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A Feasibility Cluster RCT Involving SPECTROM Staff Training Program to Help Reduce the Overmedication of Adults with Intellectual Disabilities

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ABSTRACT

Introduction: 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.

Methods: A multisite feasibility cluster randomized controlled trial involving SPECTROM training.

Results: Overall, 39 clusters were recruited (26 in the SPECTROM training and 13 in the control group). Antipsychotic medicine dose was reduced among 19% of prescriptions in the training group at 6 months post-training follow-up compared with 6% in the non-training group. PKQ-R (Psychotropic Knowledge Questionnaire-Revised) and MAVAS-R-ID (Management of Aggression and Violence Attitude Scale-Revised-Intellectual Disabilities) scores showed a statistically significant improvement at 4 weeks of follow-up ($p < .001$). The focus groups revealed that the trainees found the SPECTROM acceptable, practical, and relevant to their practice.

Conclusions: The findings of the current feasibility study support progression to a larger and more definitive RCT.

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

KEYWORDS

Cluster RCT; behaviours that challenge; STOMP; SPECTROM staff training; adults with intellectual disabilities; psychotropic medicine; caregiver

Introduction

Overmedication of people with intellectual disabilities, particularly the off-license use of psychotropic medicines for behaviors that challenge, such as

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verbal aggression, physical aggression to others or property, or self-injury in the absence of a psychiatric diagnosis, is a significant public health concern (Mehta & Glover, 2019). To address this issue, NHS England (NHSE) in the UK initiated a long-term plan, "STopping Over-Medication of People with Learning Disabilities, Autism, or Both (STOMP)," 9 years ago (Branford et al., 2018). Despite this, the rate of psychotropic use has not changed much in the last three decades (Deb & Fraser, 1994). Around half (35–63%) of adults with intellectual disabilities continue to receive psychotropic medicines (Deb, 2024; Deb, Jarkovský, et al., 2025a; Song et al., 2023), primarily antipsychotics (24–-32%), whereas the prevalence of psychosis is 2–4% in adults with intellectual disabilities for which the antipsychotics are primarily licensed (Deb et al., 2022).

About 71–81% of antipsychotic prescriptions are off-license, as no severe mental illness is recorded. Instead, in over 50% of cases, they are prescribed for behaviors that challenge (Sheehan et al., 2015; de Kuijper et al., 2010; Deb, Jarkovský, et al., 2025a; Deb, Limbu, et al., 2025b). Long-term antipsychotic medicine use increases the risk of serious adverse effects such as sedation, constipation, obesity, diabetes, and metabolic syndrome, which can impair a person's quality of life (QoL) and reduce life expectancy (Ramerman et al., 2018; Sun et al., 2023). In one study, 84.4% of 99 adults with intellectual disabilities who displayed challenging behavior had at least one psychotropic-related adverse effect, and 45.6% had over three (de Kuijper et al., 2013). The same study also found extrapyramidal symptoms in 53%, overweight or obesity in 46%, and metabolic syndrome in 11% of participants among those treated with antipsychotics. Hyperprolactinaemia and one or more elevated bone turnover markers were present in 17% and 25% of cases, respectively (de Kuijper et al., 2013).

As support staff ask for medicine to control behaviors that challenge in the first place and are apprehensive about withdrawing inappropriate psychotropic medicine, training them to build their knowledge of psychotropics, skilling them up to address behaviors that challenge without using the medicine, and giving them the confidence to consider psychotropic withdrawal when appropriate could be a helpful strategy toward the reduction of overmedication and implementation of the STOMP objectives. To address these issues, we have recently co-produced in the UK an NIHR-funded SPECTROM (Short-term Psycho-Education for Carers to Help Reduce the OverMedication of People with Intellectual Disability) (https://spectrom.wixsite.com/project) training program for support staff to help reduce the overuse of psychotropic medicines among adults with intellectual disabilities (Deb, Limbu, et al., 2020a).

Training programs for staff and caregivers are effective in many neurodevelopmental disorders, such as autism (Deb, Retzer, et al., 2020b) and ADHD (Montoya et al., 2011). Two literature reviews, including ours (Deb & Roberts, 2005), found several small studies of staff training improving the management of behaviors that challenge in people with intellectual disabilities (Rose &

Gallivan, 2019). However, unlike SPECTROM, none of these training programs were specifically designed to reduce the overuse of psychotropic medicine in adults with intellectual disabilities.

The Banerjee report (Banerjee, 2009) recommended training care staff and prescribers in non-pharmacological approaches to behavior management in patients with dementia (Pan et al., 2014). Specific training for care staff achieved 40–50% antipsychotic dose reduction in patients with dementia (Fossey et al., 2006). It should, therefore, be possible to learn from this body of work and hopefully achieve a similar rate of antipsychotic reduction among adults with intellectual disabilities with appropriate intervention, such as the SPECTROM training.

