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Randomised controlled trial of the clinical and cost-effectiveness of a peer-delivered self-management intervention to prevent relapse in crisis resolution team users: study protocol

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ABSTRACT

Introduction Crisis resolution teams (CRTs) provide assessment and intensive home treatment in a crisis, aiming to offer an alternative for people who would otherwise require a psychiatric inpatient admission. They are available in most areas in England. Despite some evidence for their clinical and cost-effectiveness, recurrent concerns are expressed regarding discontinuity with other services and lack of focus on preventing future relapse and readmission to acute care. Currently evidence on how to prevent readmissions to acute care is limited. Self-management interventions, involving supporting service users in recognising and managing signs of their own illness and in actively planning their recovery, have some supporting evidence, but have not been tested as a means of preventing readmission to acute care in people leaving community crisis care. We thus proposed the current study to test the effectiveness of such an intervention. We selected peer support workers as the preferred staff to deliver such an intervention, as they are well-placed to model and encourage active and autonomous recovery from mental health problems.

Methods and analysis The CORE (CRT Optimisation and Relapse Prevention) self-management trial compares the effectiveness of a peer-provided self-management intervention for people leaving CRT care, with treatment as usual supplemented by a booklet on self-management. The planned sample is 440 participants, including 40 participants in an internal pilot. The primary outcome measure is whether participants are readmitted to acute care over 1 year of follow-up following entry to the trial. Secondary outcomes include self-rated recovery at 4 and at 18 months following trial entry, measured using the Questionnaire on the Process of Recovery. Analysis will follow an intention to treatment principle. Random effects logistic regression modelling with adjustment for clustering by peer support worker will be used to test the primary hypothesis.

Ethics and dissemination The CORE self-management trial was approved by the London Camden and Islington Research Ethics Committee (REC ref: 12/LO/0988). A Trial Steering Committee and Data Monitoring Committee oversee the progress of the study. We will report on the results of the clinical trial, as well as on the characteristics of the participants and their associations with relapse.

Trial registration number ISRCTN 01027104;pre-results stage.

Strengths and limitations of this study

- High rates of acute care use and readmissions following a crisis are significant and expensive challenges, yet there is little evidence on how to reduce them and few studies carried out in acute mental health settings; we address this evidence gap.
- Service users have made major contributions to intervention and protocol development and are responsible for delivery of the intervention.
- Our intervention has multiple components: if effective, there will be uncertainty about which elements are required for improved outcomes.
- Peer support workers have all used mental health services but are not required to have used crisis teams; this may limit their capacity to support people in learning new skills to manage crises.
- Only people able to give informed consent and to participate in English can enter; this will limit sample representativeness.

INTRODUCTION

Background and rationale

Crisis resolution teams (CRTs)—sometimes called home treatment or crisis assessment teams—provide rapid assessment in mental health crises and, when feasible, offer intensive home treatment as an alternative to acute psychiatric inpatient admission.[1] Their target group is service users who are experiencing

a crisis of sufficient severity for hospital admission to be considered. Clinicians in primary and secondary care refer service users whom they believe to meet this criterion, and in some catchment areas, self-referrals are also accepted for assessment. Guidance regarding the model requires CRTs to 'gatekeep' hospital beds, with no admissions occurring without their agreement, although this guidance is not always fully implemented in practice.[2] They also accept early discharges of people who, without an intensive input at home, would have a prolonged stay on an inpatient ward. Since being mandated in the NHS Plan (2000),[3] CRTs have proliferated and are now available in most NHS Trust catchment areas in England. Research evaluations have been mainly positive, suggesting CRTs reduce inpatient admissions[4–8] and healthcare costs,[9 10] and increase service user satisfaction with acute care.[4 7] Service users, however, have reported considerable areas of dissatisfaction, including continuity of care between services during and following a period of CRT care.[11 12] Recent policy reports have also criticised CRTs for failings including lack of continuity and integration with other services, and insufficient attention to strategies for maintaining well-being and avoiding future crises.[13–18] This is a very significant gap as more than half of CRT users are reported to be readmitted to acute services within a year.[17] Thus demand for acute care in England remains very high in the absence of interventions to reduce repeat use.[18] A scoping review regarding interventions for mental health crisis care did not find robust evidence on how to prevent repeat crises in people leaving crisis care.[19]

The aim of the present study is to develop and test an intervention intended to achieve this. The SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines are followed in this report of the protocol.

Choice of comparators

Self-management intervention

There is substantial evidence for the effectiveness of self-management programmes supporting mental health service users to manage their own illness.[14] These commonly involve learning to anticipate and respond to signs of a crisis and developing skills to manage symptoms or other difficulties. The provision of peer support—support provided by people who have themselves experienced mental ill health—alongside existing aftercare services has also been advocated to improve outcomes for people who have just experienced a mental health crisis.[20] Hypothesised qualities of peer workers include an ability to provide support and encouragement that is particularly warm and empathic due to being rooted in personal experience, and provision of a role model for recovery.[21] These qualities suggest that peer workers are a particularly appropriate choice for delivery of programmes aimed at enhancing recovery and proactive behaviours and self-care to remain well. North American trials of peer-provided self-management programmes such as the Wellness Recovery Action Plan[22] and the Recovery Workbook[23] report some promising outcomes for service users, but their impact on admissions or relapse has not been assessed. Our goal in the current study is to develop and test an intervention with a similar self-management focus for people leaving the care of crisis teams, aiming to reduce their subsequent readmission rates and dependence on services. The employment of peer support workers to deliver self-management support to service users is becoming increasingly common within National Health Service (NHS), promoted by initiatives such as the NHS Confederation *Implementing Recovery through Organisational Change* project,[24] but thus far the effectiveness of such an intervention in reducing acute care readmission following a crisis has not to our knowledge been tested.

