

COMPEERS: contingency management and peer support feasibility study

Submission date 24/06/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/07/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 05/07/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Around 20% of community mental health team (CMHT) service users have 'dual diagnoses' of psychosis (a serious mental illness involving hearing things others cannot, fearing people mean you harm, low motivation) and drug/alcohol problems (DDp). People with DDp have complex needs with high financial costs to health and community services. Outcomes are worse than for either problem alone or for other mental illnesses. One reason is that both psychosis and the chaotic lifestyle and stigma of drug/alcohol problems make people less likely to attend treatment appointments. Increasing attendance should help improve engagement with treatment leading to better outcomes.

Aim: Conducting a small feasibility pilot of a future large trial evaluating whether Contingency Management (CM, changing behaviour with financial incentives) encourages people with DDp to attend weekly peer support worker appointments (PSW, somebody with lived experience of similar difficulties).

Who can participate?

Patients aged 18 years and older who are receiving care from a participating CMHT and have a dual diagnosis of symptoms of both psychosis/schizophrenia spectrum diagnosis and drugs /alcohol problems

What does the study involve?

Six CMHTs in one NHS trust (80 participants) will provide usual treatment (monthly CMHT worker meetings and access to recommended treatments) alongside weekly PS. Half (3/6) will be randomly chosen to also financially reward PS attendance (CM). We will judge feasibility based on: numbers agreeing to participate and providing follow-up data; PS/CM delivery; measurement of outcomes (attendance at peer support, patient/peer/team reported engagement in offered treatment, drug/alcohol use, patient-reported health-related quality of life/satisfaction, crises/relapses/inpatient admissions, treatment and intervention costs). We will interview patients, PSWs, and CMHT staff about the study's acceptability.

What are the possible benefits and risks of participating?

We hope that attending peer support meetings will be helpful for people's wellbeing and recovery. Previous research suggests this. We also hope that attending peer support might help

people attend other activities to help their wellbeing and recovery. Again, previous research has raised this possibility. Contingency management has been shown to help people make positive behaviour changes in many different settings, so it might help with attendance at peer support meetings. These are all things we want to test in our future, larger study.

We do not think there are any particular risks or hazards involved in being part of the study. However, we are asking everybody involved to please tell us if they do experience any adverse effect as this is one of the things that will be important for us to know. If we receive any new information that suggests any part of the study might be harmful, we will tell you at once, and let you know whether we are able to continue the study, and give you chance to decide if you want to carry on taking part.

Where is the study run from?

South London and Maudsley NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

January 2024 to December 2025

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

323042

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 54652, NIHR204991, IRAS 323042

Study information

Scientific Title

COMPEERS: A cluster randomised feasibility study of COntingency Management and PEER Support to promote attendance, increase treatment engagement, and improve outcomes for people with dual diagnoses of psychosis and drug/alcohol problems (DDp)

Acronym

COMPEERS

Study objectives

Primary objective:

To generate knowledge of the feasibility of conducting a future confirmatory trial to assess the clinical and cost effectiveness of Contingency Management (CM) to promote attendance at Peer Support (PS) appointments and increase engagement in recommended treatment.

Secondary objectives:

1. To estimate the additional cost of the intervention, associated treatment costs and health economic outcomes (QALYs).
2. To collect summary statistics and estimates to inform future sample size calculations, including the intraclass correlation of the clusters (Community Mental Health Teams, CMHTs).
3. To conduct qualitative interviews to assess the acceptability and feasibility of introducing CM to CMHTs to encourage individuals with a diagnosis of DDp to attend treatment appointments
4. To develop, as an output, a training manual and supervision structure for PSWs in delivering CM

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 05/06/2024, Bloomsbury Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8276; bloomsbury.rec@hra.nhs.uk), ref: 24/LO/0264

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

To follow

Health condition(s) or problem(s) studied

Dual diagnoses of psychosis/schizophrenia spectrum diagnosis and drugs/alcohol problems

Interventions

We will conduct a small trial to test the feasibility of procedures for a planned larger scale trial.

