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Care coordinator delivered method of levels therapy to improve engagement and other outcomes in early psychosis (CAMEO): A feasibility cluster-randomised controlled trial

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ABSTRACT

The Method of Levels (MOL) is a theoretically-informed, transdiagnostic cognitive therapy that could improve service user engagement and recovery for individuals with early psychosis. We aimed to assess the feasibility and acceptability of training care coordinators in early intervention in psychosis teams to deliver MOL, and to assess the feasibility of conducting a two-arm parallel-group cluster-randomised controlled trial (C-RCT) with randomisation at the level of teams. Randomisation was in a ratio of 1:2 to either (1: control) treatment as usual (TAU); or (2: intervention) TAU plus support from a care coordinator who has received training in MOL. Clinical and health economic outcomes were collected at baseline, three, and six months. Fourteen early intervention in psychosis teams (117% of target), 31 care coordinators (129% of target), and 49 service users (51% of target) were recruited. Results suggest that some aspects of this study are feasible in their current form (e.g., care coordinator recruitment), other aspects are likely to be feasible with relatively minor adjustments (e.g., service user retention), and some aspects would need substantial changes to make the delivery of an evaluation C-RCT feasible (e.g., service user recruitment; MOL supervision for care coordinators). Progression to an evaluation trial would be justified if plausible solutions can be found to address the feasibility issues identified in this study.

1. Introduction

The term 'psychosis' refers to hearing and seeing things that others cannot ('hallucinations'), holding beliefs that others might find unusual ('delusions'), difficulties thinking clearly ('thought disorder'), and problems with motivation or self-care ('negative symptoms') [1]. Without appropriate and timely support, psychosis can lead to negative personal, familial, social, and economic outcomes [2–6]. Early intervention in psychosis (EIP) services, therefore, seek to promote recovery and improve outcomes for people experiencing early psychosis through evidence based interventions [7,8].

Although EIP services aim to work with people for up three years after experiencing a first episode of psychosis, an estimated 12–54% of service users disengage before reaching this point [9–11]. Service users who discontinue their contact with EIP services prior to the planned three years are unable to benefit from the evidence-based interventions offered by these teams [7]. Calls have, therefore, been made to address the issue of disengagement from EIP services [12].

Care coordinators represent the largest staff group working in UK EIP services and have the most frequent and sustained levels of contact with

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service users. There is no specific training for the role of care coordinator, but these practitioners typically have a core professional qualification in nursing, social work, or occupational therapy and lead care planning and biopsychosocial interventions designed to support personal recovery [8]. There are some similarities between care coordinator roles in the UK and case management roles in North America, although the latter role typically has a greater emphasis on care brokerage. There is evidence that the effectiveness of EIP services is contingent on the quality of the relationship that exists between service users and care coordinators [13–15]. Currently, however, there is no systematic programme of training for care coordinators that is designed to enable them to maximise the therapeutic impact of their role. Improving the quality of contacts between care coordinators and service users could make EIP services more effective and helpful and reduce rates of disengagement.

The Method of Levels (MOL) [16,17] is a transdiagnostic cognitive therapy that applies principles derived from a theory of human behaviour called Perceptual Control Theory (PCT) [18]. Practitioners delivering MOL aim to help people resolve distressing internal conflicts that are thought to maintain distress by following two goals [16]. First, encourage the service user to talk freely about a problem. Second, look out for signs of 'disruptions' and ask about these when they occur. Disruptions are verbal and non-verbal signs that the person's awareness has drifted from the topic of conversation onto potentially relevant background thoughts. Examples include pausing, laughing, changes in facial expression, or evaluative comments (e.g., "That might sound strange to you.") In practice, a service user is invited to talk about any problem that is troubling them. The practitioner then encourages the person to keep discussing the problem in detail. Periodically, the practitioner will draw the service user's attention to potential 'disruptions' and ask about these. Should the disruption prove to be relevant to the problem being explored, the practitioner will shift the focus of their questions onto this new aspect of the problem and encourage the service user to keep discussing this. Practitioners sustain people's awareness of conflicts by following these two goals iteratively to support the process of 'reorganisation', restoring effective control and reducing levels of distress. From a PCT perspective, this is thought to be the effective component of all psychotherapeutic interventions [19].

MOL has now been evaluated in a variety of service contexts, including primary and secondary care psychology services, school counselling services, and mental health inpatient settings [20–23]. A recent mixed-methods study evaluated the feasibility of conducting a randomised controlled trial that compared treatment as usual (TAU) with TAU plus MOL delivered by a psychological therapist for people experiencing first-episode psychosis. Findings suggested that both the study design and MOL intervention were acceptable and feasible [24–26]. It has been argued that MOL could be a particularly helpful approach to psychotherapy for people experiencing psychosis [27,28].

Evidence suggests that while it is possible to train care coordinators to deliver psychosocial interventions [29], highly protocolised interventions using conventional cognitive behavioural therapy (CBT) approaches have been challenging to implement [30,31]. Unlike conventional CBT, in MOL, each session is a discrete problem-solving exercise. Therefore, it is possible that care coordinators could find it easier to implement alongside other aspects of their role. Care coordinators could use MOL for a proportion of their contact time to help service users explore whatever problem they consider to be the priority. The flexibility of MOL means that service users can engage with the approach whenever they decide it would be helpful. Unlike most CBT-informed interventions, MOL does not require service users to commit to a set number of sessions or engage with a longer-term treatment protocol. This provides flexibility both in terms of session content and mode of delivery. Part of the rationale for training care coordinators in MOL is that these practitioners have the most frequent and sustained contact with service users when accessing support from EIP services. The aim in training care coordinators in MOL would be to supplement, rather than replace, interventions delivered by specialist psychological professionals working in EIP teams. Additionally, service users report that what they value about EIP services is the ability to talk openly to their care coordinator in an atmosphere of trust [14,32]. Being encouraged to talk openly about problems is what people experiencing psychosis report is helpful about MOL [26]. Providing service users with an opportunity to resolve difficulties at an early stage during routine appointments with their care coordinator could also reduce the subsequent use of expensive crisis and inpatient services. MOL could, therefore, have advantages over existing approaches to care coordinator-delivered psychosocial interventions.

2. Aims and objectives

This study aimed to assess the feasibility of training care coordinators to deliver MOL, to understand whether this approach might improve service user engagement and recovery for individuals experiencing psychosis compared to TAU, and to assess the feasibility of conducting a cluster-randomised controlled trial (C-RCT) with randomisation at the level of teams.

