Administrative information

Title

Care Coordinator Delivered Method of Levels Therapy to Improve Engagement and other Outcomes in Early Psychosis (CAMEO): Protocol for a Feasibility Cluster-Randomised Controlled Trial

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Trial registration

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

Protocol Version

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Study sponsor

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Abstract

Background

Rates of disengagement from early intervention in psychosis (EIP) services are high. Care coordinators make up the largest staff group in EIP services and have the most frequent and sustained contact with service users. The quality of relationships between service users and care coordinators plays a central role in determining the effectiveness of EIP services. Care coordinators, however, are not routinely offered training in psychosocial interventions that could enhance the therapeutic impact of their role. Method of Levels (MOL) is a flexible, transdiagnostic cognitive therapy with potential advantages over previously evaluated approaches. Training care coordinators in MOL could make their routine contacts with service users more helpful and improve outcomes such as recovery rates and levels of engagement.

Aims

This study aims to assess the feasibility of training care coordinators in EIP services to deliver MOL, to understand whether this approach might improve service user engagement and recovery from psychosis compared to treatment as usual, and to assess the feasibility of conducting a cluster-randomised controlled trial (C-RCT) with clustering at the level of teams. Specific feasibility outcomes relate to the recruitment and retention of participants, care coordinators' level of engagement with the MOL training and supervision programme, implementation of MOL in practice, and the acceptability of the intervention amongst participants.

Methods

A feasibility parallel-group cluster-randomised controlled trial (C-RCT) design with two arms: (1) treatment as usual (TAU) or (2) TAU plus support from a care coordinator who has received training in MOL. Randomisation will take place at the level of EIP teams with an allocation ratio 1:2 in favour of the intervention arm. Our recruitment target is 12 EIP teams, 24 care coordinators working in participating EIP teams, and up to 96 service users working with participating care coordinators. Outcomes will be collected at baseline, 3 months, and 6 months. Qualitative methods will be used to understand participants' experiences of the study, MOL training programme, and MOL intervention.

Discussion

This is the first study that aims to evaluate the feasibility of training EIP care coordinators to deliver MOL in their routine practice. Training care coordinators in MOL could enhance the quality of relationships between care coordinators and service users and improve outcomes for people experiencing early psychosis. Results will be used to determine the appropriateness of progressing to a larger evaluation trial.

Background and rationale

Without effective and timely support, psychosis can lead to a range of poor psychological, physical, social, and vocational outcomes for individuals affected and their relatives (1). The economic costs of untreated psychosis are also substantial (2). Specialist early intervention in psychosis (EIP) teams have, therefore, been established to provide rapid access to evidence based biopsychosocial interventions for individuals experiencing a first episode of psychosis (3).

EIP services aim to work with people for up to three years following a first episode of psychosis. Rates of disengagement prior to the planned three years, however, are estimated to be between 12% and 54% (4,5). The therapeutic benefits of EIP are dependent upon service users' continued engagement with these services (4). If service users do not remain in contact with EIP services, it is not possible to provide the biopsychosocial interventions that NICE (6) recommend should be offered to this population. It has been argued that:

> "There is a need for extensive and innovative efforts to address the issue of service disengagement in first-episode psychosis."(Lal & Malla, 2015, p. 341)

Care coordinators make up the largest staff group working within EIP teams and generally have a core professional qualification in either mental health nursing, social work, or occupational therapy. The role of the care coordinator is to take a lead role in care planning and the promotion of personal recovery. They work flexibly to support the individual with a range of health and social care needs and are central to the functioning of EIP teams (1).

The quality of the relationship between care coordinators and service users appears to play a fundamental role in determining the effectiveness of EIP teams (8–10). Service users are more likely to engage and remain in contact with EIP services where there is alignment between their needs and the support available (11). Currently, however, there is no systematic programme of training to prepare care coordinators for their role and maximise the therapeutic impact of their interactions with service users. Training aimed at making the routine practice of care coordinators more therapeutic and helpful could enhance engagement, which, in turn, is likely to increase the overall effectiveness of EIP services and improve outcomes for people experiencing a first episode psychosis.

Previous initiatives aimed at training care coordinators to deliver psychosocial interventions have typically focused on discrete, time-limited approaches delivered over a pre-specified number of sessions (e.g., (12,13). While there is some evidence to suggest that training care coordinators in psychological interventions might be feasible (12), implementing these interventions has proved challenging without care coordinators moving into specific psychological therapist roles (13,14). More broadly, the overall implementation of psychosocial interventions for people reporting psychosis has been limited (15,16), with only 46% of service users of EIP services in England attending at least one session of cognitive behavioural therapy (17).

The Method of Levels (MOL) is a transdiagnostic psychological intervention that aims to help people resolve distressing problems and regain control over important aspects of their life. The approach has been well described in a number of treatment manuals (18,19). MOL directly applies principles from a theory of human behaviour called Perceptual Control Theory (PCT)(20), which argues that psychological distress arises when people are unable to maintain control over important aspects of their life. MOL aims to support the resolution of internal conflicts that are believed to disrupt people's capacity to maintain control (21).

Practitioners delivering MOL have two primary goals: (1) encourage the person to talk freely about their problems, and (2) pay attention for signs that the person is experiencing background thoughts and then ask about these (22). Once a relevant background thought has been identified, the practitioner shifts back to the first goal of encouraging the person to explore this new thought in more detail. Although straightforward, this iterative process of encouraging the person to talk and shift their awareness onto potentially relevant background thoughts appears to enable people to develop novel perspectives on their problems and resolve internal conflicts (23,24).

A previous feasibility randomised controlled trial (RCT) compared treatment as usual with treatment as usual with the addition of MOL for people using EIP services (23). Results demonstrated that it was feasible to recruit and retain people experiencing first-episode psychosis in the study. Qualitative work revealed that participants valued the control they had over MOL sessions and reported that the approach was helpful and acceptable (25). This supports the view that MOL could be a particularly helpful psychological intervention for people experiencing psychosis (26,27).