Six community mental health teams (CMHTs) will be randomised in a 1:1 ratio to add Contingency Management to an enhanced treatment offer, or not. The enhanced treatment offer will be usual care (monthly meetings with a care co-ordinator and access to recommended interventions) plus weekly meetings with a peer support worker (PSW). PSWs will use text messaging to remind participants of their meetings.

CM will involve financially rewarding attendance at PSW meetings (£10/meeting, an additional £10 for four consecutive meetings).

We would like to arrange access to a pseudonymised list for teams using our clinical records search service (fully anonymised for the research team) to help them identify eligible participants (anybody with a working DDP diagnosis, receiving care from the team, for whom the team deems participation safe and informed consent possible). The research team will not have access to the report, but will collect anonymised, aggregate data on numbers in each team with psychosis, or drug/alcohol problems, or both, the characteristics of those with both psychosis and drug/alcohol problems, and reasons why any of the target population are not approached /successfully contacted by the clinical team regarding participation or decline contact with the research team. Teams will be asked to identify additional, new referrals during the enrolment period. Clinical team staff will contact service users to ask if the research team may contact

them, those agreeing will receive a call or have a meeting to discuss the study and have any questions answered. If they agree to participate, they will be offered PSW meetings, with or without CM, depending on their team's allocation.

PSWs will complete measures of engagement in peer support and team meetings and of health-related quality of life, with participants at 0, 12 and 24 weeks. They will also complete weekly ratings of attendance at activities that form part of the person's individualised care plan, and any difficulties over the week, to inform routine collection of adverse events. For participants in the CM arm, PSWs will also give the financial incentive each meeting, in the form of a shopping voucher.

PSW meetings will be weekly for 12-weeks, with CM, for those teams allocated to the CM arm. After 12 weeks, everybody will receive four further PS meetings, at 14, 16, 20 and 24 weeks, without any CM.

Frontline clinical staff will also complete the engagement measure at 0, 12 and 24 weeks, as well as routine measures of drug/alcohol problems and quality of life/life satisfaction. The study research worker will collect these outcomes, along with service use outcomes (inpatient stays and crisis team involvement) and adverse events, from the clinical record. Where frontline staff have not completed outcome measures with participants, the study research worker will arrange to meet them to complete outcomes.

At the end of the study, participants, PSWs, and clinical staff will be offered the opportunity to participate in interviews about the experience of being in the study, individually or as a focus group. Interviews will be recorded and anonymised transcripts created. Transcription will be carried out by an external confidential research transcribing company under contract. Service user and PSW participants will receive £20 for participating in the interviews. Transcripts will be subjected to qualitative analysis.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Feasibility outcome measures

Screening, consent and enrolment (at baseline)

1. Number of PSWs approached (measured by screening instruments, at baseline)
 2. Percentage PSWs recruited to take part in the study (measured by screening instruments at baseline)
 3. Number and percentage of screened service users eligible for inclusion over the 12-month recruitment period and reasons for ineligibility (measured by screening instruments at baseline).
 4. Number and percentage of eligible service users who consent to participate in the trial and reasons for no consent (measured by screening instruments at baseline).
 5. Number of participants enrolled per week over the 12-month recruitment period (measured by screening instruments at baseline).
- Data completeness at baseline and follow-up assessments (at 12- and 24-weeks).
6. Number and percentage of PSW appointments at which attendance is recorded (measured by Peer Support Worker Session Summary at weeks 1 to 12).
 7. Number and percentage of engagement questionnaires completed at each assessment point

(0,12, 24 weeks) (measured by completion of the brief observer-rated engagement measure by both Peer Support Workers and participants at baseline and weeks 12 and 24).

8. Number and percentage of service users providing 12-week outcomes (measured by routine clinical data collection of ASSIST-LITE , the AUDIT, and DIALOG12 at baseline and 12 and 24 weeks and extracted from clinical records. Also, measured by the EQ5D at baseline and week 12 and 24).