Control intervention

Specific interventions to prevent relapse and promote recovery following a crisis are not currently routinely delivered in NHS settings; we are thus aiming to test whether investing in delivery of such an intervention is more effective than just providing service users with a simple resource to help them manage their mental health and recovery themselves. The control condition was therefore treatment as usual from any services to which CRT users were referred on discharge, with participants also being sent the self-management manual on which the experimental intervention was based. This manual gives details of how to develop plans for relapse prevention and for setting recovery goals.

Hypotheses/Objectives

1. The primary hypothesis to be tested is that service users receiving the experimental intervention will be less likely to relapse (indicated by readmission to acute care) over 1 year than those in the control intervention receiving treatment as usual enhanced by access to a self-management manual. The anticipated admission rates at 1-year follow-up on which study power calculation was based were 50% for control and 35% for intervention groups.
2. Secondary hypotheses are to test whether being in the experimental rather than the control condition is associated with longer time to first admission to acute care and fewer days in acute care over 1 year, and also in better perceived recovery and illness management, greater satisfaction with services, fewer symptoms, less loneliness, enhanced social networks and greater social inclusion at the 4-month and the 18-month follow-up interviews than participants in the control condition.
3. A further objective was to conduct a health economic evaluation to calculate the probability that peer-provided self-management is cost-effective compared with control over 1 year for a range of values of willingness to pay for a quality-adjusted life year (QALY) gained. A secondary analysis will calculate cost per QALY gained over 18 months.

A planned secondary use of the data is to investigate a set of hypotheses regarding loneliness, social isolation and social capital and outcomes following a crisis; these will be separately reported and disseminated.

Trial design

The CORE (CRT Optimisation and Relapse Prevention) trial of a peer-provided self-management intervention is a rater-blind, randomised controlled superiority trial with two parallel arms (allocation ratio 1:1), designed to test the hypotheses above. The trial is powered on the primary outcome, with adjustment for clustering by peer support worker.

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Setting

All participants are identified from the caseload of crisis resolution and home treatment teams (CRTs) in six NHS Trusts. Four are in London, one in the South East of England and one in the South West. Areas include inner city, suburban, mixed and rural catchment areas. All the CRTs aim to operate according to the standard NHS model. All teams are contactable 24 hours a day and see service users primarily in their homes, offering short-term care during the crisis before discharge to other secondary or primary care services as appropriate for further management. Structured self-management interventions are not widely implemented in these catchment areas,[25] so that both control and experimental arms are receiving an additional intervention. A list of participating sites is available from the authors.

Eligibility criteria

Inclusion criteria

1. On the caseload for at least a week of one of the participating CRTs because of a mental health crisis (including both participants treated only by the CRT during the crisis and those initially admitted to hospital or a crisis house and then discharged to the CRT)
2. Capacity and willingness to give informed consent to participate in the study
3. Consented to enter the trial within a month of discharge from the CRT.

Exclusion criteria

1. People presenting such a high risk to others that the CRT judged that it would be unsafe for peer support workers to meet with them even in a mental health service setting
2. People who are discharged to addresses outside the catchment area
3. People who cannot understand the intervention when delivered in English.

Criteria were deliberately broad in order to reach conclusions generalisable to the full range of CRT users. With this aim of achieving broad representativeness of CRT service users, we also set a threshold at each study site of at least 50% of participants to be identified at screening as having schizophrenia or other psychosis, or bipolar disorder. Within this stipulation, participation has been offered to all eligible service users in participating CRTs until the recruitment target for the service has been reached.

Interventions

Experimental group intervention

The peer-provided self-management intervention tested in the study has been adapted from recovery resources compiled by Dr Rachel Perkins, Dr Julie Repper and colleagues at South West London and St George's NHS Foundation Trust,[26] specifically their Personal Recovery Plan. This was in turn informed by self-management resources such as the Wellness Recovery Action Plan[22] and relapse prevention interventions.[27]

Selection and development of the intervention

The intervention was adapted and selected via the following stages, more fully described in a companion paper:

1. Initial searches: Systematic literature searches were carried out to find relevant literature on self-management interventions for people with mental health problems, and on peer support interventions.[25] A literature and internet search was also carried out and key experts consulted to identify relevant resources for self-management interventions.
2. Individual interviews to inform intervention selection: In individual interviews with 41 consenting service users, their views were explored of the types of intervention that would be feasible and useful following a crisis, how they should be offered and delivered, and the potential benefits and risks of having a peer worker deliver the interventions. These interviews were carried out by service user researchers, and were also used to elicit data relevant to the other workstream included in the CORE study, involving development and testing of an intervention to improve CRT fidelity.[29]
3. Stakeholder focus groups and adaptation of the intervention: Informed by this work, the Personal Recovery Plan[30 31] was identified by the study team and advisory groups of service users and carers, and of clinicians, involved in the study as the most promising basis for the study intervention. A series of stakeholder focus groups was then convened for discussion on how to fit this intervention within existing care pathways. The groups usually comprised six to eight participants. Twelve groups of consenting participants were convened in all: five of people with experience of using crisis services, five of CRT staff and two of carers with experience of crisis services. Following this step, the Personal Recovery Plan was adapted with the permission of its authors and under licence from the copyright holders, South West London and St George's

Mental Health Trust, to fit the context of the trial, including adaptations to make it as relevant as possible to people who have recently experienced a crisis. A protocol was also developed for peer support worker training, and for delivery of the intervention in the context of the trial.

4. Feasibility study: Following this, an uncontrolled feasibility study was conducted to test the feasibility and acceptability of the intervention. Four peer support workers were given a 4-day training in fundamentals of delivering peer support and in the delivery of our draft self-management intervention: an abbreviated and tailored version of the Nottingham Institute of Mental Health's accredited peer support worker training. Eleven participants were recruited from an inner city CRT and gave informed consent to receive the intervention over 10 sessions. Following the intervention period, a group interview was conducted with the peer support workers and individual interviews with the service user participants (n=9). Experiences of the intervention and suggestions for adaptation were explored and further minor modifications introduced throughout the intervention.

Delivery of the intervention

The intervention is delivered in a series of up to 10 sessions with a peer support worker. Each trial participant is allocated to one peer support worker. If participants specifically requested a peer support worker of their own gender, this is arranged, but no attempt beyond this is made to match peer support workers and participants. There is no consensus in the literature[32] on whether, and on the basis of which characteristics, peer support workers and clients need to be matched. In practice, with three peer support workers available in each CRT, we anticipated being unable to match on many characteristics, and felt that attempting to do so may restrict generalisability to routine NHS settings, where matching is often not feasible. The peer support worker offers sympathetic listening and seeks to instil hope through appropriate sharing of skills and coping strategies acquired in their own recovery journey. The intervention is structured round the completion of a Personal Recovery Workbook with the following structured components:

- setting personal recovery goals
- help with plans to re-establish community functioning and support networks following a crisis
- using the experience of recent crisis to identify early warning signs and an action plan to avoid or attenuate relapse
- planning strategies and coping resources to maintain well-being once a crisis has abated.

Meetings take place weekly, with the aim of completing the programme of up to 10 sessions within 3 months. The peer support worker encourages the participant to consider involving friends and family in the intervention, by showing them materials from the meetings, eliciting their help with making crisis plans or inviting them to attend a meeting. Unless clinical staff identify any risks necessitating that meetings should take place on NHS premises, they take place in the location preferred by the participants, which can be their homes, an appropriate public space or NHS premises.

Peer support workers and their training

Peer support workers have been recruited and employed by participating NHS Trusts for the study. All are people who have themselves experienced mental health problems and used mental health services, an agreed essential requirement for a mental health peer support worker.[33] We did not require CRT use, as we were not aiming for a high level of matching of participant and peer support worker experiences. More restrictive criteria might also have resulted in difficulty in prompt recruitment of people with the required personal skills as well as experience. An introductory programme of training has been arranged by the study team. This includes familiarising peer support workers with the study workbook and how to support participants in using it. It also covers more generic issues such as safety, confidentiality, appropriate self-disclosure, roles and boundaries, engagement and listening skills, and cultural sensitivity. Additional induction required by participating NHS Trusts has also been attended by peer workers. An experienced peer support worker from the study team additionally met each peer support team during the trial. A programme of group supervision has also been established by the peer workers, facilitated by clinicians from the employing Trust. Peer support workers have been encouraged to use this additional supervision to discuss general issues arising from using the Personal Recovery Workbook or from their role as a peer supporter (not specific clinical concerns relating to participants, which are addressed by local NHS supervisors), and to discuss needs for any additional 'top-up' training, to be provided as required by the study team. Standard NHS Trust procedures are followed regarding confidentiality, safety and lone working for both peer support workers and researchers, including seeing service users on NHS premises when there are safety concerns and checking researchers are safe following all contacts.

Control intervention

In the control condition, participants are sent a Personal Recovery Workbook to complete by themselves or with family and friends if they wish; this has the same content as in the experimental group.

Discontinuation criteria

Participants may withdraw from the intervention at any time without giving a reason. The intervention is also suspended if a participant becomes unwell to the extent that he or she no longer has capacity to consent to continuing the sessions or the ability to cooperate with them.

Monitoring adherence to the intervention

Peer support workers keep a brief anonymised log of the intervention, recording the content of each session and the sections of the workbook completed. Study research staff monitor the completion of this log.