Two pre- and post-training 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., 2021; Wilson et al., 2023). However, none of these were RCTs. Therefore, we conducted a feasibility RCT involving SPECTROM training. The current study aims to provide information on the feasibility of conducting a future large-scale clinical and cost-effectiveness randomized controlled trial (RCT) involving SPECTROM.

Method

The current study is a scoping exercise and a multi-center feasibility cluster randomized controlled trial (RCT).

The protocol paper (Limbu et al., 2025a) details the methodology. We followed the Consolidated Standards of Reporting Trials (CONSORT) extension to randomized pilot and feasibility trials guidelines (Eldridge et al., 2016) (see Supplementary materials). This study was approved by the West Midlands-Coventry & Warwickshire Research Ethics Committee, UK (REC reference: 23/WM/0211).

The study was conducted using the following five work packages (WPs).

WP 1 (months: 1–4): A stakeholder scoping workshop to assess the service provider organization's willingness to participate in the RCT.

WP 2 (months: 5–6): A feasibility cluster RCT. Each community home and supported living accommodations for adults with intellectual disabilities where at least one person received psychotropic medicine in different parts of England and Wales formed a cluster.

WP 3 (months: 7–12): Outcome data collection over 6 months. This involved primary outcome data in the form of anonymized psychotropic medicine prescriptions for adult residents in all the randomized community accommodations. The secondary outcomes included the assessment of the trainees' knowledge of psychotropic medicines using the PKQ-R

(Psychotropic Knowledge Questionnaire-Revised) (Wilson et al., 2023) and their attitude toward the behaviors that challenge using MAVAS-R-ID (Management of Aggression and Violence Attitude Scale-Revised-Intellectual Disabilities) (Deb et al., 2021) at baseline pre-training, and 4 weeks and 6 months post-training only in the intervention arm. The emphasis was on the four-week follow-up data, but we also included six-month follow-up data to assess any attrition over time and to evaluate any early score gains.

WP 4 (months: 13–15): A mixed methods process evaluation to assess SPECTROM intervention fidelity, barriers and promoters of future implementation, positive and negative aspects of participating in training, acceptability, practicality, and relevance of the intervention to trainee's day-to-day practice. This included focus groups with a purposive sample of SPECTROM training participants and an online questionnaire survey using the TFQ (Trainee Feedback Questionnaire) (Deb et al., 2021) (see Supplementary material), which was sent to all trainees. We also sent the control arm participants an online questionnaire (see Supplementary material) to assess contamination.

WP 5 (months: 16–18): Dissemination workshop to disseminate the project findings and plan for a future large-scale RCT.

The following feasibility outcomes were assessed in the study.

- Acceptability of the SPECTROM training intervention to the users (trainees).
- Adherence to the intervention (SPECTROM training).
- Ways to ensure representative recruitment and engagement and the organization's methods of identifying potential participants.
- The number of available eligible support staff and adults with ID who can take part in the future definitive RCT.
- The willingness of the staff to be randomized.
- The willingness of the service provider organizations to randomize their staff for SPECTROM training.
- Collect psychotropic prescription data from each house remotely and anonymously.
- Collect data for a sample size calculation.
- The choice of an adequate comparator.
- Follow-up rates, response rates to questionnaires, adherence/compliance rate, and intra-cluster correlation (ICC).
- Contamination between the trial arms.
- Time needed to collect, clean and analyze data.
- Practicality of delivering the intervention (SPECTROM training) in the proposed setting (community homes and supported living accommodations for adults with intellectual disabilities).

- Variation in the intervention delivery (SPECTROM training) in each setting.
- Patient and Public Involvement (PPI).

Recruitment and Participants

Support staff, service managers, and trainers within social service provider organizations that support adults with intellectual disabilities in community settings were eligible for participation. A senior manager in each organization approached the trainers and service managers within their respective organizations, who subsequently approached the staff team they supervised for recruitment and randomization. Each service manager was asked to choose a staff team from only one community home/supported living accommodation where at least one adult with intellectual disabilities received psychotropic medicine.

Intervention

The intervention in the current study was the SPECTROM training program, a hybrid/blended learning platform featuring numerous online resources complemented by face-to-face training. The training was delivered to service managers, their staff teams, and the organization's trainers. SPECTROM comprises 14 modules, along with internal and external resources. Two of these 14 modules were used for face-to-face training, through which the other modules and resources were introduced. These two core modules are (a) Medicine/STOMP and (b) Alternatives to medication (ATM). These two core modules were delivered online in two 4-hour sessions. All trainees were required to attend both core module sessions. They were also encouraged to explore the SPECTROM online resources and use SPECTROM tools in their day-to-day practice.