9. Number and percentage of completed baseline assessments. As above.

Adherence

10. Adherence to CM and TAU protocols by PSWs (measured by CM Adherence Scale at weeks 1 to 12).

Secondary outcome measures

Primary outcome for consideration in a future confirmatory trial

1. Attendance at weekly appointments with PSWs during treatment period (0-12 weeks).

Number of appointments offered, number and percentage attended (measured by Peer Support Worker session summary at weeks 1 to 12).

Secondary outcomes for consideration in a future trial

2. Attendance at PSW appointments during the tapering period (13-24 weeks). Number of appointments offered, number and percentage attended (measured by Peer Support Worker Session Summary at weeks 13 to 24).

3. Attendance at treatment as usual appointments during the treatment period (0-12 weeks), including monthly meetings with the Care Coordinator and other treatments provided as set out in participants' Individualised Care Plan (measured by Peer Support Worker session summary at weeks 1 to 12).

4. Attendance at treatment as usual appointments (as above) during weeks 13-24 weeks (assessed by routine clinical data collection at 13 to 24 weeks and extracted from clinical records)

5. Engagement assessed using patient-reported ratings of engagement in peer support and the wider care plan, combined with PSW and Care Coordinator/CMHT worker ratings of engagement (measured by completion of the brief observer-rated engagement measure by both Peer Support Workers and participants at baseline and weeks 12 and 24).

6. Clinical outcomes assessed from clinical records: number of inpatient and crisis team episodes, episode length (days), patient-reported drug/alcohol use, patient-reported quality of life /satisfaction as assessed by routine clinical data collection at 1 to 24 weeks and extracted from clinical records).

7. Estimated mean treatment costs per participant and quality-adjusted life years per service user (assessed by clinical records and the EQ5D as above between 1-24 weeks).

Overall study start date

01/01/2024

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Are aged 18 and over at enrolment

2. Are receiving care from a participating CMHT

3. Have a dual diagnosis of symptoms of both psychosis/schizophrenia spectrum diagnosis and drugs/alcohol problems (both ascertained according to the treating team's working diagnoses, which will be recorded on the clinical record)

4. Are able to give informed consent and safely participate (i.e. severity of psychosis, drug /alcohol problems, and/or other problems does not, in the clinical judgement of the treating team, preclude consenting and safely participating)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 80; UK Sample Size: 80

Key exclusion criteria

All participants receiving care from participating teams, with the target difficulties, judged by the team able to give informed consent and participate safely will be included. We will exclude only those participants whose care team deems their participation in the study unsafe, or considers them unable to give informed consent. This is likely to be because of the severity of their difficulties with psychosis or drug/alcohol problems.

Date of first enrolment

01/07/2024

Date of final enrolment

31/03/2025

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

South London and Maudsley NHS Foundation Trust

Bethlem Royal Hospital

Monks Orchard Road

Beckenham

United Kingdom

BR3 3BX

Study participating centre
LWC North Focused Support
332 Brixton Rd
London
United Kingdom
SW9 7AA

Study participating centre
LWC South East Focused Support
312 Brixton Rd
London
United Kingdom
SW9 6AA

Study participating centre
CMHT Camberwell and Peckham
St Giles House, St Giles Road
London
United Kingdom
SE5 7UD

Study participating centre
CMHT Dulwich
St Giles House, St Giles Road
London
United Kingdom
SE5 7UD

Study participating centre
START Lambeth & Southwark
190 Kennington Lane
London
United Kingdom
SE11 5DL

Sponsor information

Organisation
South London and Maudsley NHS Foundation Trust

Sponsor details

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slam-ioppn.research@kcl.ac.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.slam.nhs.uk/>

ROR

<https://ror.org/015803449>

Funder(s)**Funder type**

Government

Funder Name

NIHR Central Commissioning Facility (CCF)

Results and Publications**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2026

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date