Concomitant care

Otherwise usual care is received, with no treatments withheld from participants in either arm of the trial. In both conditions this may be from a relevant community mental health team to which the CRT has made a referral after discharge or to primary care services, if the threshold for continuing specialist mental healthcare in the community is not judged to be met. In order to ensure that participants' trial status did not affect other ongoing care, and in particular the discharge plans for support arranged by the CRT they were using, neither participants nor CRTs were informed of participants' trial allocation status until after they had been discharged from the CRT.

Outcomes

1. Primary outcome: The primary outcome is whether in 1 year of follow-up from study entry participants are readmitted to an acute care setting, including acute inpatient wards, CRTs, crisis houses and acute day care services.
2. Secondary outcomes: The following are measured as secondary outcomes; all are dimensions of outcome on which there are potential mechanisms for an effect from a peer-provided self-management intervention.

Service use measures over 1 year of follow-up

1. days on the caseload of an acute care service over 1 year
2. time to first relapse (indicated by admission to an acute service).

Measures at interview at 4-month and 18-month follow-up

1. *self-rated recovery*, measured by total score on the Questionnaire on the Process of Recovery,[34] a 22-item measure of self-rated recovery
2. *self-management skills*, rated by score on the Illness Management and Recovery scale—patient version,[35] a 15-item measure of self-reported management of illness and functioning
3. *overall satisfaction with mental health services*, rated by total score on the Client Satisfaction Questionnaire,[36] an eight-item measure of respondents' satisfaction with mental health services
4. *symptom severity*, measured by the Brief Psychiatric Rating Scale (BPRS),[37] a 24-item interviewer-rated measure of psychiatric symptoms rated by the researcher based on the participant's responses to a structured interview schedule
5. *loneliness*, measured by the UCLA Loneliness Scale-8,[38] an eight-item measure of perceived loneliness
6. *social network*, measured by total number of friends and relatives with whom participant has been in contact in the past month according to the Lubben Social Network Scale,[39] a six-item measure of social contact with family and friends
7. EuroQol EQ-5D three-level[40] (EQ-5D-3L) was completed by participants to derive utility scores to calculate QALYs for the health economic evaluation. Structured recording of mental health service use at 1 year was also included for this purpose.

All these measures are administered by a researcher who is blind to study condition and asked the participant not to disclose this to them. An additional measure, requiring an unblinded researcher, is the Recovery Promoting Relationships Scale (RPRS),[41] a 24-item patient-reported measure of general therapeutic alliance and specific recovery orientation of health service providers. This is administered by phone following the initial interview.

Further measures used to characterise the sample and to adjust in secondary analysis for variables known to be associated with the primary outcome include the following:

a. sociodemographic and clinical data (including age, gender, ethnicity, accommodation and living situation, employment status, educational attainment and past service use, including admissions and compulsory admissions)
b. clinical diagnosis as recorded on electronic records using the ICD-10 (International Classification of Diseases: 10th Revision) classification
c. Social Outcomes Index[42] as a measure of social circumstances; this four-item measure includes questions on employment, accommodation and social contact
d. Health and Lifestyles Survey social capital questionnaire,[43] a six-item measure of neighbourhood social capital
e. AUDIT-C (Alcohol Use Identification Test - Consumption),[44] a three-item self-report screening measure of alcohol use
f. DAST-10 (Drug Abuse Screening Test - 10 item version),[45] a 10-item self-report screening measure of drug use.

Participant timeline

This is summarised in table 1. Potential participants are approached by CRT staff initially just prior to or just after discharge from the team. Clinicians make an initial assessment of capacity to give informed consent to enter the trial; they approach only those whom they consider to have such capacity. Researchers then contact those who give permission to be approached, and further assess capacity, following Royal College of Nursing guidance.[46] For eligible participants who have given informed consent, baseline interviews including all the above measures take place as soon as possible, with a maximum of 1 month after CRT discharge for entry to the trial. Randomisation (see below) follows baseline interviews, after which participants randomised to the control group are allocated a peer support worker to begin the 3-month intervention. All participants are contacted at 4 months following entry to the study for an initial follow-up interview. Data on the

Table 1 Timeline of participant enrolment, interventions, assessments and patient records data collection

	–1	0	T1	T2	T3
	Enrolment Screening	**Allocation Baseline and randomisation**	**Follow-up 4 months**	**Follow-up 12 months**	**Follow-up 18 months**
Enrolment					
Eligibility screen	X				
Informed consent		X			
Randomisation		X			
Intervention					
Peer support worker and recovery booklet (intervention group)		←	———	→	
Recovery booklet only (control group)		X			
Assessments					
Sociodemographic information		X			
Client Satisfaction Questionnaire (CSQ)		X	X		X
Social Outcomes Index (SIX)		X	X		X
Illness Management and Recovery (IMR) scale		X	X		X
Questionnaire on the Process of Recovery (QPR)		X	X		X
EuroQol Health Questionnaire (EQ-5D)		X	X		X
UCLA Loneliness Scale-8		X	X		X
Lubben Social Network Scale-6		X	X		X
Health and Lifestyle Survey Social Capital Questionnaire		X	X		X
Brief Psychiatric Rating Scale (BPRS)		X	X		X
Alcohol Use Disorder Identification Test for Consumption (AUDIT-C)		X			
Drug Abuse Screening Test - 10 item version (DAST-10)		X			
Recovery Promoting Relationships Scale (intervention group only)			X		
Information on use of self-management materials			X		X
Patient records data (from previous 12 months to time point)					
Number of admissions to acute mental health services		X		X	
Number of compulsory admissions to acute mental health services		X		X	
Total number of days in acute care		X		X	
Number of kept appointments with community mental health services		X		X	
Number of missed appointments with community mental health services		X		X	
Primary ICD-10 diagnosis		X			
Secondary ICD-10 (International Classification of Disease - 10th revision) diagnosis		X			
Most recent care cluster		X			
Care Programme Approach status		X			