Data Analysis

As the study was not powered, we did not conduct any hypothesis testing using the primary outcome data on the psychotropic prescription rate and dose reduction. Instead, we used descriptive analysis to calculate the proportion of decrease in total dose and to identify where any dose reduction was achieved in both the training and non-training groups at 6-months post-training. To calculate the total dose reduction at the six-month follow-up, we converted the dose of antipsychotic medicines to a risperidone equivalent daily dose where possible. Similarly, we converted the antidepressant medicine dose to citalopram equivalent daily dose to calculate the total dose reduction at

follow-up. These data were used to calculate the sample size for a future large-scale RCT.

We analyzed the pre- and post-training scores of the PKQ-R at 4 weeks and 6 months and the MAVAS-R-ID at 4 weeks post-training using the Wilcoxon signed-rank paired test, as the data were not normally distributed. MAVAS-R-ID data were normally distributed at 6 months and were analyzed using paired samples t-test. To mitigate Type II errors, we applied a Bonferroni correction to the item-level analysis of PKQ-R scores ($p = .0025$) and the domain-level analysis for MAVAS-R-ID ($p = .01$). Changes over time were analyzed from participants who had complete data at all three time points (baseline at pre-training, 4 weeks and 6 months post-training) on PKQ-R and MAVAS-R-ID scores. Friedman's test with a post hoc analysis using the Wilcoxon signed-rank test and a Bonferroni adjustment of 0.017 was used to analyze changes over time for the PKQ-R score. Repeated ANOVA was used to analyze the MAVAS-R-ID score over time.

We analyzed TFQ data using descriptive statistics to determine the number and percentage of responses for each item in the scale. We analyzed focus group data using a framework analysis method (Gale et al., 2013). We used NVivo 12 Plus software (Lumivero, 2017) to assist with data coding. Two raters (BL and CV) independently coded the data to enhance the consistency of the findings. A topic guide facilitated the focus groups with support staff and service managers (see Supplementary material). All focus groups and interviews were conducted online, recorded digitally and transcribed verbatim.

Planned Procedures and Changes to Procedures

We planned to collect PKQ-R and MAVAS-R-ID data at baseline, as well as at 4 weeks, 3 months, and 6 months post-training. However, we were unable to collect data at the three-month follow-up due to staff workload and capacity constraints.

We also planned to assess SPECTROM resource use through a monthly log. However, due to staff time constraints, this was not possible. Instead, we collected SPECTROM resource utilization data through TFQ. The TFQ was sent to all participants in SPECTROM training 6 months after training. Information on SPECTROM resource utilization was also collected during the participant focus groups.

We planned a focus group with service managers in the control arm who did not receive SPECTROM training to assess contamination, specifically to determine whether the participants in the control group received any information on SPECTROM or accessed any of its resources. However, service managers declined to participate in this focus group due to a lack of capacity. Therefore, we gathered contamination-related information using a purpose-

deigned questionnaire, asking the participants if they had access to or knowledge of any SPECTROM training materials and resources (see Supplementary material). This online questionnaire was sent to all in the control group.

We planned to conduct semi-structured interviews with adults with intellectual disabilities who resided in community homes where staff received SPECTROM training, as well as their families, to understand their experiences and capture the impact of the training on staff's practice, particularly in interactions with adults with intellectual disabilities and their families. However, although adults with intellectual disabilities successfully contributed to the research through the Intellectual Disabilities Advisory Group (IDAG), service managers were unable to identify adults with intellectual disabilities and their families to participate in the interviews.

Results

Progression Criterion

The progression criterion was to recruit from more than 60% of the service provider organizations approached. This criterion was met as we recruited from six of the eight service provider organizations we approached (75%).

Acceptability of SPECTROM Training

This was measured using TFQ and focus group data. The qualitative analysis of focus group data with a purposive sample of service managers and support staff trained in SPECTROM revealed that the trainees found the training to be acceptable, applicable, practical, and relevant to their practice. The training also helped to improve staff's (a) self-reflection, (b) confidence in dealing with behaviors that challenge without using medicines, (c) knowledge of psychotropic medicines and their side effects, (d) empowered them to advocate on behalf of the adults with intellectual disabilities they support, and (e) improved the support they provided for people with intellectual disabilities (Limbu et al., 2025b). Of the 89 participants who completed TFQ, 93% found the training helpful, 94% reported a better understanding of psychotropic medicine use, 93% reported a better understanding of behaviors that challenge, 90% reported improvement in their day-to-day practice, and a similar proportion improved their engagement with people they support and their families as a result of the training (see Table 1).

