants, including support staff, home managers, adults with mild to moderate ID and their family carers.

A questionnaire will be sent to all service managers and support staff who took part in the training to gather information on the impact of training. The questions will be based on the focus group findings and interviews.
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 ID with good communication skills willing to participate in the interview with their family cares. Once identified, the RA will then formally assess the capacity of the interested participants with ID to consent. An accessible version of the participant information sheet and consent form will be used to gain informed consent from people with ID. Only adults with ID who can give informed consent will be recruited for interviews accompanied by their family carers.
WP5: 2nd stakeholders' workshop We will hold a 2nd stakeholders' workshop, including representatives of service provider organisations, representatives of people with ID and their families/advocates to discuss the findings of the study and how to proceed to the definite full-scale RCT involving SPECTROM (particularly cover the issues that need to be addressed during the programme of research). We envisage 30-40 delegates will attend the workshop. This is a post-study dissemination and future planning exercise and is not part of the main study. Therefore, people attending this workshop are treated similarly to the research team and not as study participants. We will prepare an agenda for this workshop but no patient information sheet. Attendance at the workshop will be counted as their consent for participation.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 06/03/2024:
1. Staff knowledge of psychotropic medicines measured using the Psychotropic Knowledge Questionnaire-Revised (PKQ-R) before and two weeks, three months, and six months after the training
2. Staff attitudes toward managing Behaviours that challenge (BtC) measured using the Management of Aggression and Violence Attitude Scale-Revised-ID (MAVAS-R-ID) will be used before and two weeks, three months, and six months after the training
3. The feasibility of implementing SPECTROM resources within the care service provider organisation's existing programme will be measured by a monthly SPECTROM Implementation Log for six months
4. The acceptability and relevance of SPECTROM training to staff practice will be measured using the Trainee Feedback Questionnaire (TFQ) before and after the training at two weeks, three months, and six months
5. Anonymised prescription data from randomised services will be used to calculate the sample size for a future RCT involving SPECTROM training
6. The barriers and facilitators of SPECTROM training will be assessed using focus groups, interviews, and questionnaires at a six-month follow-up

Previous primary outcome measures:
1. Staff knowledge of psychotropic medications measured using the Psychotropic Knowledge Questionnaire-Revised (PKQ-R) before and after the training at 2 weeks, 3 months and 6 months
2. Staff attitude toward the management of Behaviours that challenge (BtC) measured using the Management of Aggression and Violence Attitude Scale-Revised-ID (MAVAS-R-ID) before and after the training at 2 weeks, 3 months and 6 months
3. The feasibility of SPECTROM Implementation within the care service provider organisation's existing training programme measured using the SPECTROM Implementation Log at the end of

the study
4. SPECTROM acceptability and relevance measured using Trainee Feedback Questionnaire (TFQ) before and after the training at 2 weeks, 3 months and 6 months
5. Sample size calculation for a future RCT involving SPECTROM training measured using research data and anonymised prescription data from the intervention and the control group at the end of the study
6. Evaluate barriers and facilitators of SPECTROM training measured using focus groups, interviews and questionnaires parallel to data collection WP3 (3-6 months after training completed)

Secondary outcome measures
Current secondary outcome measures as of 06/03/2024:
1. The recruitment rate, attrition and randomisation measured using research data at six months follow-up
2. The potential number of residents in each community home receiving psychotropics for BtC measured using research data at the end of the study
3. The feasibility of remote anonymised prescription data collection will be assessed by asking service managers from community homes to provide these data throughout the study
4. The 'training the trainer' model will be assessed from the number of such successful training sessions at the end of the study
5. The process evaluation interviews with people with ID and their families will be used to assess the best way to involve them in future RCT. Contamination between the two arms (if any) will be measured using focus group with staff from the control arm at the end of the study