Because care coordinators are the staff group with the most contact with service users, it could be more practical and effective to train them in the approach, rather than rely on the use of specialist psychological therapists who are in contact with service users for a comparatively short time.

The delivery of MOL does not require a planned number of sessions or follow a pre-specified protocol. This could address concerns that care coordinators find it difficult to implement protocolised psychological interventions within their current role (14). Because each MOL session is a discrete problem-solving exercise, care coordinators can be flexible about how they incorporate the intervention into their practice.

Service users report that the experience of talking and being heard by their care coordinator and having the opportunity to disclose problems in an atmosphere characterised by trust are the key things that they value about EIP services (9,28). It is precisely this process of being encouraged to talk openly about problems that people experiencing psychosis report is helpful about MOL (25). Care coordinators trained in MOL would be equipped to have these conversations using a theoretically informed approach. MOL, therefore, has the potential to improve the quality of relationships between service users and care coordinators. Improving the therapeutic relationship is itself an important target. It also increases the likelihood that service users will remain engaged with the care coordinator and take advantage of other interventions that EIP teams provide.

Where service users can resolve their difficulties at an early stage through MOL discussions with their care coordinator, this might reduce the need for subsequent use of resource intensive services, such as crisis and inpatient services. In addition to improving service users' outcomes and experiences, avoiding the use of these expensive services could use finite healthcare resources more efficiently.

Aims and Objectives

The decision to conduct a feasibility study has been informed by the MRC guidance on developing complex interventions (29). This study aims to assess the feasibility of training care coordinators to deliver MOL, to understand whether this approach might improve service user engagement and recovery from psychosis compared to treatment as usual, and to assess the feasibility of conducting a cluster-randomised controlled trial (C-RCT) with clustering at the level of teams.

Specific feasibility objectives are as follows:

1. 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. Establish the most appropriate primary outcome measure for an evaluation trial.
6. Generate further evidence on the promise of the intervention via estimates of effectiveness on key outcome measures.
7. Estimate key parameters to inform a sample size calculation for an evaluation trial.
8. To determine the feasibility of conducting an economic evaluation of MOL as part of an evaluation RCT.

Method

Design

A feasibility parallel-group cluster-randomised controlled trial (C-RCT) design with two arms: (1: control) treatment as usual (TAU); (2: intervention) TAU plus support from a care coordinator who has received training in MOL. Randomisation will take place at the level of EIP teams with an allocation ratio 1:2 in favour of the intervention arm. Whilst this is a feasibility trial, it is embedded within a superiority framework.

Study setting

The study is being conducted within EIP services based in three 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).

Eligibility criteria

EIP team eligibility criteria

EIP teams operating within three participating NHS Trusts (GMMH, LSCFT, and MCFT) will be included in the study when organisational support is provided for at least two care coordinators to engage with the MOL training and supervision.

Care coordinator participant eligibility criteria

Care coordinator participants will be (1) working within EIP services based within participating NHS Trusts, (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.

Service user participant eligibility criteria

Service user participants will be (1) current users of an EIP service that is included in the study, (2) have an allocated care coordinator who is participating 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.

Team manager participant eligibility criteria

Team manager participants will be (1) currently acting as a team manager of a participating EIP service and (2) be able to provide informed consent to participate in the study.

Interventions

Control: Treatment as usual (TAU)

Service user participants allocated to the treatment as usual (TAU) arm will continue to receive whatever support they would usually receive from their EIP team.

Intervention: TAU+MOL-trained care coordinator

Service user participants will continue to receive access to the support that they would usually receive from their EIP service. In addition, the care coordinators of participants in this arm of the trial will receive training and supervision in the MOL approach. A two-day block of MOL training will be delivered online, with a subsequent day delivered face-to-face one month later. The initial two-day training block will use a combination of taught material, experiential exercises, role play, case studies, and self-directed learning to support the development of skills in the delivery of MOL. The in-person training day delivered one month later aims to consolidate clinical skills learnt in the first two days of training and will provide an opportunity to address any potential barriers to implementation that have been encountered by care coordinators. After the initial two-day training block, care coordinators will be offered monthly online clinical supervision to support their use of MOL in clinical practice. We will record care coordinators' attendance at training and supervision sessions. Training and supervision will be guided by existing MOL treatment manuals (22,30) and will focus on understanding the theoretical basis for MOL and the acquisition of core skills relating to the delivery of the intervention in clinical practice. MOL training will be developed and delivered by RG and ST. Care coordinators will be observed delivering MOL within the training programme and the MOL Session Evaluation Form (31) will be used to support care coordinators to maintain fidelity to the approach. MOL-trained care coordinators will decide how they implement the intervention in their clinical practice. This includes decisions about which service users should be offered the intervention and when this should take place.

Clinical outcomes

While this study is primarily interested in addressing the feasibility objectives described above, we will also invite participants to complete a range of clinical outcome measures.

Service user participant measures

Questionnaire about the Process of Recovery (QPR; Neil et al., 2009) (33): Measures personal recovery from psychosis across 15 items and two sub-scales: interpersonal functioning and intrapersonal functioning. It has demonstrated good internal consistency. A change greater than 4 points on the QPR indicates a minimal important difference (MID) in between-group comparisons (34).

DIALOG (35): Measures subjective quality of life and treatment satisfaction across 11 items and has demonstrated acceptable psychometric qualities.

Reorganisation of Conflict Scale (ROC) (36): We will use an 11-item sub-scale of the ROC, which has shown satisfactory internal reliability, to measure goal conflict reorganisation, the putative mechanism of change in MOL.

Working Alliance Inventory-Short Revised (WAI-SR) (37): Measures the quality of the therapeutic alliance between clinician and service user across three areas: agreement on tasks, agreement on

goals, and the affective bond. This 15-item measure has demonstrated good psychometric properties.