Adherence to SPECTROM Training and Resources

This was measured using TFQ and focus group data. The fidelity rating of two raters' video recordings of training sessions delivered by a trainer (BL + SD) using a structured questionnaire showed good adherence to the training protocol. Whereas 140 trainees attended the required number of training sessions,

Table 1. Trainee feedback questionnaire (TFQ) (n=89).

Question	Yes, N (%)	No, N (%)
Q1. I have found the training and resources useful to my everyday practice.	83 (93%)	6 (7%)
Q2. I often use/check the information available in SPECTROM while discussing the care planning of people I support.	73 (82%)	16 (18%)
Q3. I now better understand psychotropic medications and their use in people with intellectual disabilities.	84 (94%)	5 (6%)
Q4. The training has helped me make more informed decisions about when and when not to use psychotropic medication.	83 (93%)	6 (7%)
Q5. I now understand better the side effects of psychotropic medications.	85 (96%)	4 (4%)
Q6. I now better understand why some people show behaviors of concern (behaviors that challenge/challenging behavior).	83 (93%)	6 (7%)
Q7. I now understand better the medication review and withdrawal process.	84 (94%)	5 (6%)
Q8. I have visited the SPECTROM website.	66 (74%)	23 (26%)
Q8a. How often did you visit the SPECTROM website and what did you explore?	Ranged from once to very often, and mainly for its resources, and medication information.	
Q9. Our team has used the STOMP action planning review checklist (STAR)/ Medication review checklist in SPECTROM.	61 (71%)	25 (29%)
Q9a. If you used SATR/Medication review checklist, how many clients have you completed this for?	Ranged from none (staff used as practice) to seven service users	
Q9b. Did the STAR review lead to a medical medication review?	34 (63%)	20 (37%)
Q9c. Did the medical review lead to a reduction in psychotropic medicine?	35 (65%)	19 (35%)
Q10. Our team has used CATS (trigger checklist).	41 (53%)	38 (48%)
Q10a. If you have used CATS (trigger checklist), how many clients have you completed a CATS for?	Ranged from none to seven service users.	
Q10b. Did CATS help with completing ABC charts?	37 (95%)	2 (5%)
Q11. Our team has used MOAS.	32 (43%)	43 (57%)
Q11a. How many clients have you completed the MOAS for?	Ranged from none to seven service users.	
Q12. Our team has used CC-QoLS (Quality of Life Scale).	44 (59%)	30 (41%)
Q12a. For how many clients have you administered the CC-QoLS (Quality of Life Scale)?	Ranged from none to six service users.	
Q13. Our team has used the accessible psychotropic medication leaflets.	44 (59%)	30 (41%)
Q13a. If you have used the accessible psychotropic medication leaflets, for how many clients have you used this and how often?	Ranged from none to six service users.	
Q13b. Did it help with the shared decision-making involving the person you support and their families?	35 (81%)	8 (19%)
Q14. I feel that my practice has improved.	66 (90%)	7 (10%)
Q15. My attitude to behaviors of concern has changed for the better.	70 (96%)	3 (4%)
Q16. I now engage with people I support more effectively.	69 (95%)	4 (5%)
Q17. I now communicate with people I support more effectively.	69 (95%)	4 (5%)
Q18. I now engage with the families of people I support more effectively.	67 (92%)	6 (8%)
Q19. I now engage more effectively with multidisciplinary team members, such as doctors, psychiatrists, nurses, etc.	62 (85%)	11 (15%)

four-hour online sessions on core modules 1 and 2, five additional trainees completed only one of the two core modules. This provides an adherence figure of 97%. A high proportion of trainees used SPECTROM resources and tools after the training. For example, according to TFQ data (see Table 1), 71% of trainees utilized the STAR review resource, which led to a formal medicine review by doctors in 63% of these cases, resulting in a reduction in inappropriate medicine use in 65% of these cases. Similarly, 53% of trainees used the Comprehensive Assessment of Triggers for Behaviours of Concern Scale (CATS) (Limbu et al., 2021). Additionally, 43% of trainees used the MOAS (Modified Overt Aggression Scale) (Ratey & Gutheil, 1991), 59% used the CC-

QoLS (Caregiver's Concerns-Quality of Life Scale) (Unwin & Deb, 2014), and 59% utilized accessible psychotropic medicine leaflets.

Recruitment of a Representative Sample

To ensure a representative sample, we recruited through both large and small service provider organizations from a wide geographic area in England and Wales, including urban, rural, affluent, and deprived regions.