primary outcome are collected from clinical records at 1 year, and participants are contacted 18 months following randomisation for a final follow-up interview with the measures above.

Sample size

A sample size of 440 is required to detect a difference in admission rates during the follow-up period of 50% in the control group versus 35% in the experimental group, with 80% power and 5% significance. We have based group allocation on an initial allocation rate of 1:1.37 prior to adjustment for clustering, resulting in 159 in the intervention arm and 217 in the control arm. The intervention arm is then inflated for clustering (peer support worker) using an intraclass correlation coefficient of 0.03, and after rounding this gives 220 participants in the intervention arm and 220 participants in the control arm (a total of 440 participants) from six CRTs, all in different NHS Trusts. Thus our initial allocation rate has been selected so as to result in equal numbers following inflation for clustering, making trial randomisation logistically more straightforward. An intraclass correlation coefficient of 0.03 is confirmed as a relatively conservative estimate by a meta-analysis of therapist effects in low-intensity mental health interventions.[47] It is expected that, on average, there will be at least four peer support workers within each CRT, with an average cluster size of 11. Of these 440 participants, 40 were recruited during the internal pilot conducted in one Trust only to establish acceptability of our trial procedures and feasibility of recruitment to a randomised controlled trial of the intervention. It was agreed by the Trial Steering Committee (TSC) and the study funders that changes to study procedures and to the intervention following this internal pilot were sufficiently minimal (increased support for peer support workers; addition of measures of loneliness, social network, social capital and social outcome) for the internal pilot sample to be included within the main study sample.

Recruitment strategies

Close liaison is maintained by research staff with the participating CRT staff, who have been strongly encouraged to consider every CRT client's eligibility for the trial. Leaflets, a website and a Twitter account are among the methods used to raise awareness of the study among staff and local service users.

METHODS: ASSIGNMENT OF INTERVENTIONS

Group allocation

Following baseline assessment, consenting clients are block-randomised into treatment and control groups, stratified by site. Randomisation is conducted by the study data officer or trial manager using an independent randomisation service, 'Sealed Envelope' commissioned by the Priment Clinical Trials Unit. Once the data officer learns from 'Sealed Envelope' which group participants have been allocated to, and once the participant has been discharged from the CRT, the data officer contacts participants to let them know and, for those in the treatment group, to confirm arrangements that a peer support worker will contact them.

Blinding

It is not feasible to blind participants to whether they are allocated to the treatment or control group. Data for the study's primary outcome (readmission to acute care during the follow-up period) are provided by administrators from participating NHS Trusts, who are not informed by researchers of participants' treatment allocation. The study data officer or trial manager conducts randomisation and informs the CRT which treatment group each participant has been allocated to. To avoid discharge plans being influenced by the availability of a peer support worker, we delay disclosing group allocation until the point of CRT discharge. Blinding of other clinicians involved in care following discharge is not feasible as Trust clinical procedures require peer support workers to record visits in electronic records. The data officer, or sometimes in their absence the trial manager, also conducts the section of the follow-up interview with participants in the treatment group which relates to their experience of the intervention. Study researchers, blind to participants' allocation status, conduct the 4-month and 18-month follow-up interviews. Maintaining blinding of researchers is not likely to be achieved in full for secondary outcomes collected during a follow-up interview, as it is likely some participants may disclose in the course of the follow-up interview whether they have received the peer-supported programme. Researchers seek to minimise this by prompting participants not to disclose which trial group they were in, both when setting up interviews and during the interview itself. Data will be analysed blind to allocation with the exception of the RPRS, which will be analysed after the analyses of other outcomes have been checked and agreed.

METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS

Data collection

Baseline interviews

Once written consent to participate in the study has been obtained, but before participants are randomly allocated to intervention or control groups, a study researcher completes the study baseline measures with all participants as a structured interview. This interview takes about 1 hour to complete. It may take place at the participant's home, NHS or university premises, as the participant prefers within any limits advised by CRT clinicians during the recruitment process. Following completion, participants are offered a £20 gift of cash to acknowledge their time and help with the study.

Researchers were given specific training in using the BPRS outcome measure, which unlike other study outcome measures is not participant self-report, but requires the researcher to rate symptoms in 24 domains,

based on a structured interview. Training was delivered by the trial manager and the principal research clinician on the study; it involved guidance and practice at interviewing and rating subjects using role play and videos of clinical interviews. Researchers' practice ratings were assessed against agreed correct ratings, and further training provided in the event of unreliable scoring.