EQ-5D-5L (EuroQol Group): This is a standardised measure of health over five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), each scored from 1 (worst possible) to 5 (best possible). This measure is recommended by NICE for the economic evaluation of health technologies (38).

Resource Use Questionnaire (RUQ): Service user participants will be asked to complete this bespoke questionnaire that asks about their use of health and social care services (including inpatient, outpatient, A&E, GP) during the study. This questionnaire asks participants about the number of contacts they have had with different mental health professionals during the previous six months. It also asks about the number of times they have attended Accident and Emergency services, number of hospitalisations, and number of contacts with primary care services.

We will also aim to collect routine service data on the number of clinical contacts between care coordinator and service user participants during the study period that could provide an insight into service users' degree of engagement with care coordinators.

Care coordinator participant measures

Maslach Burnout Inventory: Human Services Survey (MBI-HSS) (39): This 22-item survey measures burnout in health and social care professionals across three sub-scales (emotional exhaustion, depersonalisation, and personal accomplishment).

Care Coordinator use of MOL Questionnaire: To understand more about the impact of MOL training and supervision, each week for the duration of the trial, we will ask a randomly selected sub-sample of two care coordinators from the treatment arm to complete this short, bespoke questionnaire. This questionnaire uses a combination of multiple choice and open-ended questions to gather data about care coordinators' use of MOL in the previous seven days (e.g., "Have you used MOL in your clinical practice at any point in the last seven days? (Yes/No)"; "Do you have any other comments about using Method of Levels in your clinical practice?"). The questionnaire also includes a series of statements that care coordinators are asked to rate on a five-point Likert scale (from "strongly agree" to "strongly disagree"). These statements relate to care coordinators' attitude towards delivering MOL in practice (e.g., "Method of Levels training and supervision has improved the support I am able to provide to service users").

Sample size

As a feasibility study, a formal sample size calculation was not performed. The total recruitment target for this study will be n=12 teams, n=24 care coordinators, and up to n=96 service users. This equates to an intention to recruit an average of up to four service user participants from the caseload of each care coordinator participant. This sample size will give good precision in the estimation of retention of service user participants (95% confidence interval [CI] of width ≤16.9% if retention is ≥80%) and is otherwise chosen on pragmatic grounds to collect sufficient data at each level (team, care coordinator, service user) to assess the feasibility and acceptability of the intervention and the feasibility of the C-RCT. The sample size (an average of up to 4 service users per care coordinator) was also chosen to increase the chances that at least one service user participant will be retained for each participating care coordinator.

Recruitment

Managers of EIP teams in participating NHS Trusts will be approached to assess the team's capacity to support at least two care coordinators from the team to engage with the study. Recruiting two care coordinators per team will increase the likelihood of at least one care coordinator being retained for the duration of the study. Additionally, if a participating care coordinator withdraws from the study or leaves the team, this approach also provides the option for the care of participating service users on their caseload to be transferred to another MOL-trained care coordinator. Care coordinators identified by their EIP managers as willing to participate in the study will be approached by the study team to seek informed consent. Care coordinator participants will be invited to review their caseloads against the study's inclusion and exclusion criteria to identify potentially eligible service user participants. Care coordinators (or another suitably qualified member of the clinical team) will then seek verbal consent for the research team to contact potential service user participants to share more information about the study and seek written consent to participate. EIP team managers will also be invited to participate in focus groups (see the *Qualitative Study* section).

Randomisation

Teams will be allocated to groups in random permuted blocks within strata formed by NHS Trust, using an online randomisation service (Sealed Envelope Ltd., 2021) set up by a statistician independent of the research team. Because we are primarily interested in the feasibility of the training programme and the use of the intervention, group allocation will be in a ratio of 1:2, with twice as many teams allocated to the intervention arm than the control arm. To ensure that there is a mix of EIP teams allocated to both control and treatment arms within each Trust, randomisation will be stratified based on participating NHS Trust. As is key to maintain allocation concealment and limit the selection bias that can be a particular risk in C-RCTs, randomisation of teams will be performed only after two care coordinators and two service user participants have been recruited and approximately 2 weeks prior to a previously-scheduled MOL training course. This level of recruitment across all teams will enable us to achieve at least an amber outcome on our pre-specified success criteria.

Masking

This study is primarily interested in the feasibility and acceptability of MOL delivered by care coordinators rather than the effectiveness of the intervention. Neither the study team nor participants, therefore, will be masked to group allocation. Should we proceed to a larger effectiveness trial in the future our intention would be to use masked outcome data collectors.

Data collection

Although participants might be recruited to the study up to eight months before the randomisation of teams, baseline measures for both service user and care co-ordinator participants will be completed no more than two months prior to the point of randomisation. The assessment schedule is presented in Table 1. Depending on participant preference, data collection will be completed remotely or face-to-face with a research assistant. Alternatively, participants will be given the option to complete the measures themselves and return these to the study team.

[INSERT TABLE 1 AROUND HERE]

Data management

To preserve participant anonymity, each participant will be allocated a trial identity code number. This will be used for outcome measures, case report forms (CRFs), audio or video recordings, and electronic databases where participant data are stored. Data collected using standardised outcome

measures and CRFs will be inputted to databases by authorised members of the research team. Paper copies of consent forms and outcomes measures will be kept securely in locked NHS premises. Electronic databases will be password protected and only authorised members of the study team will have access to these. Individual participants' data will only be identifiable through their trial identity code number. Any data that could lead to the identification of individual participants will be stored separately. The study's research assistants (NW and SO) will be responsible for inputting data to databases. Research assistants will check 10% of each other's data entry for accuracy. If the proportion of data entry errors are <1%, then an acceptable level of accuracy for data entry will be assumed. If the amount of data entry errors is ≥1%, the entire dataset will be checked for errors.