Willingness of Staff to Be Randomised

Our target was to randomize support staff and service managers from at least eight clusters (community homes and supported living accommodations for adults with intellectual disabilities where at least one resident is prescribed psychotropic medicine). We eventually randomized staff and service managers from 39 community homes and supported living accommodations instead of a minimum of eight. Assuming an average of 10 support staff in each community home (cluster), our target was to train at least 80 support staff and service managers. We eventually trained 140 support staff and service managers. The enthusiasm for participating in the project and being randomized varied from service manager to service manager and their staff teams. The demographic characteristics of staff that were randomized to the SPECTROM arm are presented in Table 2. The questions were optional, and some participants declined to answer them.

Willingness of Organisations to Randomise Their Staff

Our target was to recruit from at least four social service provider organizations. We eventually recruited from six. The enthusiasm of service provider organizations for recruiting and randomizing their staff for the project varied.

Randomisation

Initially, we considered randomizing the clusters in a 1:1 ratio between the SPECTROM training and the control group. However, we eventually decided to randomize using a 2:1 ratio so that for each community home in the control arm, we recruited two in the SPECTROM training group to increase the number of participants in the training. Participants were randomly assigned (2:1) remotely and blindly by the study statistician to receive SPECTROM training along with the organization's standard training or the organization's standard training alone but not the SPECTROM training using a random number generator. However, gathering written consent from all staff in each community home in the control arm was not always possible.

Table 2. Demographic data of managers and support staff randomized to SPECTROM training arm.

Service managers			n response
Gender	Male	4	16
	Female	12	
Age	Mean	40	16
	Range	27–68 years old	
Highest Qualification	Graduate degree or above	8	15
	National Vocational Qualification	7	
Number of years of experience	Mean	7 years	16
	Range	2.5–31 years	
Level of staff	Service managers	15	16
	PBS practitioner	1	
Support staff			**n response**
Gender	Male	56	123
	Female	67	
Age	Mean	39 years old	117
	Range	18–72 years old	
Highest Qualification	Graduate degree or above	52	113
	National Vocational Qualification	47	
	School leavers	13	
	Studying	1	
Number of years of experience	Mean	6 years	113
	Range	0 months to 40 years	
Level of staff	Support Staff	100	124
	Deputy	9	
	Senior	15	

Outcome and Its Characteristics

The primary outcome measure used in this study is the change in psychotropic medicine dose, particularly antipsychotics, 6-month post-SPECTROM training. The baseline and six-month follow-up psychotropic prescription data were successfully collected remotely and anonymously. Service managers supplied the information to the researcher anonymously.

Psychotropic prescription data were available at baseline and six-month follow-ups for 43 antipsychotics in the SPECTROM training and 31 in the non-training group, for whom a risperidone equivalent daily dose could be calculated for all antipsychotics. There was a 7.5% reduction in the total group dose in the SPECTROM training group at follow-up compared with a 2.7% dose reduction in the non-training group. At follow-up, antipsychotic dose reduction was observed in eight of 43 (18.6%) prescriptions in the SPECTROM training group compared with two of 31 (6.5%) in the non-training group (Deb, Limbu, et al., 2025b).

Data were available for 10 antidepressant prescriptions in the SPECTROM training and 22 in the non-training group at baseline and 6-month follow-up for whom a citalopram equivalent daily dose could be calculated for all antidepressants. In the SPECTROM training group, the total daily citalopram equivalent dose of antidepressants was reduced by 2.4% at follow-up compared with a 1.2% dose reduction in the non-training group. At follow-up, there was a reduction in antidepressant dose in one of ten (10%) prescriptions

in the SPECTROM training group compared with 1 of 22 (4.5%) in the non-training group (Deb, Limbu, et al., 2025b).

The secondary outcome measure, PKQ-R, was completed by 126 trainees at baseline and within 4 weeks of SPECTROM training. There were less than 2% missing data in the 4 weeks and 1% in the 6-month PKQ-R and MAVAS-R-ID. All available data were analyzed without exclusion. The PKQ-R total score showed statistically significant post-training improvements ($p < .001$) at 4-week post-training, with a large effect size ($r = 0.84$) (Kerby, 2014). There was a post-training improvement at 4 weeks in PKQ-R scores for 42 of the 43 questions (97.7%), with 22 statistically significant differences ($p < .001$) (Limbu et al., 2025b). At 6 months, the total PKQ-R scores showed a statistically significant improvement compared with the baseline pre-training score ($p < .001$) and no statistically significant drop in score compared to the four-week follow-up data (see Figure 1). This indicates that the gains in knowledge at 4 weeks post-training were maintained at 6 months. The MAVAS-R-ID was completed at baseline and within 4 weeks of training by 125 trainees. The MAVAS-R-ID total score showed statistically significant post-training improvements ($p < .01$) at 4-week post-training, with a moderate effect size ($r = 0.35$) (Kerby, 2014). Individual domain score analysis showed a statistically significant improvement in one of the five domains related to attitude regarding the use of medicine for behaviors that challenge (Limbu et al., 2025b). The change-over-time analysis revealed a significant difference in mean scores across three different time points ($p < .001$) (see Figure 2).