Follow-up interviews at 4 and 18 months

At these time points, researchers contact participants again using their preferred contact details. They remind participants of the study details, and ask if they are willing to meet to complete the follow-up. If so, the researcher sends another copy of the study information sheet and arranges a time and place to meet. At this meeting, the researcher again seeks written informed consent from the participant to complete the follow-up research interview, and completes an interview if this is obtained. If for any reason (eg, a move to a distant part of the country) a participant is willing but a face-to-face interview is not feasible, a phone interview is offered, but the BPRS not completed as this depends on observer ratings.

Data from patient records

Once all participants from a participating NHS Trust have been recruited into the study, a study researcher contacts the appropriate administrators or informatics team within the Trust regarding collection of data from patient records. The study researchers provide a list of consenting participants' names, dates of birth and study identification numbers and a standardised schedule of the information required for each patient, with the time period for which data are needed clearly specified. Administrators are then asked to provide the data to the research team, identifying each patient by study ID number only to avoid data protection risks from transferring identifiable patient data.

One year after all participants from a participating NHS Trust have been recruited into the study (6 months and 1 year for the pilot trial), a study researcher again contacts the Trust's administrators to collect outcomes data, using similar procedures to those described above.

Minimising loss to follow-up

Primary outcome

Research Ethics Committee approval allows data on the primary outcome to be collected even if participants are lost to follow-up, minimising missing values on this measure. If service use data relating to the primary study outcome are not available through Trust patient records, study researchers will attempt to collect these data from other NHS Trust or general practitioner (GP) records or the participant, in accordance with the written consent provided by the participant.

Follow-up interviews

Response rate is maximised by making at least three attempts to contact each participant, and by obtaining multiple contact details (eg, email, landline, mobile phone, a close relative's phone) at the time of the baseline to maximise the likelihood of making contact. A £20 honorarium is offered at each interview to thank participants for their time and effort.

Data entry and management

All data recorded on paper forms are stored securely (in locked cabinets in locked offices) on university sites in accordance with university data protection procedures. Data collection forms identify participants only by their study ID. Participant consent forms, contact details and a single master copy linking participants' names and IDs are held separately from other data.

Data are entered using a web-based system set up by Sealed Envelope. This has been set up so that it mirrors the data collection sheets in order. It also has range checks and consistency checks, and for closed questions gives a number of options plus 'other' where appropriate. Assessors who enter data have no access to the group allocation through this system.

With the checks in place, there should not be any issues with illegal values being entered or inconsistent data being entered, so necessary cleaning should be minimal. However, data are checked by the statistician before analysis and any problems reported to the assistant/trial manager, who rectifies them as appropriate before data analysis.

Data analysis

General principles

The assumptions underpinning each statistical method will be checked. For example, normality and equality of variances will be checked for t-tests. The use of transformations or non-parametric methods will be considered if assumptions do not hold. Adjusted analyses will be performed if baseline imbalances are observed. The impact of missing data will be explored in all analyses. Supportive analyses will be performed if non-compliance is considered to be a problem.

The primary analyses will be complete case. All analyses will be performed according to the original assigned randomisation groups. Data will be analysed using Stata Version 14.

Descriptive statistics

Initial analyses will look at summary statistics for all variables, both overall and by randomised group. Summary statistics for continuous variables will be mean, median, standard deviation, lower quartile, upper quartile, minimum and maximum. These variables will also be plotted to check their distribution. If variables are skewed, then median and interquartile ranges will be reported, otherwise mean and standard deviationwill be reported. Summary statistics for categorical variables will be frequency and percentage within each category. No statistical significance tests for baseline characteristics by randomised group will be performed, but balance will be assessed visually.

Primary outcomes

Data on readmission during the study period will be analysed using logistic regression with random intercepts, with clustering by peer support worker being modelled using random effects. Those in the control group will be considered to be clusters of size 1 for analysis purposes. Condition (psychosis vs no psychosis) and centre will be entered into the model as fixed effects. This analysis will be reported in terms of an odds ratio and 95% confidence intervals.

Secondary outcomes

For the analysis of the scales, linear regression with random intercepts will be used (with peer support worker as the random effect), controlling for the baseline value of the outcome, condition (psychosis vs no psychosis) and centre. These will be reported in terms of mean difference in outcome between the two randomised groups with associated 95% CIs.

To assess the total days spent in acute care, we will perform Poisson regression analysis with random intercepts, with the peer support worker being entered as a random effect. Centre will be entered into the model as a fixed effect. This analysis will be reported as coefficient and 95% CI.

Time to first readmission during the study period will be analysed using Cox regression frailty model. However, if the frailty model fails to converge, then Cox regression with robust SEs will be used. The condition (psychosis vs no psychosis) and centre will be added as fixed effects.

