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Care coordinator delivered method of levels for psychosis

Submission date 18/02/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 29/04/2022	**Overall study status** Completed	
Last Edited 06/03/2025	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

The term psychosis describes a range of distressing experiences, including hearing and seeing things others cannot, holding beliefs others find unusual, and feelings of persecution. People experiencing a first episode of psychosis should receive support from early intervention services for up to 3 years and be allocated a care coordinator, often a nurse or social worker, who takes a lead in care planning and promoting recovery. Many service users, however, do not remain in contact with early intervention services for the full 3 years, limiting their access to evidence-based interventions. There is evidence that what people value about early intervention services is the opportunity to talk openly about their difficulties in an atmosphere of trust. Care coordinators are not routinely offered training on how to make these conversations as beneficial as possible. Improving the quality of support offered by care coordinators could make these services more helpful and encourage service-users to remain in contact with them. The aim of this study is to find out if it is feasible to conduct a study where care coordinators are trained to deliver a psychological intervention called Method of Levels, which could support people's recovery and improve relationships between care coordinators and service users.

Who can participate?

Care coordinators from early intervention teams and service users aged 18 years or older who are working with them

What does the study involve?

Teams will be randomly allocated to one of two groups. Teams in both groups will continue offering their usual support to service users. Care coordinators working in teams in the second group will also be offered Method of Levels training and supervision. To help them to decide whether a larger trial is justified, the researchers will then examine differences in outcomes and experiences between groups, including psychosis recovery rates and the quality of relationships between service users and care coordinators.

What are the possible benefits and risks of participating?

Many people report that taking part in research of this kind is a helpful experience. Others say that it is rewarding to take part in research that helps to improve mental health services for other people. Participants might find it helpful to talk about their difficulties or their

experiences of working with an Early Intervention in Psychosis service. It is possible that topics will be discussed when completing questionnaires or during interviews that some people find distressing. The researchers think that it is unlikely that participants will experience any long-term distress from taking part in this study. Participants are not under any pressure to take part in this study. The decision about whether to participate will not affect the support received from the Early Intervention in Psychosis service or any other support that participants would usually receive. Participants can choose to skip any questions that cause discomfort or distress and can end participation in the study at any time without giving a reason. The research team will ask for regular feedback about participants' experiences of taking part in the study.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
October 2021 to March 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Robert Griffiths
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
307103

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 307103, CPMS 52424, NIHR203475

Study information

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

Acronym
CAMEO

Study objectives
This study investigates the use of a transdiagnostic psychological intervention, called Method of Levels (MOL), delivered by care coordinators working in Early Intervention in Psychosis services.

Primary objective:
Establish the feasibility of recruiting and retaining participants (care coordinators and service-users) in a cluster randomised controlled trial comparing the effects of MOL-trained care coordinators versus treatment as usual on outcomes (engagement and recovery) for people experiencing first-episode psychosis.

Secondary objectives:
1. Establish the acceptability of the MOL training programme amongst care coordinators and of MOL delivered by care coordinators amongst service-users.
2. Identify barriers and facilitators to MOL delivered by care coordinators.
3. Refine the MOL training programme and implementation plan based on participant feedback.
4. Establish the most appropriate primary outcome measure for a definitive trial.
5. Generate further evidence on the promise of the intervention via estimates of effectiveness on key outcome measures.
6. Estimate key parameters to inform a sample size calculation for a definitive trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/04/2022, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, HRA1 Meeting Room, NG1 6FS, UK; +44 (0)207 104 8010; blackcountry.rec@hra.nhs.uk), ref: 22/WM/0073

Study design
Feasibility cluster randomized controlled trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
First-episode psychosis

Interventions
The study uses a feasibility cluster randomised controlled trial (C-RCT) design with two parallel conditions: (1) treatment as usual (TAU) or (2) TAU plus support from a care coordinator who has received training in Method of Levels (MOL). Randomisation will take place at the level of EIP teams. Approximately 12 teams will be allocated to groups in random permuted blocks using an online randomisation service (Sealed Envelope Ltd., 2021). Because the researchers 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. Future allocations will be concealed until teams are randomised. Care coordinators working in teams allocated to TAU will not receive MOL training but will continue to have access to any training and supervision normally available. Care coordinators in teams allocated to the treatment arm will receive access to a 3-day MOL training course and monthly MOL supervision sessions for the duration of the study, in addition to any training and supervision they would normally receive. To reduce contamination risk, teams will be located at separate geographical locations and/or be operationally distinct from each other. Care coordinators trained in MOL will be asked to avoid discussing the approach with practitioners based in other teams.

Care coordinator participants will receive supervision to support the delivery of the intervention for 6 months. The final follow up will be at 6 months.

Intervention Type
Other

Primary outcome(s)
Feasibility of recruiting and retaining service user and care coordinator participants, assessed using the number of participants who consent to participate who remain in the study until the end of follow-up at 6 months

Key secondary outcome(s))
To help determine the most appropriate primary and secondary outcomes for a definitive trial, participants will be asked to complete a range of standardised outcome measures.

Service user participants will be asked to complete the following measures at baseline, 3, and 6 months:
1. Personal recovery from psychosis measured using the Questionnaire about the Process of Recovery (QPR)
2. Quality of life and treatment satisfaction measured using DIALOG
3. Goal conflict reorganisation measured using the Reorganisation of Conflict Scale (ROC)
4. Quality of the therapeutic alliance between clinician and service-user measured using the Working Alliance Inventory-Short Revised (WAI-SR)
5. Health outcome (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) measured using EQ-5D-5L (EuroQol Group)

6. Use of health and social care services (including inpatient, outpatient, A&E, GP) during the study measured using the Resource Use Questionnaire (RUQ)

Care coordinator participants will be asked to complete the following measure at baseline and 6 months:
Burnout measured using the Maslach Burnout Inventory: Human Services Survey (MBI-HSS)

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Early Intervention in Psychosis (EIP) team eligibility criteria:
EIP teams operating within three participating NHS Trusts (Greater Manchester Mental Health [GMMH], Lancashire and South Cumbria NHS Foundation Trust [LSCFT], and Merseycare) 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:
1. Working within EIP services based within participating NHS Trusts
2. Likely to remain in their current post for the duration of the study
3. Have organisational support from their employer to engage with MOL training and supervision
4. Willing and able to engage with MOL training and supervision
5. Provide informed consent to participate in the study

Service user participant eligibility criteria:
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 the 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
6. Aged 18 years or older

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
06/05/2022

Date of final enrolment
25/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
United Kingdom
M25 3BL

Study participating centre
Lancashire and South Cumbria NHS Foundation Trust
Sceptre Point
Sceptre Way
Walton Summit
Preston
Andorra
PR5 6AW

Study participating centre
Merseycare NHS Trust
V7 Building
Kings Business Park
Prescot
United Kingdom
L34 1PJ

Sponsor information

Organisation
Greater Manchester Mental Health NHS Foundation Trust

ROR
https://ror.org/05sb89p83

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		31/08/2024	02/09/2024	Yes	No

HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	Statistical and Health Economic Analysis Plan (SHEAP) version 1.0	16/01/2024	29/11/2024	No	No