Specific feasibility objectives were as follows:

1. To determine the feasibility of recruiting and retaining participants (care coordinators and service users) in a C-RCT comparing the effects of MOL-trained care coordinators versus treatment as usual on outcomes (engagement and recovery) for people experiencing first episode psychosis.
2. Establish the acceptability of the MOL training programme amongst care coordinators and of MOL delivered by care coordinators amongst service users.
3. Identify barriers and facilitators to MOL delivered by care coordinators.
4. Refine the MOL training programme and implementation plan based on participant feedback.
5. Generate further evidence on the promise of the intervention via estimates of effectiveness on key outcome measures.
6. Establish the most appropriate primary outcome measure for a definitive trial.
7. Estimate key parameters to inform a sample size calculation for a definitive trial.
8. To determine the feasibility of conducting an economic evaluation of MOL as part of a full C-RCT.

Feasibility objectives and outcomes results are presented in Table 1.

3. Methods

3.1. Design

A feasibility parallel-group C-RCT design with two arms: (1: control) TAU; (2: intervention) TAU plus support from a care coordinator who has received training in MOL. Randomisation took place at the level of EIP teams with an allocation ratio of 1:2 in favour of the intervention arm. The decision to conduct a feasibility study was informed by the MRC guidance on developing and evaluating complex interventions [33].

3.2. Study setting

The study was conducted within EIP services based in three National Health Service (NHS) mental health trusts in the Northwest of England: Greater Manchester Mental Health NHS Foundation Trust (GMMH), Lancashire and South Cumbria NHS Foundation Trust (LSCFT), and Mersey Care NHS Foundation Trust (MCFT).

Table 1
Feasibility objectives, outcomes, and results.

Feasibility objectives and results for outcomes with pre-specified 'RAG' progression criteria					
Objective	**Feasibility outcome**	**Result**	**RAG rating**		
			Red	Amber	Green
1. To determine the feasibility of recruiting and retaining participants (CCs and SUs) in a C-RCT comparing the effects of MOL-trained CCs versus treatment as usual on outcomes (engagement and recovery) for people experiencing first episode psychosis.	1A. Care coordinator recruitment	31/24 (129%) CCs recruited	< 60%	60% - < 75%	**≥ 75%**
	1B. Care coordinator retention	28/31 (90%) CCs retained	< 60%	60% - < 80%	**≥ 80%**
	1C. Service user recruitment	1.58 SUs recruited per CC	**< 2**	2 - < 3	≥ 3
	1D. Service user retention	33/49 (67%) SUs retained	< 60%	**60% - < 80%**	≥ 80%
2. Establish the acceptability of the MOL training programme amongst CCs and of MOL delivered by CCs amongst SUs	2A. Percentage of CCs attending all 3 sessions of initial MOL training	14/20 (70%) CCs attended all 3 sessions of initial MOL training	< 60%	**60% - < 80%**	≥ 80%
	2B. Average number of monthly MOL supervision sessions completed by CCs	CCs attended an average of 1.3 monthly MOL supervision sessions	**< 2**	2 - < 4	≥ 4

Feasibility objectives and results for outcomes without pre-specified RAG progression criteria			
Objective	**Feasibility outcome**	**Measure**	**Result**
2. Establish the acceptability of the MOL training programme amongst CCs and of MOL delivered by CCs amongst SUs	2C. Acceptability of MOL amongst care coordinators	Percentage of CC reports of acceptability	100% (13/13 CCs)
	2D. Acceptability of MOL training programme amongst care coordinators	Percentage of CC reports of MOL being 'acceptable' as an intervention to support SUs	85% (11/13 CCs)
3. Identify barriers and facilitators to MOL delivered by CCs	This objective will be assessed via the study's qualitative component	No measures were used for this objective. Qualitative data were collected using focus groups and semi-structured interviews.	MOL training supported care coordinators' delivery of MOL, but high workloads were a barrier to attending supervision, which impeded implementation. Full details published separately (Griffiths et al., 2024).
4. Refine the MOL training programme and implementation plan based on participant feedback	Whilst this objective is primarily addressed using qualitative data collected in focus groups with care coordinators and team managers, quantitative outcomes will also be used to help address this objective	Percentage of CC reports indicating use of MOL in their clinical practice at any point in the last seven days	72% (16/22 CC)
		Mean number of clinical contacts in which CC report using MOL to some extent in the past seven days	2.2
		Mean percentage of clinical contacts seen in the past 7 days in which CC report using MOL to some extent	22%
		Percentage of CC reports indicating that MOL principles have informed their clinical practice in the last seven days	86% (19/22 CC)
		Percentage of CC reports of use of MOL over the past 7 days	77% (17/22 CC)
5. Generate further evidence on the promise of the intervention via estimates of effectiveness on key outcome measures.	N/A	Estimates of the effects of the intervention on the QPR outcome data at 3 months and 6 months, separately, MBI-HSS outcome data at 6 months and DIALOG, RoC and WAI-SR tools at 3 and 6 months, separately will be obtained using exploratory multi-level models	Presented in Tables 4, S4, S5 and S6: effect estimates are small on all service user measures. A minimal important difference of 4 points on the QPR is within the bounds of 95% CI at both 3 and 6 months (Dehmahdi et al., 2021). There were no apparent effects of MOL on care coordinator outcomes, apart from on the *emotional exhaustion* subs-scale, which showed an negative impact of MOL.
6. Establish the most appropriate primary outcome measure for a definitive trial.	N/A	The views of the study's Public and Patient Involvement (PPI) group regarding the most appropriate outcome for a definitive trial will be sought. The promise of the intervention on the QPR, and other putative primary outcome measures, as appropriate, will be considered as detailed for Objective 5.	QPR confirmed by PPI group as most appropriate primary outcome measure for a definitive trial. Some limited promise of the intervention on the QPR, primarily at 3 months.
7. Estimate key parameters to inform a sample size calculation for a definitive trial.	Level 2 and Level 3 residual variance estimates; SU retention rate.	Estimates of the residual variance from the 3-level model for QPR will be used to inform a sample size calculation. Retention rate will also be used here to inform the inflation necessary to allow for withdrawal and non-completion of the putative primary outcome measure.	The residual variance from the 3-level model is 41.45 The Level 2 variance estimate of CC is 0.0000252 The Level 3 variance estimate of EIP team is 0.0000397; SU Retention rate = 67%
8. To determine the feasibility of conducting an economic evaluation of MOL as part of a full C-RCT	N/A	Level of missing data on EQ-5D-5L and health resource use questionnaire as indicators of acceptability and data quality	Between 94-100% of active participants completed the 5 domains of the EQ-5D-5L at each time point. All active participants in the study at 6 months completed the resource use questionnaire. Care coordinators found it too burdensome to complete logs of their contacts with trial participants therefore an alternative method for capturing this accurately is needed.

RAG, red, amber, green rating; CC, care coordinator; SU, service user; MOL, Method of Levels.

3.3. Eligibility criteria

3.3.1. EIP team eligibility criteria

EIP teams were included in the study when organisational support was given for ≥2 care coordinators based in the team to engage with the MOL training and supervision programme.