Supportive analyses

Supportive analyses using methods analagous to the primary analyses will be conducted on the primary outcome, adjusting for any marked differences in randomised groups in terms of: demographic characteristics, service use in the year preceding entry to the study and scores on outcome measures; amount of improvement for both groups between baseline and follow-up. Aalyses of outcomes will be conducted adjusting for non-compliant participants in the treatment group using a dichotomous variable, with compliant defined as three or more meetings attended. Aalyses will also be carried out with adjustment for whether peer support schemes were already established in the catchment area or newly introduced for the study. Those in the treatment as usual group will be assigned to the same category as those who are non-compliant in the intervention group.

Participants attending fewer than three meetings with a peer support worker will be defined as non-compliant. Non-compliance will be examined using Complier Average Causal Effect (CACE) analysis. We will look at baseline predictors of attending fewer than three meetings using random effects logistic regression (those in the intervention group only).

Process analysis

The following descriptive information will be provided about the content of the intervention and the degree of match between the peer support workers and the participants:

Use of the Personal Recovery Plan

a. From participant data at follow-up: the proportion of participants in the treatment and control groups discussing or reading each of four sections of the recovery plan. A composite score of 0–4 will be reported for overall extent of awareness of the recovery plan, combining participants' reports of whether they had looked at each section of the workbook.
b. From participant data at follow-up: the proportion of participants in the treatment and control groups making a written plan for each of four sections of the recovery plan. A composite score of 0–4 will be reported for overall extent of development of a written recovery plan by combining participants' reports of whether they had looked at each section of the workbook.
c. From a random sample of contact records provided by peer support workers: We will report the proportion of meetings at which the recovery plan was discussed or a written plan developed, and the frequency with which other informal or professional carers were involved.

Peer support workers' style

The mean RPRS total and index scores (recovery promoting strategies and core relationship) and range of mean scores among peer support workers will be reported.

Degree of match between peer support workers and participant

The proportion of participants who were matched with their peer support workers will be reported regarding the following:

a. diagnosis
b. experience of hospital admission (ever admitted yes/no)
c. gender
d. ethnicity
e. age.

In the event of positive study outcomes, an exploratory regression analysis will be conducted to model the relationship of these process factors to study outcomes.

Missing data

It is not expected that there will be much missing data for the primary outcomes, as these data will come from the Trust's informatics department. However, there may be missing data for other outcomes. All items within a scale may be missing, or individual items within a given scale may be missing. Some scales have recognised ways to impute missing items up to a given number of items, which will be used as appropriate. The extent and patterns

of missingness will be evaluated to determine whether it is associated with any of the outcomes. If variables are associated with missingness, these will be controlled for in complete case analysis to maintain the missing at random assumption.

Analysis plan for the economic evaluation

Aim

The aim of the economic evaluation is to calculate the probability that peer-provided self-management is cost-effective compared with control over 1 year for a range of values of willingness to pay for a QALY gained. The cost perspective is in alignment with the National Institute for Health and Care Excellence Technology Assessment Guidance, which provides guidance on the implementation of new healthcare technologies in the English NHS.

Outcomes

- mental health service use (community and acute services) during 1-year follow-up period
- EQ-5D-3L at baseline and 4 months and 18 months.

Analyses

All analyses will follow the assumptions made in the statistical analysis plan regarding missing data, loss to follow-up and clustering. In line with the statistical analysis, the primary economic evaluation will be a complete case analysis. Sensitivity analyses will be conducted accounting for loss to follow-up and missing data as described below (sensitivity analyses).

Cost of the intervention

Information on peer support worker costs (salaries and oncosts) and time spent with patients on peer support worker will be used to calculate the average cost per patient of the peer-provided self-management intervention.

Cost of mental health service use

Acute and community mental health service use for the intervention and control group will be collected from electronic patient records held by the mental health trust at baseline and 1 year. Costs will be calculated for each patient using unit costs from the most recent Unit Costs of Health and Social Care, published by the Personal Social Services Research Unit.[7] The mean cost per patient at baseline and 1 year for intervention and control groups will be reported by type of service use.

To extrapolate 12-month service use to 18 months, we will develop a time to event model to predict the probability of acute readmission between 12 months and 18 months for the intervention group compared with the control group. The average cost of an admission as calculated from baseline and 12-month data will be applied to any readmissions.

Quality-adjusted life years

We will calculate the mean cost per QALY gained of peer-provided self-management compared with control over 1 year. QALYs will be calculated using the EQ-5D-3L and the formula developed by Dolan.[48] We will calculate the mean area under the curve for each group from baseline to 4 months, controlling for any baseline differences using regression analysis.[49] CIs will be constructed using non-parametric bootstrapping. To calculate QALYs over 1 year, we will assume both groups have a linear return to their patient-specific baseline EQ-5D at 1 year, unless they have had an acute readmission. Patients with an acute readmission between 4 months and 1 year will have a QALY decrement attributed, calculated using regression analysis and 4-month patient data.

Baseline, 4-month and 18-month EQ-5D-3L responses will be used to calculate QALYs over 18 months. This will also be calculated as area under the curve adjusting for baseline (Hunter *et al* 2015).[43]

Confidence Intervals

95% confidence intervals for mean costs and QALYs will be calculated using non-parametric bootstrap with replacement.