Choice of Adequate Comparator

This was achieved by ensuring that both randomized groups received their organization's standard training as usual. Thus, the comparison was between SPECTROM training and the organization's regular training versus the organization's usual training without additional SPECTROM training. We also ensured that there was no contamination in the control group by sending them an online questionnaire, which confirmed that no staff in the control group had accessed or were aware of the SPECTROM training program and its online resources.

Follow-Up Rates, Response to Questionnaires, Adherence and Compliance

There was no attrition in the anonymized psychotropic prescription data collection at the 6-month follow-up, which was the primary outcome of the project. Of those who participated in the SPECTROM training, 90% completed PKQ-R and MAVAS-R-ID questionnaires at the 4-week follow-up and 33.6% at the 6-month follow-up. Of those who participated in the SPECTROM training, 63.6% completed TFQ at the 6-month

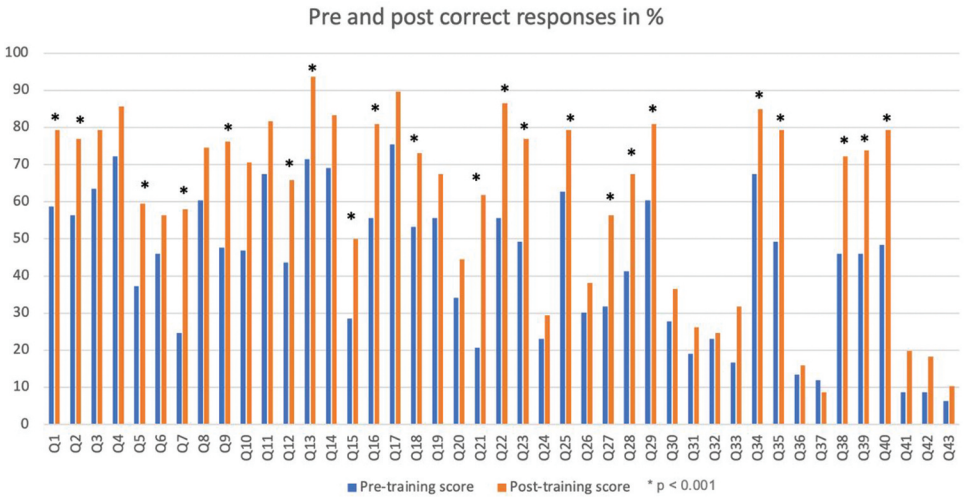

Figure 1. PKQ-R correct answers pre and four weeks post-training in %

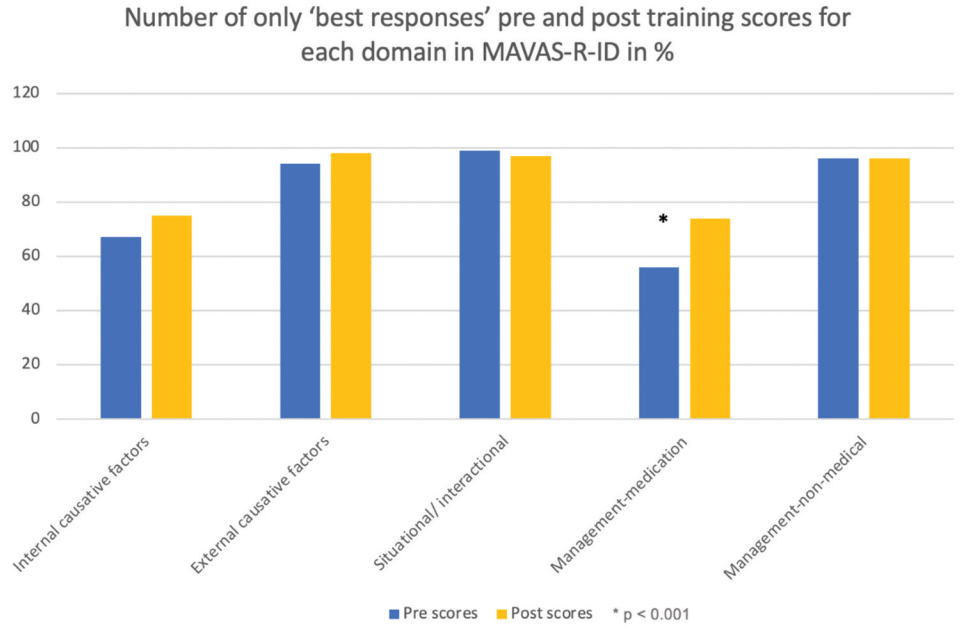

Figure 2. Number of only "best responses" pre and four weeks post training in % for each domain in MAVAS-R-ID. A higher "disagree" score for internal causative factor and management-medication, and a higher "agree" score for external, situational/interactional causative factors, and management non-medical mean an improvement in staff attitude toward Behaviours that Challenge and the person with intellectual disabilities. *p = <0.001

follow-up. However, the researcher required much tracking of the participants to collect questionnaire data. The main reason was that the researcher was unable to travel to all community homes as they were

scattered throughout England and Wales. Therefore, she collected data online, which required considerable effort. Also, in many cases, the researcher did not have access to the e-mails of the support staff who received training. So, for many of these participants, the researcher had to rely on their service managers to forward the questionnaires to their staff teams for completion.