3.3.2. Care coordinator eligibility criteria

Care coordinators met the following criteria: (1) working within EIP services based within a participating NHS Trust, (2) likely to remain in their current post for the duration of the study (i.e., for 6 months after the randomisation of EIP teams), (3) have organisational support from their employer to engage with MOL training and supervision, (4) be able to provide informed consent to participate in the study. Any care coordinators who had not recruited at least one service user participant were excluded from the trial prior to randomisation of their EIP team. Although not amongst the eligibility criteria defined a priori, care coordinators were also excluded if they did not have any service users from their case load participating in the study or a valid Maslach Burnout Inventory: Human Services Survey (MBI-HSS) [34] completed by the point of randomisation.

3.3.3. Service user eligibility criteria

Service user participants met the following criteria: (1) current user of an EIP service that is included in the study, (2) have an allocated care coordinator who has consented to take part in the study, (3) due to remain under the care of their EIP service until the end of the study, (4) have capacity to provide informed consent to participate in the study, (5) have sufficient written and verbal English language skills to complete outcome measures and engage with the MOL intervention, and (6) be aged 18 years or older. Since we were primarily interested in the impact of the MOL intervention on service user outcomes, service user participants were also excluded if their care coordinator was not participating in the study or they did not have a valid *Questionnaire about the Process of Recovery* (QPR) [35] completed by the point of randomisation. Again, although these were not eligibility criteria defined a priori, it became apparent over the course of the study that it would be problematic to include service user participants who did not meet these criteria. These changes were described in the study's Statistical and Health Economic Analysis Plan that was approved prior to analysis (available at https://www.isrctn.com/ISRCTN14082421).

3.3.4. Team manager eligibility criteria

Team manager participants met the following criteria: (1) currently acting as a team manager of a participating EIP service, and (2) able to provide informed consent to participate in the study.

3.4. Interventions

3.4.1. Control: Treatment as usual (TAU)

Service user participants received their usual support from their EIP team in addition to any other support that they would ordinarily receive.

3.4.2. Intervention: TAU + MOL

Service user participants to receive their usual support. In addition, service users' care coordinators are trained and receive supervision in MOL.

MOL training and supervision were delivered by the first and second authors (RG and ST). Care coordinators were offered two days' online MOL training followed by one day of in-person training one month later. They were also offered monthly one-hour, online supervision sessions for 6 months. Training was focused on understanding the theoretical basis for MOL and on acquiring skills relating to its delivery in practice, using taught material, experiential exercises, role play, and case studies. Care coordinators were also directed to resources and materials that could support self-directed learning. Supervision focused on developing expertise in delivering MOL and supporting its implementation in practice. Training and supervision were guided by existing MOL treatment manuals [16,17]. Care coordinators were observed delivering MOL during training and supervision, and the MOL Session Evaluation Form [36] was used to encourage fidelity to the approach. Care coordinators were encouraged to implement MOL flexibly within their practice.

3.5. Feasibility outcomes

All red, amber, green (RAG) feasibility criteria were agreed a priori with the study's trial management group, trial steering committee, public and patient involvement panel, and funder. A 'green' result indicates that this aspect of the study appears feasible, 'amber' indicates that some adjustments are required to the approach used to make sure it is suitable for a future trial, and a 'red' result would indicate that the approach used in this study was not feasible in its current form and would need substantial changes to make it fit for purpose in a larger evaluation trial. RAG criteria relating to the recruitment of care coordinator and service user participants were equivalent to those in other trials of complex interventions for people reporting psychosis (e.g., [37]). Retention rates were informed by a review which concluded that trials of complex intervention for people with psychosis should seek to avoid attrition rates higher than 20% to mitigate the risk of bias [38]. RAG criteria relating to MOL training and supervision were informed by the experience of two study authors with experience of training health professionals in the approach (RG and ST). Feasibility objectives are presented in Table 1.

3.6. Clinical outcomes

Participants were invited to complete several clinical outcome measures. These data were used to address feasibility objectives 5–8 (see Table 1).

3.6.1. Service user participant measures

Questionnaire about the Process of Recovery (QPR) [35]: Measures personal and social recovery for individuals with psychosis with 15 items across two sub-scales (interpersonal and intrapersonal functioning). It has shown good internal consistency. This measure is our putative primary outcome measure for a future evaluation trial, should it be deemed feasible. A change greater that 4 points indicates a minimal important difference (MID) in between-group comparisons [39].

DIALOG [40]: Measures subjective quality of life and treatment satisfaction across 11 items and has acceptable psychometric properties.

Reorganisation of Conflict Scale (ROC) [41]: This study used an 11-item subscale of the ROC that measures goal conflict reorganisation, the putative mechanism of change for MOL. The ROC has shown satisfactory internal reliability.

Working Alliance Inventory-Short Revised (WAI-SR) [42]: Measures the quality of the therapeutic relationship across 15-items and three areas: agreement on tasks, agreement on goals, and the affective bond. The WAI-SR has demonstrated good psychometric properties.

EQ-5D-5L (EuroQol Group) [43]: Standardised measure of health over five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. It is recommended by NICE for economic evaluations [44].

Resource Use Questionnaire: This bespoke measure asked service user participants about their use of health and care services (including inpatient, outpatient, A&E, and GP services) over the preceding six months.

Routine service data that showed the number of contacts between care coordinators and service users was also collected.

3.6.2. Care coordinator participant measures

Maslach Burnout Inventory: Human Services Survey (MBI-HSS) [34]: Measures burnout in health and social care professionals across 22 items

and three sub-scales: emotional exhaustion, depersonalisation, and personal accomplishment.

Care coordinator use of MOL Questionnaire: This bespoke questionnaire uses multiple-choice and open-ended questions to understand more about the impact of MOL training and supervision on care coordinators' practice and their views on the approach. In the period between randomisation and completion of follow-up measures at six months, two care coordinators were randomly selected each week to complete this questionnaire. It covers issues such as their use of MOL in the preceding seven days, and the extent to which MOL training and supervision had improved the support they offered service users.

3.7. Sample size

The total recruitment target for the study was $n = 12$ EIP teams, $n = 24$ care coordinators, and $n = 96$ service users. This equated to an average of four service user participants from the caseload of each care coordinator participant. The sample size aimed to give good precision in estimating rates of service user participant retention (95% confidence interval [CI] of width $\leq$ 16.9% if retention was $\geq$80%). It was also chosen on pragmatic grounds to collect sufficient data at each level (team, care coordinator, and service user) to address the study's feasibility objectives.

