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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

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WP 1: Stakeholder scoping workshop

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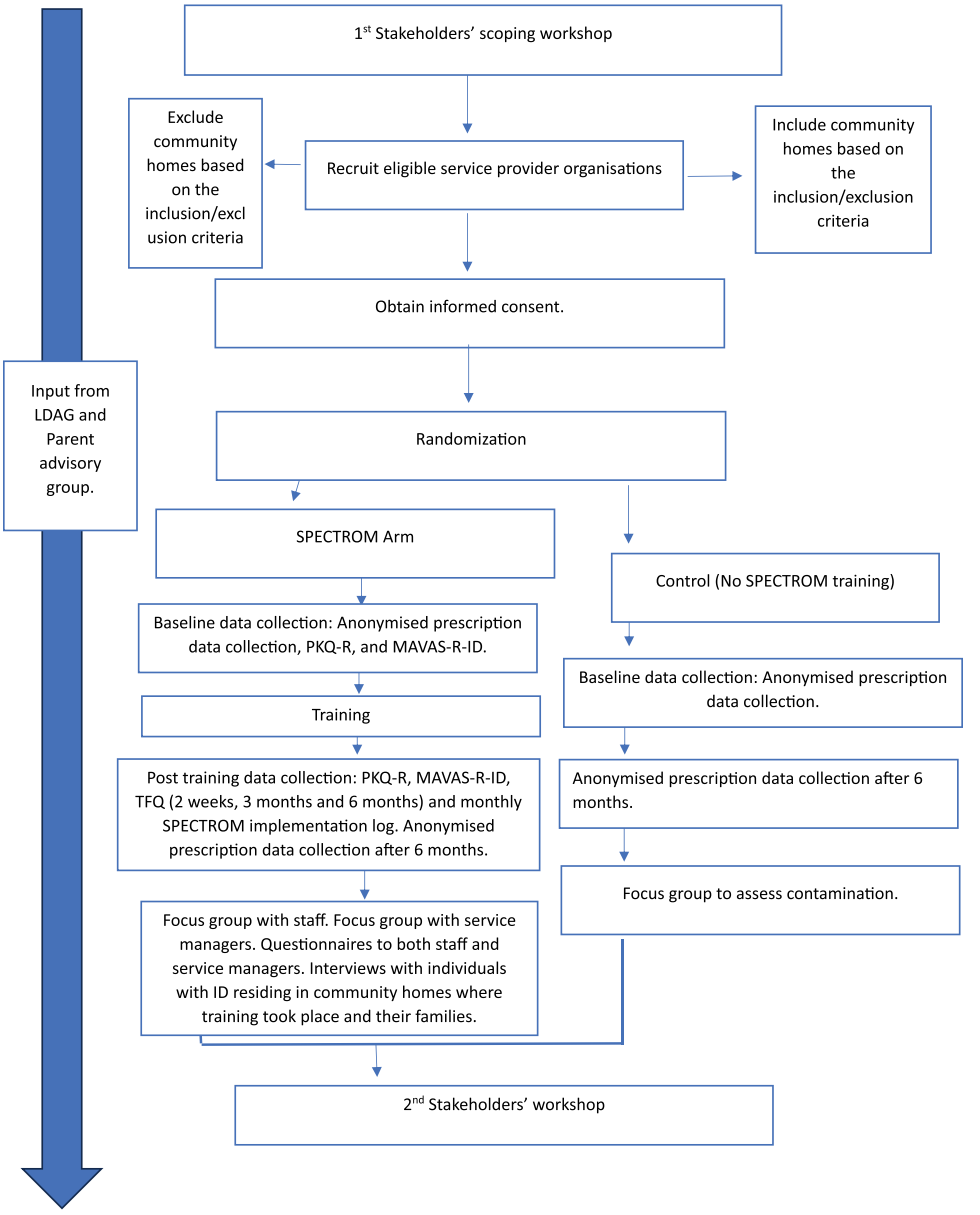

Figure 1. Flow diagram illustrating the sequence of work packages and participant flow.

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WP 2: Feasibility cluster rct

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WP 3: Follow-up data collection

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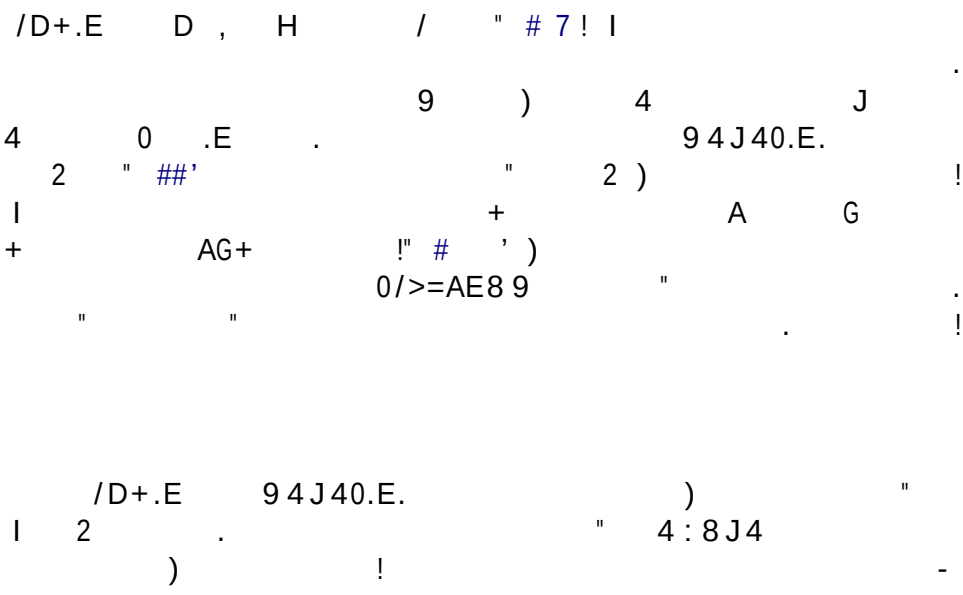
Assessment	Study period										
	Screening	Baseline	Week 1	Week 2	1 M (Month)	2 M	3 M	4 M	5 M	6 M	7 M
Eligibility screen	A										
Informed consent	B										
Randomization/ allocation	B										
SPECTROM Intervention			I								
Demographics		I									
PKQ-R		I		I			I			I	
MAVAS-R-ID		I		I			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.



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WP 4: Process evaluation

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Data collection and analysis

Questionnaire survey

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WP 5: Dissemination workshop

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Progression criteria

Data management and confidentiality

Dissemination plans

Discussion

Acknowledgments

Disclosure statement

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Author contributions

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Data availability statement

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Trial registration

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References

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