Statistics and data analysis

Analysis and reporting of results will be consistent with the CONSORT extension for pilot and feasibility studies (40) and all analyses will be performed on the intention-to-treat population in which all care co-ordinator and service user participants will be analysed according to the allocated trial arm. Descriptive statistics will be used to summarise the study's main feasibility outcomes, with 95% CIs as appropriate. These descriptive analyses will include details such as 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 co-ordinator usage and acceptability data) will primarily focus on tabulated frequencies and percentages or summaries of means and standard deviations, as appropriate for all participants at each time-point, although multilevel models will be fitted, if feasible, to estimate the potential effect of the intervention on key outcome measures (via the 'sliding confidence interval' approach (41)). Prior to analysis, item-level imputation (using the mean score for items present for that participant) will be applied using the guidance specified for the outcome measure, where that exists, or if no more than 20% of items have missing data otherwise. Multilevel modelling will be based on a complete case analysis (i.e., no imputation of missing scale or sub-scale scores will be performed). We will also estimate the intra-cluster correlation coefficient (ICC), and other clustering parameters, although precision will be limited. We will use this ICC estimate, together with external evidence from the literature, to inform the potential design and sample sizes (at each level) for a future trial. A detailed statistical and heath economic analysis plan (SHEAP) will be developed and approved by the TSC prior to commencing data analysis. CONSORT diagrams are presented in Figures 1, 2, and 3. A summary of the trial's main feasibility success criteria are presented in Table 2.

[INSERT CONSORT DIAGRAMS AROUND HERE]

[INSERT TABLE 2 AROUND HERE]

Health economic analysis

To determine the feasibility of conducting a full economic evaluation, the feasibility of collecting data to measure the resource use (costs) and health benefits associated with the intervention and control will be explored.

Resource use will include relevant health and social care services as reported by service user participants in both study arms, and the training and supervision of the care coordinators delivering the intervention. Care coordinators in both study arms will keep logs of the number and duration of all contacts with study participants. This will be used to understand more about the impact of delivering MOL on care coordinator workload. An approximate intervention delivery cost will be estimated based on the contact logs and the costs associated with care coordinator time(42). At 6-month follow-up, service user participants will be asked to complete a bespoke resource use questionnaire (RUQ) regarding their use of health and social care services (including inpatient,

outpatient, A&E, GP services) during the study. This will help to clarify whether the RUQ is acceptable to participants and provide an opportunity to assess the quality of resource use data collected. The RUQ will be collected at a single time-point to minimise participant burden, but we will consider whether recall and completeness is acceptable when the RUQ is used at the 6-month time-point only. The number of contacts participants have with different services will be summarised descriptively. The level of missing data will be explored to understand more about the acceptability of the questionnaire design. Exploring data on healthcare resource utilisation will also enable us to capture the types of care people are accessing as part of TAU, which will allow better understanding of what the appropriate comparator intervention should be for the full trial. Participants will be asked to complete the EQ-5D (5-level version) at each assessment point (baseline, 3-months, 6-months). The EQ-5D will be used to derive health utility values as per the method recommended by NICE at the time of the analysis (38). Descriptive statistics for EQ-5D responses and utility values will be presented and the level of missing EQ-5D data reported.

Qualitative study

A nested qualitative study will help understand the feasibility and acceptability of MOL delivered by care coordinators in EIP teams, and clarify whether adjustments to the training programme, intervention, or study design are required prior to proceeding to a larger trial. A subsample of service user participants (n=15) will be invited to take part in semi-structured interviews. They will be asked about their experiences of working with an MOL-trained care coordinator, experiences of trial participation, helpful and unhelpful aspects of engaging with the MOL intervention, and whether refinements are required to the intervention or its method of delivery.

A subsample of care coordinator participants will be invited to participate in a series of focus groups, comprising 6-10 care coordinators who received MOL training. Focus groups will be informed by a four-stage process for evaluating training programmes (43). This is an established model for determining whether a training programme meets its stated objectives (44). Specifically, care coordinator participants will be asked about their reaction to MOL training and supervision, what they learned, the application of learning in practice, and the degree to which MOL achieved its intended outcomes.

We will also run one focus group with 6-10 EIP team managers from the three participating NHS Trusts. Team managers will be asked about their overall experience of the CAMEO study, their experience of identifying potential care coordinator and service user participants for the study, any impacts on service delivery arising from trial participation, and any potential adjustments that could be made to trial processes to support the delivery of a future larger study.

Interviews and focus groups will take place after care coordinator participants have completed MOL training and had an opportunity to implement the intervention in practice but prior to the end of the trial.

Trial oversight

A Trial Steering Committee (TSC) consisting of the following independent members: service user, clinical-academic, statistician, and care coordinator representatives, plus the Chief Investigator (RG), will provide study oversight, reporting to the Trial Management Team, Sponsor and Funder, as appropriate. As a small, low-risk feasibility study, a full Data Monitoring and Ethics Committee (DMEC) is not deemed necessary given the low-risk nature of the intervention. The functions of the TSC will include reviewing serious adverse events and ensuring adherence to the study protocol.

Safety monitoring

We will closely monitor, record, and report any serious adverse events (SAEs) and adverse events (AEs) that occur between participant enrolment and the study end date. Potential SAEs and AEs will be recorded and 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 is thought to be related to trial proceedings, the CI will share this information with the Research Ethics Committee. The Trial Management Group and sponsor will be informed of all potential SAEs and AEs.

In addition to monitoring SAEs, in accordance recent recommendations (45), we will monitor and record incidents of possible AEs. For the purposes of this trial, incidences of actual or threatened participant overdose, self-harm, or harm to others will be reported, even if these do not meet the criteria for classification as an SAE; other AEs will not be reported unless they meet the criteria for SAE but will be collected if the AE is a *potential* SAE.

If there are concerns about participant safety that are related to the study or MOL intervention, the Chair of the TSC can recommend that the trial is stopped or paused. The study may be audited by the project sponsor, but no external audits are planned.

Ethical and regulatory considerations

This study is sponsored by Greater Manchester Mental Health NHS Foundation Trust and has received ethical approval from the West Midlands - Black Country Research Ethics Committee (REC Reference: 22/WM/0073; IRAS ID: 307103). Ethical approval will be sought for protocol amendments prior to their implementation.