3.8. Recruitment

Managers of EIP teams within participating NHS trusts were contacted to establish whether there was sufficient capacity for staff to participate in the study. Where managerial support was provided, posters, leaflets, and presentations were used to raise awareness of the study amongst EIP team members. Care coordinators who expressed an interest in the study were given a participant information sheet and provided written consent to take part. Participating care coordinators were asked to review their caseloads to identify eligible service users and approach them about the study. If interested, service users were contacted by the study team to facilitate informed written consent.

3.9. Randomisation

Group allocation was in a ratio of 1:2 in favour of the treatment arm. Randomisation was stratified based on participating NHS Trust to ensure there was a mix of EIP teams allocated to both control and treatment arms within each Trust. EIP teams within Trusts were allocated to groups in random permuted blocks of size 3 using an online randomisation service (Sealed Envelope Ltd., 2021) set up by a statistician who was independent of the research team. To maintain allocation concealment, randomisation was completed after recruitment was completed and two weeks prior to a scheduled MOL training course.

3.10. Masking

Neither the study team nor participants were masked to group allocation because we were primarily interested in the feasibility of MOL delivered by care coordinators, rather than the effectiveness of the intervention. Our intention for a future evaluation trial would be to use masked data collectors.

3.11. Data collection

Care coordinator and service user participants were recruited up to eight months prior to the randomisation of teams. Baseline measures were completed less than two months prior to randomisation. Depending on participant preference, outcome measures were completed either remotely or face-to-face with a research assistant, or participants could self-complete measures.

3.12. Data management

To preserve participant anonymity, each participant was allocated a trial identity code number used for outcome measures, case report forms (CRFs), audio and video recordings, and electronic databases where participant data were stored. Paper copies of consent forms and outcomes measures were kept securely in locked NHS premises. Electronic databases were password protected, and only authorised members of the study team had access to these. Individual participants' data was only identifiable through their trial identity code number and data that could lead to the identification of individual participants was stored separately. The study's research assistants (NW and SO) inputted data to databases. Research assistants checked 10% of each other's data entry for accuracy. The proportion of data entry errors were $<$ 1%, which was deemed an acceptable level of accuracy for data entry and so no further checking of the other 90% of data was performed.

3.13. Statistics and data analysis

Analysis and reporting of results is consistent with the CONSORT extension for pilot and feasibility studies [45]. Analyses were performed on the intention-to-treat population, with all care coordinator and service user participants analysed according to their allocated trial arm. Descriptive statistics summarise the study's main feasibility outcomes, with 95% confidence intervals (CIs) included as appropriate. Descriptive analyses include details of participant flow and the proportion of teams, care coordinators, and service users approached to take part in the study who agreed to participate. Reporting of questionnaire data (including outcome and care coordinator usage and acceptability data) primarily focuses on tabulated frequencies and percentages or summaries of means and standard deviations, as appropriate for all participants at each time-point. Multilevel models were fitted, where feasible, to estimate the potential effect of the intervention on key outcome measures (via the 'sliding confidence interval' approach using confidence levels of 75%, 80%, 85%, 90% and 95% [46]). Prior to analysis, item-level imputation (using the mean score for items present for that participant) was applied using the guidance specified for the outcome measure, where that existed, or if no more than 20% of items have missing data otherwise. Multilevel modelling was based on a complete-case analysis (i.e., no imputation of missing scale or sub-scale scores was performed). We also estimated the intra-cluster correlation coefficient (ICC) although precision was expected to be limited. For the QPR as the putative primary outcome measure, we used this ICC estimate, together with external evidence from the literature, to inform the potential design and sample sizes (at each level) for a future evaluation trial. A detailed Statistical and Heath Economic Analysis Plan (SHEAP; available at https://www.isrctn.com/ISRCTN14082421) was developed and approved by the Trial Steering Committee (TSC) prior to commencing data analysis.

3.14. Health economic analysis

The feasibility of collecting data to measure the health impact and resource use (costs) associated with the intervention and control were explored to determine the feasibility of conducting a full economic analysis.

Service user participants were asked to complete the EQ-5D-5L at each assessment point (baseline, three-months, six-months). The EQ-5D-5L was used to derive health utility values, using the mapping approach [47] recommended by NICE at the time of the analysis [44]. Quality adjusted life years (QALYs) were calculated from the utility values using an area under the curve approach. Descriptive statistics for EQ-5D-5L responses and derived utility values and QALYs are presented and the level of missing EQ-5D-5L data reported.

At six-month follow-up, service user participants were asked to complete a bespoke resource use questionnaire (based on similar

versions used previously in mental health trials) which captured their use of health and social care services (including mental health, inpatient, outpatient, emergency, and primary care services) during the study. Our feasibility aim was to ascertain whether the questionnaire was acceptable to participants and to assess the quality of data collected. The questionnaire was collected at a single time-point to minimise participant burden. The number of contacts participants had with different services is summarised descriptively and the level of missing data is described.

3.14.1. Intervention cost

We planned to estimate bottom-up intervention delivery costs based on logs of all service user contacts kept by care coordinators. However, care coordinators reported that maintaining these logs would be excessively burdensome and continuing with this plan could have impacted on the retention of these participants in the study. As such, these data were not collected. As an alternative, we obtained data from medical records on the number of face-to-face contacts within the participating mental health Trusts for participants in both study arms. These data have been summarised descriptively.

3.15. Qualitative study

A nested qualitative study was used to help understand the feasibility and acceptability of MOL delivered by care coordinators in EIP teams. Full details of the qualitative study are published separately [48]. A summary of the main findings, however, will be presented here.

3.16. Trial oversight

A TSC provided study oversight. The TSC consisted of independent members (including service user, clinical-academic, statistician, and care coordinator representatives) along with the CI (RG). The TSC reported to the Trial Management Group, Sponsor, and Funder, as appropriate. The functions of the TSC included reviewing serious adverse events and ensuring adherence to the study protocol.

3.17. Safety monitoring

Serious adverse events (SAEs) and adverse events (AEs) that occurred between participant enrolment and their study end date were monitored, recorded, and reported. Potential SAEs and AEs were reviewed by the TSC Chair and CI in the first instance. If the event was judged to meet the criteria for an SAE (as defined by Health Research Authority) and was thought to be potentially related to trial proceedings, this information would be shared with the Research Ethics Committee by the CI. The Trial Management Group and Sponsor were informed of all potential SAEs and AEs. In addition to monitoring SAEs, in accordance with recent recommendations [49], we monitored and recorded incidents of possible AEs, including incidences of actual or threatened participant overdose, self-harm, or harm to others, even if these did not meet the criteria for classification as an SAE.

3.18. Ethical and regulatory considerations

This study was sponsored by Greater Manchester Mental Health NHS Foundation Trust and received ethical approval from the West Midlands - Black Country Research Ethics Committee (REC Reference: 22/WM/0073; IRAS ID: 307103).