Calculation of Sample Size and ICC

One of our feasibility aims was to calculate the sample size for a future large-scale randomized controlled trial (RCT) using data derived from the current study, which we successfully achieved. This was based on the rate of antipsychotic medicine dose reductions in the training group compared with the non-training group. In the training group, 19% of cases achieved an antipsychotic dose reduction at the 6-month follow-up, compared with 6% in the non-training group. The intra-cluster correlation (ICC) was 0.124. Based on these proportions in the two groups, the project statistician calculated that, at 90% power and 5% significance, a sample size of 134 participants (adults with intellectual disabilities) per group would be required. Using an ICC of 0.124 and a cluster size of 2.5 adults with intellectual disabilities prescribed psychotropic medicine in each cluster (community home/supported living accommodation), we will require 159 participants in each arm. This equates to 64 clusters (159/2.5) in each arm, totaling 128 clusters. Although there was no attrition in collecting prescription data at the 6-month follow-up in the current feasibility study, we have allowed for 15% attrition in our sample size calculation. Hence, the sample size consists of 152 clusters ($n = 380$ adults with intellectual disabilities) for a future large-scale randomized controlled trial (RCT).

Time to Collect, Clean and Analyse Data

The primary outcome of the current study was the collection of anonymized prescription data remotely. These data could be collected on time, albeit requiring the researcher to chase the service managers several times. The secondary outcome measure data collection, conducted at 6 months using the PKQ-R and MAVAS-R-ID, was slightly delayed and required considerable follow-up from the researcher. We envisage that, as we plan to involve trainers from participating organizations to train their own staff teams in the future RCT, they will be able to help collect data on time, primarily using Qualtrics, which staff can access through their mobile phones. This was not possible in the current study as the researcher did not have access to the e-mail addresses of many staff members. Therefore, the researcher relied on the service

managers to distribute the questionnaires to their staff teams and collect the data in a timely manner. However, once the primary and secondary outcome data were collected, they were cleaned and analyzed within the allocated time without any delay.

The Practicality of Delivering the SPECTROM Training within Community Homes

As we recruited participants from a wide geographic area in the UK, we decided to deliver the training online to save staff time and expenses. In the future, the plan is for the organization's trainers to roll out the training to their staff teams. This will provide them with flexibility. They could deliver the session online or in person by integrating SPECTROM training within the organization's existing training program.

Variation in Delivery in Each Setting

In the current study, we planned to train service managers and trainers to roll out the training to their staff teams. However, despite enthusiasm from some service managers, this was not possible. However, when we trained a trainer in one organization, she successfully delivered the training to the staff team. Therefore, we decided that, in the future, for large-scale RCT, the research team should train the trainers to roll out the training to their staff teams. In the current study, we delivered training in two 4-hour sessions. However, many trainees preferred to have the training delivered over a shorter time span in several sessions. Although this could not be achieved in the current study due to time constraints, it could be implemented in a future RCT, given the involvement of the organization's own trainers, who would have more flexibility in terms of time and the method of SPECTROM training delivery.

Discussion

The current feasibility study successfully met all feasibility goals, and the findings indicate that a large-scale randomized controlled trial (RCT) is feasible. The study showed (a) that adequate recruitment was possible and (b) that the attrition rate was low for collecting the primary outcome data on antipsychotic dose at follow-up. Although the attrition rate for the secondary outcome measures of PKQ-R and MAVAS-R-ID data was acceptable at the four-week follow-up, which was the study's main aim, this was high at the six-month follow-up. However, in future RCTs, we envisage this rate to be much lower due to the direct involvement of the organizer's own trainers in rolling out the training and also helping to collect data. We have also factored in a reasonable attrition rate in our sample size calculation to mitigate against potential attrition. It was possible to involve adults with intellectual disabilities and their families in the research. However, it was not possible to recruit them for interviews.

Data were collected, cleaned and analyzed on time. Additionally, a sufficient number of organizations were willing to recruit and randomize participants, although enthusiasm to participate varied from organization to organization. For example, larger organizations with more resources and a greater commitment to implementing the STOMP program were more enthusiastic than smaller organizations with fewer resources, which were not fully committed to implementing the STOMP initiative. Similarly, there was variable enthusiasm among the service managers and staff teams to participate and be randomized.