Access to data

An anonymised trial dataset will available after the completion of the study. This will be shared on request, at the discretion of the authors.

Dissemination

Results will be disseminated through open-access peer-reviewed journals, at relevant conferences, at stakeholder dissemination events organised within host and partner institutions, and at an international webinar. A plain English summary of study results will be shared with all participants. Final authorship of articles describing our findings will be decided nearer to the point of publication.

Public and patient involvement

This study benefits from strong patient and public involvement (PPI). A lived-experience co-applicant (AJ) has been involved in the development of the project from its early stages. They will participate in project management meetings, co-facilitate PPI panel meetings with the CI, contribute to the interpretation of study findings, and support the study's dissemination activities. A PPI panel of people with lived experience of psychosis will meet quarterly for the duration of the project. The panel will have input into any participant-facing materials, topic guide development, interpretation of study findings, and contribute to study dissemination activities.

Discussion

Evidence suggests that the quality of relationships between care coordinators and service users play an integral role in determining the effectiveness of Early Intervention in Psychosis services (8–10). At present, however, care coordinators are not routinely offered post-qualifying training in psychosocial approaches that might enhance the therapeutic benefits of their contact with service users. This study aims to evaluate the feasibility of recruiting and retaining participants (service users and care

coordinators) in a C-RCT that compares the effects of routine treatment versus routine treatment with the addition of an MOL-trained care coordinator on engagement and recovery rates.

Although previous research has established the feasibility and acceptability of MOL delivered to people experiencing first-episode psychosis (23,25), this is the first study that seeks to determine whether it is possible to train care coordinators to deliver MOL in routine clinical practice. In addition, while previous research has focused on training care coordinators in protocolised psychosocial interventions (e.g., (12,13), to our knowledge, this is the first study that seeks to train this staff group in an intervention that can be delivered flexibly alongside other aspects of their role. Should this approach prove promising, this could increase the effectiveness and perceived helpfulness of routine contacts between service users and care coordinators. It could also contribute to addressing the longstanding barriers to accessing psychosocial interventions that have been identified for people experiencing psychosis (15,16).

While it was thought to be important in this study to give care coordinators the flexibility to implement MOL in ways that they think will be most appropriate, one potential limitation of the trial design is that it will not be possible for the research team to monitor care coordinators' use of MOL directly. It will also not be possible to directly assess the degree to which care coordinators are maintaining fidelity to the MOL approach outside of training and supervision sessions. For this reason, the findings of the nested qualitative study will be important to consider when interpreting the results of this trial. The qualitative study will give an insight into the ways that care coordinators have been able to implement degree MOL in their routine practice and what barriers might exist that could impede this process.

This study is taking place during a challenging period for UK mental health services. It is important, therefore, to establish the feasibility of conducting a study of this kind within the context of rising demand for mental health services and staff shortages (46).

Recruitment of care coordinator and service user participants to the study began in May 2022. Data collection is due to end in December 2023, and the overall study end date is March 2024. Findings from the qualitative and quantitative components of this study will be used to determine whether progression to a larger, evaluation trial is justified.

1. NHS England, the National Collaborating Centre for Mental Health, National Institute for Health and Care Excellence. Implementing the Early Intervention in Psychosis Access and Waiting Time Standard: Guidance. 2016. p. 57.

2. Tsiachristas A, Thomas T, Leal J, Lennox BR. Economic impact of early intervention in psychosis services: Results from a longitudinal retrospective controlled study in England. BMJ Open. 2016;6(10):1–9.

3. National Institute for Health and Care Excellence (NICE). Psychosis and schizophrenia in adults: prevention and management. Nice. 2014.

4. Mascayano F, van der Ven E, Martinez-Ales G, Henao AR, Zambrano J, Jones N, et al. Disengagement from early intervention services for psychosis: A systematic review. Psychiatric Services. 2021;72(1):49–60.

5. Solmi F, Mohammadi A, Perez JA, Hameed Y, Jones PB, Kirkbride JB. Predictors of disengagement from Early Intervention in Psychosis services. British Journal of Psychiatry. 2018;213(2):477–83.

6. National Institute for Health and Care Excellence (NICE). Psychosis and schizophrenia in adults: prevention and management. Nice. 2014.

7. Lal S, Malla A. Service engagement in first-episode psychosis: Current issues and future directions. Canadian Journal of Psychiatry. 2015;60(8):341–5.

8. Reichert A, Jacobs R. The impact of waiting time on patient outcomes: Evidence from early intervention in psychosis services in England. Health Economics (United Kingdom). 2018;27(11):1772–87.

9. Barr K, Ormrod J, Dudley R. An exploration of what service users value about early intervention in psychosis services. Psychology and Psychotherapy: Theory, Research and Practice. 2015;88(4):468–80.

10. Watkins S, Sanderson C, Richards V. Service user perspectives of an early intervention in psychosis service: a service evaluation. Mental Health Review Journal. 2018;23(3):156–64.

11. Cowan T, Pope MA, MacDonald K, Malla A, Ferrari M, Iyer SN. Engagement in specialized early intervention services for psychosis as an interplay between personal agency and critical structures: A qualitative study. International Journal of Nursing Studies. 2020;108.

12. Lobban F, Taylor L, Chandler C, Tyler E, Kinderman P, Kolamunnage-Dona R, et al. Enhanced relapse prevention for bipolar disorder by community mental health teams: Cluster feasibility randomised trial. British Journal of Psychiatry. 2010;196(1):59–63.

13. Waller H, Landau S, Fornells-Ambrojo M, Jolley S, McCrone P, Halkoree R, et al. Improving implementation of evidence based practice for people with psychosis through training the wider workforce: Results of the GOALS feasibility randomised controlled trial. Journal of Behavior Therapy and Experimental Psychiatry. 2018;59(August 2017):121–8.