3.19. Public and patient involvement

The study's eighth author (AJ) is a lived-experience co-applicant and has contributed to all stages of research delivery. AJ co-facilitated public and patient involvement (PPI) meetings with the study's first author (RG). The PPI panel met quarterly for the duration of the study and had input into the development of participant-facing materials, topic guide development, analysis of qualitative data, interpretation of study findings, and dissemination planning and delivery. The TSC also included a lived-experience representative.

4. Results

4.1. Participants

Recruitment for the CAMEO study took place over 11 months between 06/05/2022 and 25/04/2023. The recruitment window for all sites was approximately 9 months. The managers of 17 EIP teams agreed that care coordinators within their teams could be invited to participate in the study. Of the 17 EIP teams, 14 teams were included in the study at the point of randomisation.

The main CONSORT diagram is presented in Fig. 1. Additional CONSORT diagrams showing the flow of care coordinator and service user participants are presented in Figs. 2 and 3 in Supplementary Materials.

Table S1 describes the number of participating EIP teams, care coordinators, and service users by site for each treatment arm. Baseline characteristics of EIP teams and care coordinators are presented in Tables S2-S3. EIP teams in both treatment arms had generally been established for several years and had dedicated psychology and psychiatry input. Relative to the EIP teams in the TAU arm, teams allocated to TAU+MOL had higher total team caseloads, fewer overall staff, but slightly larger numbers of care coordinators. Care coordinator participants were predominantly White British, female, and had a professional background in mental health nursing. Participants in the TAU+MOL arm had, on average, been qualified as mental health professionals, worked as care coordinators, and worked in EIP services for longer than those in the TAU arm.

Baseline characteristics for service user participants are presented in Table 2. Most service user participants identified as White British, had received a mental health diagnosis and prescribed medication, were single, lived in mainstream accommodation, and were unemployed. There were some observed differences between characteristics of both service user and care coordinator participants which is not unexpected for a feasibility C-RCT.

4.2. Feasibility and acceptability

Feasibility objectives and outcomes with results are presented in Table 1. Objectives 1A and 1B, which relate to the recruitment and retention of care coordinator participants, were both a ‘green’ result. Objective 1C related to the recruitment of service user participants and was a ‘red’ result. Objective 1D related to the retention of service user participants and was an ‘amber’ result.

Objective 2A related to care coordinators' attendance at MOL training sessions and was an ‘amber’ result. Care coordinator attendance at MOL supervision sessions was assessed in objective 2B and was a ‘red’ result.

Data collected using the bespoke *‘Care coordinator use of MOL Questionnaire’* were used in conjunction with the qualitative study to address feasibility objectives 2C, 2D, and 4. The questionnaire was sent to care coordinators on 47 occasions during the study, and a total of 22 questionnaires were completed by 13 different care coordinators.

Of the 20 care coordinators working in teams allocated to the TAU+MOL arm, 16 completed at least some of the MOL training provided. One EIP team was unable to release three participating care coordinators to complete any of the MOL training because of workload pressures. One care coordinator from another team did not attend any MOL training for the same reason.

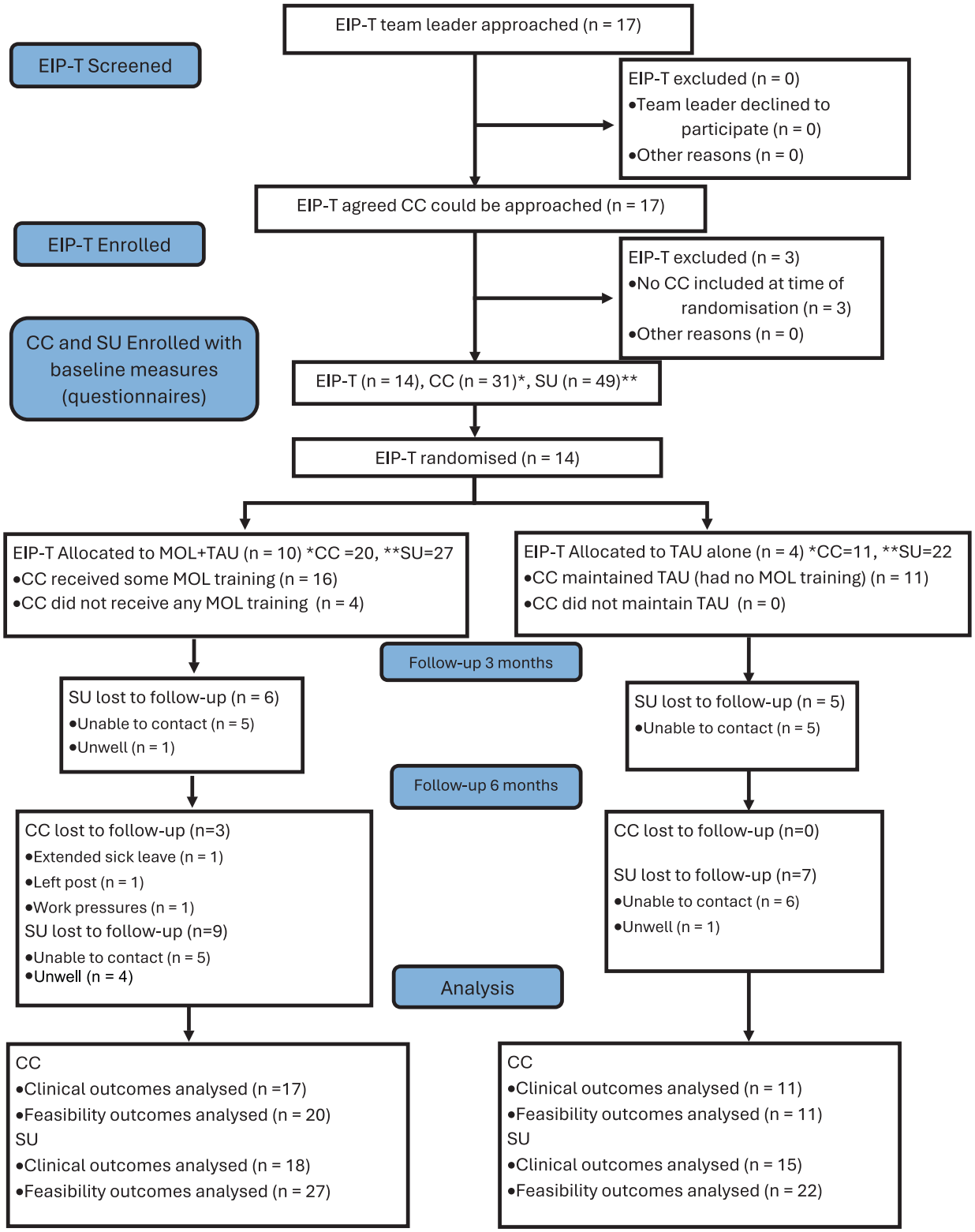

Fig. 1. Main CONSORT diagram.
EIP-T, early intervention in psychosis team; CC, care coordinator; SU, service user; MOL, Method of Levels; TAU, treatment as usual.