An adequate number of support staff and service managers were willing to participate in the study and were randomized. However, despite the service manager's consent, difficulties were encountered in obtaining consent from all staff in the control group. Again, we envisage this to improve when their own trainers approach service managers and staff for recruitment and consent.

The SPECTROM training demonstrated a positive impact on both primary (psychotropic medicine dose reduction) and secondary outcome measures (PKQ-R and MAVAS-R-ID, which assess gains in trainees' knowledge of psychotropic medicines and improved attitudes toward behaviors that challenge). The early improvement in the PKQ-R score at 4 weeks was maintained at 6 months. The adherence rate of 97% of those who participated in both required training sessions was high. The rating of the trainer's video-recorded training sessions showed good adherence to the training protocol. The trainee feedback showed a high level of satisfaction with the training, which improved their knowledge of pharmacological and non-pharmacological management of behaviors that challenge and made them more confident in dealing with such behaviors without relying on medication. They also found the training acceptable, practical, and relevant to their practice. The trainee feedback also showed a high level of adherence to accessing and using SPECTROM resources in their daily practice.

Barriers to Implementing SPECTROM Training

The primary barrier to implementing the training is the limited time and capacity of the staff and their managers. This was overcome by many with their enthusiasm to participate. It was felt that unless the training is made mandatory, there will always be some reluctance to participate. As the training has cost implications for the organizations, it requires the highest level of commitment from the organization's board of Directors. There has to be something in it for both the organizations and the staff. Organizations are expected by their regulators and paymasters to put a strategy in place to implement the NHS England STOMP initiative, and SPECTROM training will support this effort. The training will enhance the staff's professional development, enabling them to provide

better support to adults with intellectual disabilities and improve their quality of life.

Plan for the Future Large-Scale, More Definitive RCT

The plan for future large-scale RCTs is for the research team to train trainers within the organization to roll out the training among staff teams. This will have several advantages. As trainers are known to the staff, this will facilitate the recruitment, consent, and collection of outcome data. Trainers could be flexible regarding the setting, timing, and training delivery method that suits the staff. As trainers are familiar with the organization's current training program, they can avoid overlap and integrate SPECTROM training within its existing framework. We have initiated discussions with numerous service provider organizations for future RCTs, and 12 organizations have already agreed to assist with recruitment. Among them, they provide service in more than 1000 community homes in the UK. This number will likely increase as we continue to discuss and negotiate with many more organizations. We will recruit through both large and small service provider organizations from vast geographic areas in England, Wales, and Scotland, including urban and rural, as well as affluent and deprived areas of the country, to ensure the recruitment of a representative sample.

In the future RCT, the primary outcome will be an improvement in the QoL of the person with intellectual disabilities through a reduction in the antipsychotic medicine dose, which will lead to a reduction in side effects. Therefore, QoL measures such as EQ-5D-3 L (Dolan, 1997) and CC-QoLS (Unwin & Deb, 2014) will be used in conjunction with psychotropic medicine data to compare scores at baseline and at 10- and 18-month follow-ups. We will use two follow-up points to assess the proportion of cases in which initial antipsychotic dose reduction fails and results in the re-reinstatement of these medications.

Strengths and Limitations

This study suggests that a future large-scale randomized controlled trial (RCT) involving SPECTROM training is feasible. The primary outcome measure showed that the training had a positive impact on reducing antipsychotic medication doses without increasing antidepressant medication doses. Similarly, the secondary outcome measures showed that the training helped improve staff knowledge of psychotropic medicines and their attitude toward addressing challenging behaviors without relying on medication. The focus group and online questionnaire survey revealed that the trainees appreciated the training and found it beneficial. They also used many SPECTROM resources after the training.

Although some protocol variations occurred, they did not impact the primary feasibility outcomes and could be addressed in a future

randomized controlled trial (RCT). We were unable to collect patient-related health data, such as quality of life measure scores, due to ethical restrictions, including the requirement for patient consent to gather these data. We hope to overcome this problem by involving the organization's trainers in data collection and consenting. As we have limited time and resources for this feasibility study, we had to restrict the number of staff teams each service manager can recruit for participation. This was subjected to selection bias. However, most service managers supported only one staff team, thus eliminating this potential bias in most cases. In a future large-scale RCT, we should be able to randomize all consented staff teams, avoiding any selection bias.

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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 collected and analyzed data. 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.

Data Availability Statement

The research team, steering committee and the sponsor's research and development department 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.

Informed Consent Statement

All participants provided written consent before inclusion in the study.

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).

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