14. Jolley S, Onwumere J, Kuipers E, Craig T, Moriarty A, Garety P. Increasing access to psychological therapies for people with psychosis: Predictors of successful training. Behaviour Research and Therapy. 2012;50(7–8):457–62.

15. Haddock G, Eisner E, Boone C, Davies G, Coogan C, Barrowclough C. An investigation of the implementation of NICE-recommended CBT interventions for people with schizophrenia. Journal of Mental Health [Internet]. 2014;23(4):162–5. Available from: http://www.tandfonline.com/doi/full/10.3109/09638237.2013.869571

16. Ince P, Haddock G, Tai S. A systematic review of the implementation of recommended psychological interventions for schizophrenia: Rates, barriers, and improvement strategies. Psychology and Psychotherapy: Theory, Research and Practice. 2015;89(3):324–50.

17. Royal College of Psychiatrists. Royal College of Psychiatrists National report for England Early Intervention in Psychosis Audit. 2022;

18. Carey TA. The Method of Levels: How to do Psychotherapy Without Getting in the Way. Hayward, CA: Living Control Systems Publishing; 2006. 179 p.

19. Mansell W, Carey TA, Tai S. A transdiagnostic approach to CBT using method of levels therapy: Distinctive features. London, United Kingdom: Routledge; 2013. 175 p.

20. Powers WT. Behavior: The Control of Perception. Second. New Canaan, CT: Benchmark Publications; 2005.

21. Marken RS, Carey TA. Understanding the Change Process Involved in Solving Psychological Problems: A Model-based Approach to Understanding How Psychotherapy Works. Clinical Psychology and Psychotherapy. 2015;22(6):580–90.

22. Carey TA. The Method of Levels: How to do Psychotherapy Without Getting in the Way. Hayward, CA: Living Control Systems Publishing; 2006. 179 p.

23. Griffiths R, Mansell W, Carey TA, Edge D, Emsley R, Tai SJ. Method of levels therapy for first-episode psychosis: The feasibility randomized controlled Next Level trial. Journal of Clinical Psychology. 2019;75(10):1756–69.

24. Jenkins H, Reid J, Williams C, Tai S, Huddy V. Feasibility and Patient Experiences of Method of Levels Therapy in an Acute Mental Health Inpatient Setting. Issues in Mental Health Nursing. 2020 Apr 9;1–9.

25. Griffiths R, Mansell W, Edge D, Carey TA, Peel H, J. Tai S. 'It was me answering my own questions': Experiences of method of levels therapy amongst people with first-episode psychosis. International Journal of Mental Health Nursing. 2019 Jan 31;28(3):1–14.

26. Tai SJ. Using Perceptual Control Theory and the Method of Levels to work with people who experience psychosis. The Cognitive Behaviour Therapist. 2009 Sep 9;2(03):227.

27. Tai SJ. An introduction to using the method of levels (MOL) therapy to work with people experiencing psychosis. American Journal of Psychotherapy. 2016;70(1):125–48.

28. Tindall RM, Simmons MB, Allott K, Hamilton BE. Essential ingredients of engagement when working alongside people after their first episode of psychosis: A qualitative meta-synthesis. Early Intervention in Psychiatry. 2018;12(5):784–95.

29. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: The new Medical Research Council guidance. BMJ [Internet]. 2008 Sep 29 [cited 2016 Oct 17];337(7676):979–83. Available from: http://discovery.ucl.ac.uk/168426/

30. Carey TA, Mansell W, Tai SJ. Principles-Based Counselling and Psychotherapy. Hove, United Kingdom: Routledge; 2015.

31. Carey TA, Tai SJ. MOL session evaluation. In: Mansell W, Carey TA, Tai SJ, editors. transdiagnostic approach to CBT using method of levels therapy: distinctive features. London, UK: Routledge; 2012. p. 139–41.

32. Neil ST, Kilbride M, Pitt L, Nothard S, Welford M, Sellwood W, et al. The questionnaire about the process of recovery (QPR): A measurement tool developed in collaboration with service users. Psychosis. 2009;1(2):145–55.

33. Neil ST, Kilbride M, Pitt L, Nothard S, Welford M, Sellwood W, et al. The questionnaire about the process of recovery (QPR): A measurement tool developed in collaboration with service users. Psychosis [Internet]. 2009 [cited 2017 Apr 19];1(2):145–55. Available from: http://www.informaworld.com

34. Dehmahdi N, Law H, Pyle M, Byrne R, Jones W, Peel H, et al. Estimating the minimum important difference for the questionnaire about the Process of Recovery (QPR): an anchor-based approach. Psychosis. 2021;00(00):1–11.

35. Priebe S, Golden E, McCabe R, Reininghaus U. Patient-reported outcome data generated in a clinical intervention in community mental health care - psychometric properties. BMC Psychiatry. 2012;12.

36. Higginson Sally, Mansell Warren. What is the mechanism of psychological change? A qualitative analysis of six individuals who experienced personal change and recovery. Psychology and Psychotherapy: Theory, Research and Practice. 2008 Sep;81(3):309–28.

37. Munder T, Wilmers F, Leonhart R, Linster HW, Barth J. Working alliance inventory-short revised (WAI-SR): Psychometric properties in outpatients and inpatients. Clin Psychol Psychother. 2010;17(3):231–9.

38. National Institute for Health and Care Excellence [NICE]. Position statement on use of the EQ-5D-5L value set for England (updated October 2019) [Internet]. 2019. Available from: Position statement on use of the EQ-5D-5L value set for England (updated October 2019)

39. Maslach C, Leiter MP, Jackson SE. Maslach Burnout Inventory. 4th Editio. California: Mind Garden, Inc.; 2018.

40. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. BMJ (Online) [Internet]. 2016 [cited 2017 Jun 14];355. Available from: http://dx.doi.org/10.1136/bmj.

41. Lee EC, Whitehead AL, Jacques RM, Julious SA. The statistical interpretation of pilot trials: Should significance thresholds be reconsidered? BMC Med Res Methodol. 2014;14(41):1–8.