4.3. Clinical outcomes

Descriptive statistics for services users' clinical outcomes are presented in Table 3. Estimates of treatment effects for the QPR at 3 and 6 months are presented in Table 4. Differences between the groups are small at both time points, although confidence intervals (CI) are wide. A minimal important difference of 4 points in between group comparisons for the QPR is within the bounds of the 95% CI at both 3 and 6 months [39]. Treatment effect estimates for other service user outcomes at 3 and 6 months are presented in Supplementary Material in Tables S4–5. For the ROC, participants in the TAU+MOL arm were 5.00 points lower than the TAU arm at 3 months but were 3.66 points higher at 6 months.

Table 2
Baseline characteristics of service user participants.

	TAU + MOL (n = 27)	TAU (n = 22)	Total (n = 49)
Age in years (Mean (SD))	30.5 (9.4)	35.1 (12.8)	32.6 (11.2)
Participant gender			
Female	13 (48%)	14 (64%)	27 (55%)
Male	14 (52%)	6 (27%)	20 (41%)
Non-binary	0 (0%)	2 (9%)	2 (4%)
Ethnicity			
Asian/ Asian British	3 (11%)	0 (0%)	3 (6%)
Black African	1 (4%)	0 (0%)	1 (2%)
Black British	2 (7%)	0 (0%)	2 (4%)
White British	19 (70%)	17 (77%)	36 (74%)
White and Black Caribbean	0 (0%)	1 (5%)	1 (2%)
White and Black African	1 (4%)	1 (5%)	2 (4%)
Other White/Ethnic Group	1 (4%)	3 (14%)	4 (8%)
Diagnosis of any mental health conditions?			
Yes	20 (74%)	17 (77%)	37 (76%)
No	5 (19%)	4 (18%)	9 (18%)
Unsure	2 (7%)	1 (5%)	3 (6%)
Diagnosis of any physical health conditions?			
Yes	9 (33%)	7 (32%)	16 (33%)
No	17 (63%)	15 (68%)	32 (65%)
Unsure	1 (4%)	0 (0%)	1 (2%)
Months since acceptance to EIP team services (Mean (SD))	19.4 (15.2)	20.1 (12.2)	19.7 (13.8)
Received psychological or talking therapies?			
Yes	10 (37%)	2 (9%)	12 (24%)
No	17 (63%)	20 (91%)	37 (76%)
Number of admissions to hospital because of mental health (Mean (SD))	1.2 (0.6)	1.2 (0.4)	1.2 (0.5)
Prescribed medication?			
Yes	25 (93%)	20 (91%)	45 (92%)
No	2 (7%)	2 (9%)	4 (8%)
Current relationship status			
Single	24 (89%)	16 (73%)	40 (82%)
Married/co-habiting	2 (7%)	6 (27%)	8 (16%)
Divorced/Separated	1 (4%)	0 (0%)	1 (2%)
Accommodation status			
Mainstream housing	26 (96%)	22 (100%)	48 (98%)
Supported accommodation	1 (4%)	0 (0%)	1 (2%)
Employment			
Unemployed	16 (59%)	14 (64%)	30 (61%)
Paid employment	8 (30%)	6 (27%)	14 (29%)
Education/training	2 (7%)	2 (9%)	4 (8%)
Unpaid employment	1 (4%)	0 (0%)	1 (2%)

MOL, Method of Levels; TAU, treatment as usual; EIP, early intervention in psychosis.

Descriptive statistics for the three sub-scales of the MBI-HSS completed by care coordinator participants are presented in Table 5. Estimates of treatment effects on care coordinators for the MBI-HSS subscales at 6 months are presented in Table S6 (supplementary material). Results suggested that there was little or no effect of MOL on the *depersonalisation* or *personal accomplishment* sub-scales, but there was a potential negative impact of MOL on the *emotional exhaustion* subscale.

4.4. Health economics

There are signs that the TAU group had slightly worse health at baseline than the TAU+MOL group. For example, in the TAU+MOL group, 30% report no or slight problems with anxiety/depression, whereas only 19% reported slight problems (0 report no problems) in the TAU group. The completeness of the EQ-5D-5L was 98% at baseline, and amongst participants who remained in the study, completeness was 100% at 3-months and 94% at 6-months. This suggests that the EQ-5D-5L was acceptable to the participants and no individual domains were left out; it was either completed in its entirety or not at all. There was a small number (n = 3) of participants who did not complete the visual analogue scale (VAS) component of the EQ-5D-5L at the 3-month assessment despite completing the rest of the instrument.

Table 3
Clinical outcome measure results for service user participants.

Measure	Time-point	Group					
		TAU + MOL			TAU		
		n	*Mean*	*SD*	n	*Mean*	*SD*
QPR Total Recovery score	Baseline	27	38.7	12.7	22	33.7	12.7
	3 Months	18	39.0	12.5	16	33.1	13.5
	6 Months	18	43.2	11.0	15	38.0	13.8
DIALOG Subjective Satisfaction score	Baseline	27	4.7	1.1	21	4.2	0.9
	3 Months	18	4.8	1.5	16	4.6	1.0
	6 Months	17	5.0	1.1	14	4.7	1.0
DIALOG Treatment Satisfaction score	Baseline	25	5.9	0.9	21	5.5	1.0
	3 Months	17	5.6	1.3	15	5.7	1.0
	6 Months	17	5.8	0.8	14	5.6	1.1
RoC score	Baseline	27	66.8	19.9	21	61.8	20.8
	3 Months	18	70.5	25.8	16	66.3	15.8
	6 Months	17	72.8	16.5	14	63.3	19.5
WAI-SR: Goal subscale score	Baseline	26	17.8	2.5	21	17.2	2.8
	3 Months	18	16.7	3.2	16	14.9	3.8
	6 Months	17	17.9	2.5	14	15.7	4.3
WAI-SR: Bond subscale score	Baseline	26	18.3	2.5	20	17.2	3.1
	3 Months	17	17.4	3.5	16	16.2	4.1
	6 Months	17	18.8	2.0	14	17.1	4.1
WAI-SR: Task subscale score	Baseline	27	16.4	2.8	21	15.9	3.2
	3 Months	18	14.9	4.4	16	13.8	4.1
	6 Months	17	16.9	2.6	14	14.6	4.6

MOL, Method of Levels; QPR, Questionnaire about the Process of Recovery; RoC, Reorganisation of Conflict Scale; TAU, treatment as usual; WAI-SR, Working Alliance Inventory-Short Revised.