Previous secondary outcome measures:
1. Assessment of the feasibility of recruitment and randomisation measured using research data at the end of the study
2. Assessment of the feasibility of train the trainer model measured using research data at the end of the study
3. Assessment of the feasibility of anonymised remote prescription data collection from community homes measured using research data at the end of the study
4. Impact of training staff in SPECTROM measured using mixed methods process evaluation of questionnaires and conducting a focus group after training is complete
5. Assess how best to involve adults with ID and their families in the future RCT using research data at the end of the study
6. Assess the potential number of residents in each community home receiving psychotropics for Behaviours that challenge (BtC) using anonymised prescription proforma at the end of the study

Overall study start date
01/07/2023

Completion date
31/03/2025

Eligibility

Key inclusion criteria
For different work packages (WP), there are different eligibility criteria.
For WP2 randomisation (SPECTROM training), eligibility criteria are below:
1. Support staff, service managers, and PBS trainers working with adults with ID within Social Care provider organisations within a community setting.

2. Service care provider organisations that support adults with ID in a community setting.
3. Service care provider organisations located in England and Wales.

For the WP4 mixed methods process evaluation, eligibility criteria are below:
1. Support staff and service managers who were in the SPECTROM arm of the trial.
2. Support staff and service managers who were in the control/TAU arm of the trial.
3. People with mild to moderate ID with good communication skills who resided in the homes where staff received SPECTROM training and their families.
4. People with ID who can provide informed consent.
5. Adults with ID aged 18 or over.

Participant type(s)
Employee, Resident

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Estimate participants for WP2 (randomisation): 80 (eight or more community homes will be randomised. On average, each home will likely have 10-12 support staff.) Estimate participants for focus groups: 6-8 support staff, 6-8 service managers, 6-8 adults with ID with their families and 4-6 staff from the control arm.

Total final enrolment
175

Key exclusion criteria
Different exclusion criteria for different WPs.
For WP2 randomisation (SPECTROM training), exclusion criteria are below:
1. Support staff, service managers, and PBS trainers working solely with children with ID and/or within a hospital setting.
2. Service care provider organisations that do not support adults with ID.
3. Service care provider organisations located outside England and Wales.

For WP4 mixed methods process evaluation, exclusion criteria are below:
1. People with ID and their families/advocates who were not involved in the SPECTROM project.
2. People with ID who do not have the capacity to consent.
3. Individuals with ID under the age of 18.

Date of first enrolment
11/10/2023

Date of final enrolment
03/06/2024

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Keys Group
Second Floor, Maybrook House, Queensway
Halesowen
United Kingdom
0121 728 7800

Study participating centre
Achieve Together
Q4, First Floor, The Square, Randalls Way
Leatherhead, London
United Kingdom
KT22 7TW

Study participating centre
Dimensions
1230 Arlington Business Park, Theale
Reading
United Kingdom
RG7 4SA

Study participating centre
Aspens Cornford Lane
Aspens
Cornford Lane
Tunbridge Wells
United Kingdom
TN2 4QU

Study participating centre
Milestones Supported Living Service
Unit 7, Eclipse Office Park

High Street, Staple Hill
Bristol
United Kingdom
BS16 5EL

Study participating centre
Marcus and Marcus
142 St Marks Road
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EN1 1 BJ

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Sponsor type
Hospital/treatment centre

Website
https://www.cnwl.nhs.uk/

ROR
https://ror.org/05drfg619

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals and through workshops

Intention to publish date
31/03/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof Shoumitro (Shoumi) Deb, s.deb@imperial.ac.uk and approval from the sponsor. Anonymised raw data will be shared only, after the project ends. Consent was obtained for participating in the project but not for data sharing as that will be analysed anonymously. All data will be anonymised. We will ask participants to choose a pseudonym for the qualitative data gathered through focus groups, and interviews. Quantitative data will not have any personal identity associated with it. Where there are initials on the form, it will be anonymised and replaced with a participant number. Patient data sharing needs approval from both the sponsor and the funder.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/03/2025	11/03/2025	Yes	No