42. Curtis LA, A. B. Unit Costs of Health and Social Care. PSSRU, University of Kent; 2020. 185 p.

43. Kirkpatrick DL, Kirkpatrick JD. Evaluating Training Programmes. Third, editor. San Francisco, CA, US: Berrett-Koehler; 2006. 392 p.

44. Smidt A, Balandin S, Sigafoos J, Reed VA. The Kirkpatrick model: A useful tool for evaluating training outcomes. Journal of Intellectual and Developmental Disability. 2009;34(3):266–74.

45. Duggan C, Parry G, McMurran M, Davidson K, Dennis J. The recording of adverse events from psychological treatments in clinical trials: evidence from a review of NIHR-funded trials. Trials. 2015;15(335).

46. House of Commons Committee of Public Accounts. Progress in improving NHS mental health services. 2023.

Declarations

Ethics approval and consent to participate

This study is sponsored by Greater Manchester Mental Health NHS Foundation Trust and has received ethical approval from the West Midlands - Black Country Research Ethics Committee (REC Reference: 22/WM/0073; IRAS ID: 307103). Written consent to participate in this study was received from all research participants.

Consent for publication

All authors consent to the publication of this manuscript.

Availability of data and materials

An anonymised trial dataset will available after the completion of the study. This will be shared on request, at the discretion of the authors.

Competing interests

The authors have no competing interests to declare.

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Authors contributions

All authors have contributed to the development of the study protocol. RG and KL are leading the project. RG is responsible for overall trial management and is leading on the qualitative study. RG, KL, CS, ST, EC, JD, JPC, and AJ are all grant holders. NW, SO, and AD are responsible for data collection. RG, JD, JPC are site leads within participating NHS Trusts. CS and AK are trial statisticians. CS is leading on the development and implementation of the statistical analysis plan. EC is leading on the health economic analysis. AJ has provided lived experience input and is leading on the project's public and patient involvement activities. ST and RG are responsible for the delivery of Method of Levels training and supervision.

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Authors' information (optional)

Not applicable.

Table 1. Assessment schedule summary

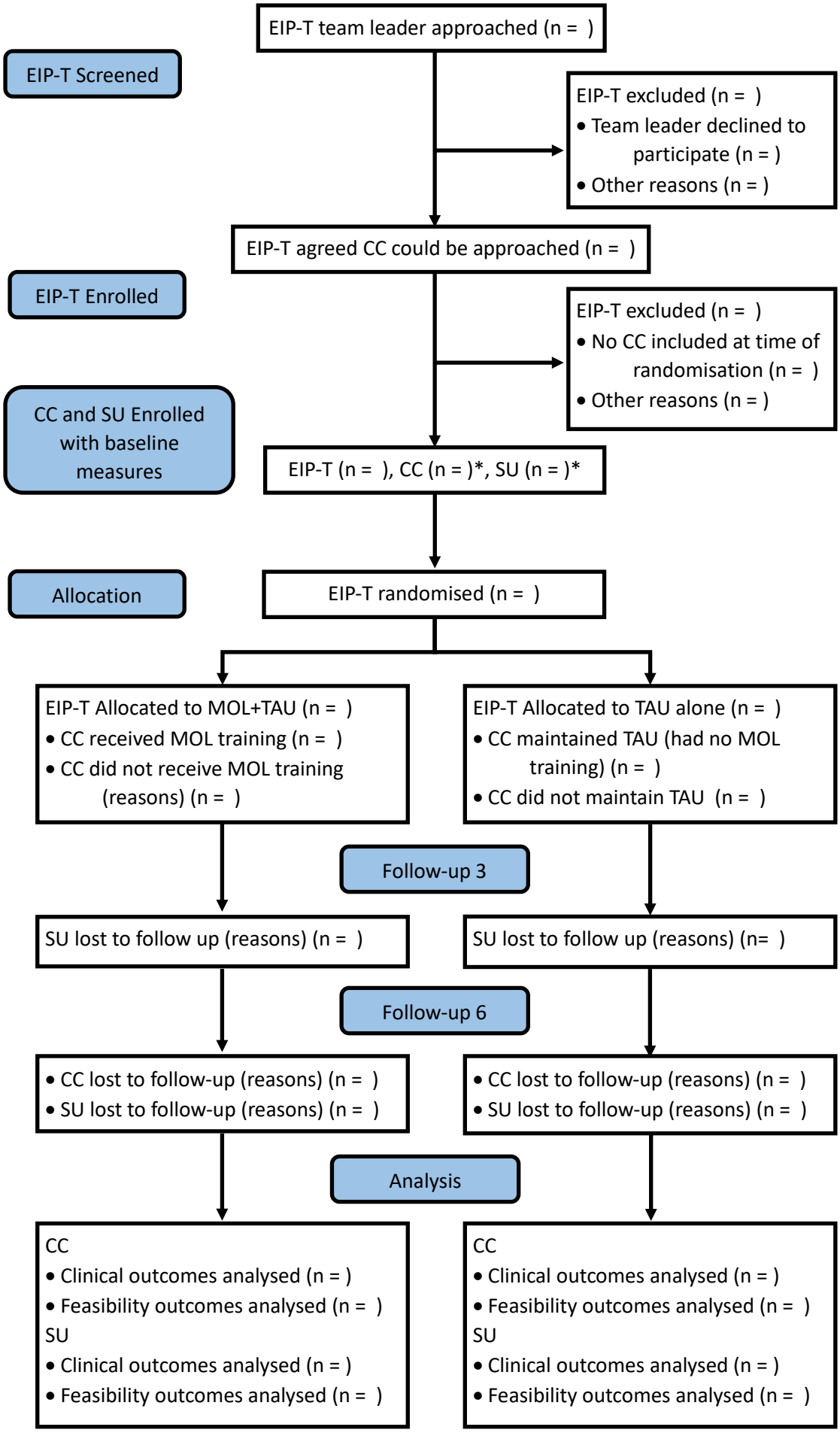
Participant type	Measure	Baseline	3 months	6 months
Service user	QPR[1]	✓	✓	✓
	DIALOG	✓	✓	✓
	ROC[2]	✓	✓	✓
	WAI-SR[3]	✓	✓	✓
	EQ-5D-5L[4]	✓	✓	✓
	RUQ[5]			✓
Care coordinator	MBI-HSS[6]	✓		✓