Data from the EQ-5D-5L are summarised in Table 6. At baseline, the mean utility value was notably higher in the TAU+MOL group than the TAU group. Over the course of the study the two groups showed the opposite direction of change in utility values. Over the whole study period, QALYs were higher in the TAU+MOL group. The unadjusted net QALYs were 0.084 (95% CI -0.034 to 0.202) in favour of the TAU+MOL group. The confidence interval, however, spans 0 and the apparent effect of MOL on QALYs was largely driven by the difference in baseline utility values (higher in the TAU+MOL group) therefore this should be interpreted with caution.

The healthcare resource use questionnaire was generally well-completed. Of the 33 participants who had a follow-up at 6 months, there were only 2 who did not complete the resource use questionnaire, one from each treatment group. There were no missing data for participants who completed the resource use questionnaire. There were some outlying responses in terms of number of contacts with services reported, but it is unknown if these were due to misreporting or true outliers. However, the quality of the data was generally good. The resource use questionnaire is well designed for data collection when administered in an interview format by field researchers as done here. Data on resource use are summarised in supplementary materials (including Tables S7-S8).

Based on data provided by the study sites on face-to-face contacts with care coordinators, there was one participant in each treatment group who did not have any contacts during the study period. The mean number of contacts was lower in the TAU+MOL group (5.8; 95% CI 4.5, 7.1) than the TAU group (8.5; 95% CI 6.1, 10.9). The number of contacts ranged from 0 to 13 in the TAU+MOL group and 0 to 21 in the TAU group. This may be indicative of a potential for cost-savings on healthcare resources in the TAU+MOL group that can be further explored in a follow-on RCT.

Table 4
Treatment effect estimates for the QPR at 3 and 6 months.

Time-point	Treatment effect (Ref. = TAU)	Confidence Interval				
		95%	90%	85%	80%	75%
3 months	0.54	−4.18 to 5.25	−3.42 to 4.49	−2.92 to 4.00	−2.54 to 3.62	−2.23 to 3.30
6 months	−0.50	−5.54 to 4.53	−4.73 to 3.72	−4.20 to 3.20	−3.80 to 2.79	−3.46 to 2.45

QPR, Questionnaire about the Process of Recovery; TAU, treatment as usual.
Note: Positive treatment effect values favour the MOL intervention.

Table 5
MBI-HSS results at baseline and 6 months.

Measure	Timepoint	Group					
		TAU+MOL			TAU		
		n	*Mean*	*SD*	*n*	*Mean*	*SD*
MBI-HSS Emotional Exhaustion score	Baseline	20	23.9	10.7	11	20.1	6.1
	6 Months	17	25.2	10.4	11	17.2	6.4
MBI-HSS Depersonalisation score	Baseline	20	5.2	3.8	11	5.0	3.9
	6 Months	17	4.9	4.4	11	4.7	3.9
MBI-HSS Personal Accomplishment score	Baseline	20	37.1	5.1	11	34.0	6.3
	6 Months	17	37.5	5.8	11	34.5	4.4

MBI-HSS, Maslach Burnout Inventory - Human Services Survey; MOL, Method of Levels; TAU, treatment as usual.

Table 6
Summary of utility, QALYs, and VAS scores by treatment group.

	Mean (95% CI)	
	TAU + MOL	*TAU*
Utility at baseline	0.59 (0.49, 0.70) n = 27	0.47 (0.33, 0.60) *n* = 19
Utility at 3-months	0.58 (0.41, 0.75) n = 18	0.57 (0.40, 0.73) *n* = 14
Utility at 6-months	0.61 (0.46, 0.77) *n* = 17	0.52 (0.33, 0.71) n = 12
QALYs (baseline to 6-months)	0.33 (0.26, 0.40) *n* = 15	0.25 (0.13, 0.36) *n* = 10
Net QALYs (95% CI)	0.08 (−0.03, 0.20) *n* = 25	
VAS at baseline	58 (48, 67) n = 27	50 (40, 60) *n* = 21
VAS at 3-months	59 (45, 73) n = 17	54 (39, 69) n = 14
VAS at 6-months	67 (54, 80) n = 17	58 (47, 69) n = 14

MOL, Method of Levels; TAU, treatment as usual; QALY, quality-adjusted life year, VAS, visual analogue scale.
Note: These values are derived from the EQ-5D-5L.

4.5. Harms

There were a relatively low number of serious adverse events (SAEs; $n = 5$) and adverse events (AEs; $n = 1$) and these were distributed evenly between the two arms of the trial. After investigation, no events were deemed to be related to trial participation or the MOL intervention.

4.6. Qualitative findings

A detailed account of the qualitative findings is presented in a separate article [48]. Key findings were that MOL delivered by care coordinators in EIP teams was seen to be a feasible and acceptable approach by both service user and care coordinator participants. Participants reported that the approach helped service users explore their difficulties in more depth and enabled them to find their own solutions to problems. Care coordinators reported feeling prepared to deliver the intervention in practice following the initial MOL training but subsequently found it difficult to attend supervision sessions. This reduced their confidence in using the approach in clinical practice.

5. Discussion

This C-RCT sought to establish the feasibility of training care coordinators to deliver MOL to establish whether progression to an evaluation C-RCT is justified. Our results suggest that some aspects of this study are feasible in their current form, other aspects are likely to be feasible with some relatively minor adjustments, and some aspects would need substantial changes to make the delivery of an evaluation C-RCT feasible.

EIP teams in both arms of the study appeared to be broadly similar, with equivalent levels of input from psychiatry and clinical psychology staff. Teams in TAU + MOL had slightly larger team caseloads, and average care coordinator caseloads were also marginally higher. Care coordinator participants in both arms were typically White British, female, from mental health nursing backgrounds, and had received previous training in some form of psychological therapy. Care coordinators in TAU + MOL had worked in EIP services for longer on average. There were some moderate differences between the characteristics or service user participants allocated to the two trial arms. In particular, service users in the TAU + MOL arms were more likely to have been offered psychological interventions in the past.

Whilst the number of care coordinator participants recruited exceeded the a priori target, the number of service user participants was substantially lower than intended. This suggests that a different approach to recruitment would be needed for this group of participants in a larger trial. The study relied on care coordinators to gain verbal consent from service users on their caseload for the research team to contact potential service user participants. Our interpretation was that relying on care coordinators to identify and seek permission to pass on details to the research team regarding the trial acted as a barrier to recruitment. This interpretation is based on informal feedback from care coordinators and the findings of our qualitative study, where care coordinators described workload pressures limiting the extent to which they were able to engage with the study [48]. It cannot be discounted, however, that recruitment would have been even more challenging if we had not relied on care coordinators to identify and approach service users with whom they had an existing relationship.

Existing qualitative research suggests that researchers must adopt a flexible approach to recruitment that is tailor made for different clinical teams and aim to establish collaborative relationships with care coordinators [50]. While every effort was made in this study to build relationships with clinical teams and care coordinators, a future evaluation study should consider how the approach could be enhanced. Successful recruitment of service user participants via care coordinators also requires researchers to take an assertive approach to engaging with clinical teams [50]. For future studies, consideration should be given to alternative approaches to recruitment (including those that reduce the burden on care coordinators to recruit service participants) and whether additional resources are required to support these. Service user retention in the trial was a borderline ('amber') result. With some relatively minor adjustments aimed at increasing retention, such as using newsletters to maintain contact with service users between data collection points [51],

the approach used here is likely to be feasible in a larger study. The length of time that service users were required to be in the study (with service users being recruited up to 8 months prior to randomisation) might also have impacted on retention. A future evaluation trial should consider whether the length of time service users need to be involved in the study can be reduced. The problems described above with care coordinators identifying and approaching service users about the study are also relevant to the issue of retention. More efficient methods of recruitment, including those that are less reliant on care coordinators, could reduce the overall length of time that service users are required to be in the study.

The proportion of care coordinators completing the three-day MOL training programme as planned was a borderline ('amber') result. While most care coordinators were able to attend the MOL training, workload pressures prevented care coordinators from one participating EIP team from attending. MOL supervision attendance was substantially below our target of at least four sessions attended by all care coordinators in EIP teams allocated to TAU + MOL over the course of the six-month treatment window. Qualitative findings suggest that workload pressures represented a barrier to engagement with supervision sessions. Average caseloads for care coordinators in the TAU + MOL group were 20.3, which is higher than the recommended caseload of no more than 15 [52]. This issue is likely to have impacted on care coordinators' capacity to attend MOL training and supervision. While care coordinators had organisational support to attend MOL training and supervision, they were not given protected time or a reduction in other duties. Lack of time is acknowledged to be a significant barrier to engagement with supervision [53,54]. Future studies should consider methods of protecting care coordinators' time to enable them to engage with supervision. High caseload sizes are also likely to have impacted on care coordinators capacity to support the recruitment of service user participants.

MOL delivered by care coordinators for people experiencing first-episode psychosis was judged to be an acceptable intervention by care coordinator participants. This finding is consistent with the nested qualitative study conducted as part of this project [48], and with existing evidence that MOL is an acceptable intervention for people experiencing psychosis [25,26]. Additionally, there was evidence that most care coordinators found the training programme acceptable and were using MOL in their practice on a regular basis.

Estimated effects of MOL on the QPR (the proposed primary outcome measure) were small. Results show a small positive impact of MOL in QPR scores at 3 months, and a small negative impact of MOL at 6 months. While these effect estimates were small, CI were wide, and a minimal important difference of 4 points lies within the bounds of the 95% CI at both 3 and 6 months. For other measures, effect estimates between arms were small, although it should be noted that this trial was not powered to detect effects of MOL and the limited engagement of some care coordinators and low response rate to usage questionnaires, which may suggest low usage in some cases, may have impacted on the effect estimates.

There are disagreements about how to define 'engagement' and distinguish it from related concepts, such as attendance, which has made it challenging to develop standardised outcome measures of engagement [55]. Whilst the QPR is proposed as the primary outcome, and might be considered a proximal measure of engagement, a future evaluation trial should also consider the possibility of including a direct measure of engagement.

Effects of MOL on the MBI-HSS for care coordinator participants were minimal, aside from a potential adverse effect on emotional exhaustion at 6 months. It is unclear whether the latter was linked to trial participation but could relate to the increased burden of attending MOL training and supervision in addition to performing the care coordinator role as usual. This assumption is consistent with the findings of our qualitative study, where care coordinators cited high workloads as a significant barrier to implementing new ways of working [48]. Consideration should be given to how care coordinators could be trained in this approach without increasing their workload or potential for burnout. Protected time for training and supervision could be one solution to this issue.

The data required to conduct an economic evaluation (EQ-5D-5L and healthcare resource use) was very well-completed by active participants. It should be noted that, in order to calculate QALYs, participants need to have completed the EQ-5D-5L at all study time-points and need to indicate a binary sex (used as part of the utility calculation process). For the healthcare resource use data reported by participants, those who attempted the questionnaire provided complete data.

6. Limitations

One limitation of this study is that the majority of service user and care coordinator participants were White British. Future studies should seek to recruit a more diverse sample to ensure the results are generalisable and applicable to different communities.

The recruitment of service participants via care coordinators proved challenging for this study, and the recruitment target was not met for this group. While this was an important feasibility finding, it did mean that sample size for this group was lower than anticipated. Additionally, the low recruitment rate, combined with the low retention rate, meant that we had 3-month (QPR) data on only 34 service user participants ($n = 18$ TAU+MOL; $n = 16$ TAU) rather than the target of at least 80% of $n = 96$ (i.e., a minimum of $n = 77$). Low response rates to MOL usage questionnaires might also have had an impact on the study's findings. It might be the case, for example, that care coordinators who were less likely to use MOL in practice were also less likely to complete usage questionnaires.

Although this study was not primarily designed to evaluate effectiveness of MOL, we have provided estimates of effectiveness on key service user and care coordinator outcome measures. A further limitation is that these estimates may be affected by the observed imbalance in baseline characteristics, some of which are likely to have been prognostic of outcome, meaning that additional care should be taken in the interpretation of these estimates in terms of the 'promise' of MOL.

While fidelity scales were employed in MOL training and supervision sessions, it was not possible to measure care coordinators' fidelity to the MOL approach in routine clinical practice. Care coordinators were asked to use MOL flexibly in their routine practice. Monitoring fidelity in this context would have required care coordinators to audio record all (or at least a reasonable proportion) of their clinical interactions with service user participants so these could be assessed for fidelity by someone with sufficient expertise in MOL. This was not thought to be practicable in the context of this feasibility study. Therefore, the extent to which care coordinators were maintaining fidelity to the approach in their practice is not known.

7. Conclusions

This is the first study that has sought to train care coordinators working in EIP services in MOL. Results suggest that progression to a larger trial would be justified if plausible solutions could be found to address the feasibility issues identified in this study. The most significant issues to be resolved relate to care coordinators' engagement with MOL supervision, implementing the intervention without increasing care coordinators' risk of burnout, and the recruitment of service user participants. For this study, while care coordinators had organisational support to attend training and supervision, they were not given protected time or a reduction in other duties to support this. Lack of time is acknowledged to be a significant barrier to engagement with supervision [53,54]. Future studies should, therefore, consider methods of protecting care coordinators' time.

Protocol version

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Study sponsor

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Trial registration

This study was prospectively registered with the ISRCTN Registry (Reference: 14082421).

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.comppsych.2026.152668.

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