[1]Questionaire about the Process of Recovery; [2]Reorganisation of Conflict Scale; [3]Working Alliance Inventory-Short Revised; [4]EQ-5D (five-level version); [5]Resource Use Questionnaire; [6]Maslach Burnout Inventory: Human Services Survey

Table 2. Summary of feasibility trial success criteria

Criterion	Feasibility outcome
Recruitment	Successful recruitment of care coordinator and service-user participants within 8 months (for care coordinators: ≥75% = green; 60-<75% = amber; <60% = red; for service users: average ≥3 per care coordinator = green; 2-<3 = amber; <2=red).
Retention	Successful retention of care coordinator and service user participants at final follow up (for both groups: ≥80% = green; 60-79% = amber; ≤59% = red).
Engagement with MOL training and supervision	Attendance at initial MOL training (≥80% = green; 60-79% = amber; ≤59% = red) and monthly MOL supervision sessions (average of ≥4 sessions per care coordinator = green; 2-<4 = amber; <2=red).
Implementation	Evidence that care coordinators believe that they can deliver the MOL intervention in clinical practice.
Acceptability	Evidence that MOL delivered by care coordinators is perceived to be acceptable and helpful by service-users.

Figure 1: CONSORT Diagram



*Please see Figure 2 and Figure 3 below for the CONSORT flow diagrams for care coordinators and service users.

EIP-T = Early Intervention in Psychosis Team

SU = Service user

CC = Care coordinator

MOL = Method of Levels

TAU = Treatment as usual

Figure 2: CONSORT flow diagram for care coordinators

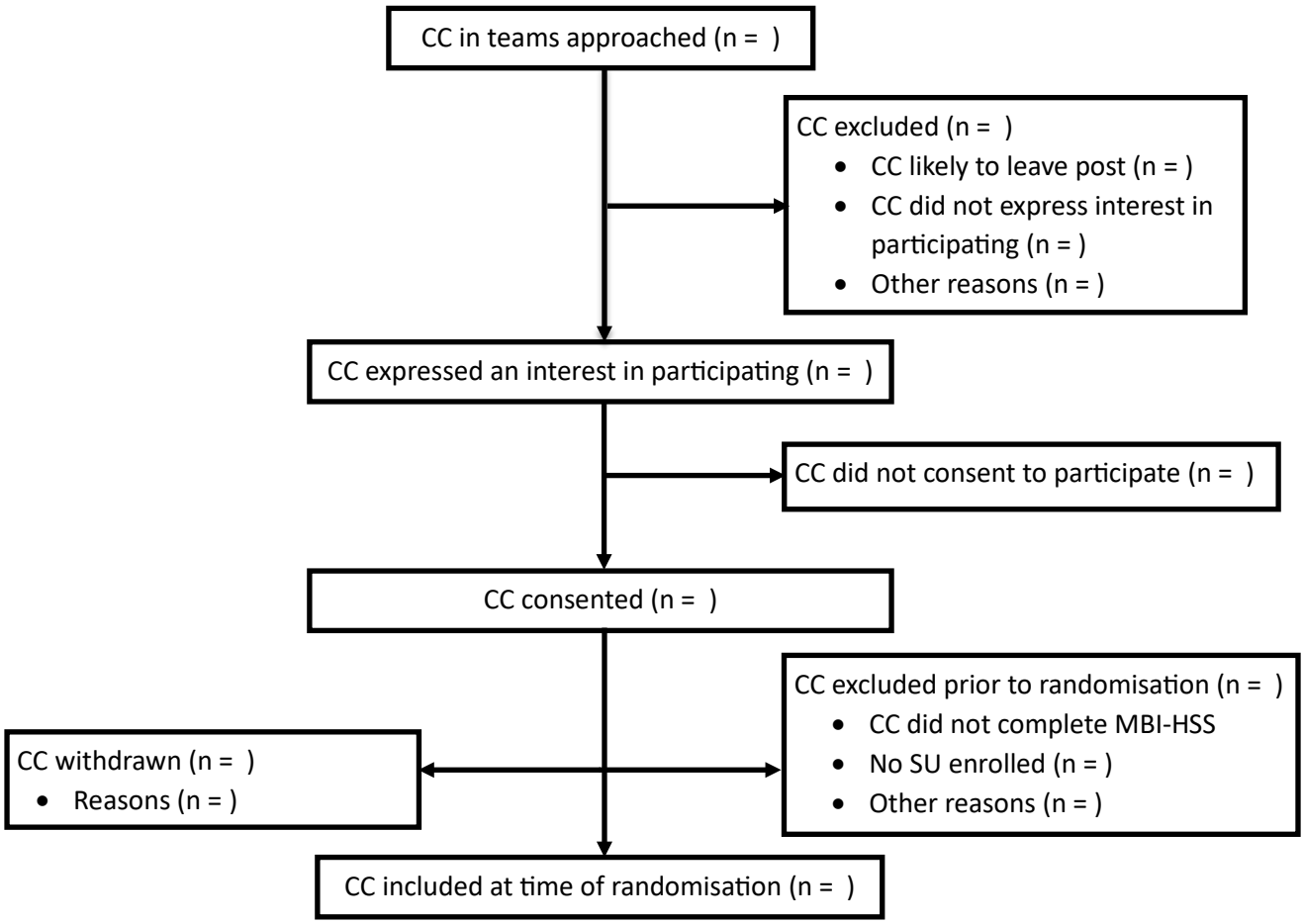


Figure 3: CONSORT flow diagram for service users