Incremental cost-effectiveness ratio

The mean costs and QALYs calculated above will be used to calculate the mean incremental cost per QALY gained of peer-provided self-management compared with control at 1 year using 1-year modelled QALYs and 1-year costs. An 18-month incremental cost-effectiveness ratio (ICER) will be calculated using 18-month QALY data and 18-month modelled cost data.

Cost-effectiveness plane and cost-effectiveness acceptability curve

The results of the non-parametric bootstrap will be presented on a cost-effectiveness plane. A cost-effectiveness acceptability curve (CEAC) will also be constructed using the bootstrap data from a range of values of willingness to pay for a QALY gained. The probability that the peer-provided self-management is cost-effective compared with control at a willingness to pay for a QALY gained of £20 000 will be reported.

Supportive analyses

The following sensitivity analyses will be conducted and the new ICER and CEAC reported:

- Cost-effectiveness complete case analysis at 4 months.
- Housing, employment and GP contacts are recorded at baseline and 4 months only. No other healthcare contacts or societal costs were collected so as to minimise patient burden when completing questionnaires. Two analyses will be conducted, one including employment and one excluding employment, using the 4-month data only for the three variables, each costed using Personal Social Services Research Unit and assuming mean national values for wages.
- Testing the impact of a range of assumptions about QALYs over the 4-month to 12-month period.
- Different values for the QALY decrement as a result of an inpatient admission.

- Any subgroup analyses identified including the ICER for different levels of engagement with the peer support worker in the intervention group, including CACE analysis.

If any key assumptions become apparent during the analysis, these will also be tested for as part of the sensitivity analyses.

METHODS: MONITORING AND APPROVALS

Monitoring

The trial is overseen throughout by a TSC and a Data Monitoring Committee (DMC). These meet regularly to monitor trial progress and advise on any proposed amendments. The DMC comprises three senior academics with experience of trials and mental health services research: a clinical academic psychologist who chairs the DMC, a non-clinical social scientist and a statistician. The DMC is independent of the sponsor; it has no competing interests. Minutes and recommendations from DMC meetings are sent by the DMC Chair to the Chair of the Independent TSC in advance of TSC meetings.

No interim analyses are planned, but the trial standard operating procedures (agreed by the Priment Clinical Trials Unit, which oversees this trial) require all adverse incidents of any kind to be reported in the first place to the Chair of the TSC. Criteria for defining adverse events are agreed with the overseeing Clinical Trials Unit. Adverse events are monitored by the trial manager and the study data officer through monthly checks with peer support workers' supervisors at each site and monthly screening of NHS patient records, arranged by the supervisor or the site principal investigator at each site. Adverse events are recorded on a standard form by the study data officer, with information provided by an involved clinician from the NHS site. They are then assessed for severity and study-relatedness by the study chief investigator, who acts as the trial's clinical reviewer, and the Chair in the independent TSC, who acts as an independent clinical reviewer and makes the final judgement about study-relatedness and any need to alert the DMC immediately. Participant deaths are reviewed immediately by the Chair of the DMC. Any study-related serious adverse events will be reported immediately to the sponsor and the Research Ethics Committee. A summary of all serious adverse events is reviewed at all DMC meetings.

Auditing

The trial sponsor regularly audits a sample of their sponsored trials, including inspection of processes and procedures for storing data.

Ethics and dissemination

Ethical approval

Ethical approval has been obtained from the London Camden and Islington Research Ethics Committee (REC ref: 12/LO/0988), which has approved all amendments to protocol. The main substantial amendment since the study was originally approved has been the addition of a follow-up interview at 18 months (also approved by the Research Ethics Committee). The current version of the protocol is V.5, which includes the additional 18-month follow-up interview that was added to the original study design. The version of the protocol in use during participant recruitment was V.3, 17 November 2013. The consent form used during participant recruitment was V.2, 17 November 2013. An updated consent form used to reconfirm consent for 18-month follow-up interviews was V.4, 4 November 2015. Both consent forms are included as online supplementary files.

Consent

Clinical staff from the CRT (or on occasion clinicians from other services who are known to the patient) contact patients initially to explain the study briefly and ask if patients are willing to be contacted by a study researcher to discuss participation further. At this stage, clinicians will screen out service users who are unwilling participate in the study, who pose a serious risk of harm to others or who clearly lack capacity to provide consent. Clinicians note this willingness to be contacted in clinical records and then pass on names and contact details to researchers. A study researcher contacts potential participants to explain what the study involves and answers any questions. For those still willing to participate, the researcher sends a written information sheet about the study and arranges a time to meet potential participants to seek written informed consent. Research staff seeking consent provide both a written patient information sheet and a verbal explanation of the study, and establish that participants understand the trial and intervention procedures before seeking written informed consent.

Confidentiality

All data recorded on paper forms is stored securely at University College London or the University of the West of England (for data collected by a study researcher based there) in accordance with university data protection procedures. Data collection forms identify participants only by their study ID. Participant consent forms, contact details and a single master copy linking participants' names and IDs will be held separately from other data. All data are held in locked filing cabinets in locked offices within university buildings.

An independent data management service (Sealed Envelope) commissioned by the Priment Clinical Trials Unit has overseen the development and management of a secure database for all quantitative study data. Participants are identified only by a study identification number in the database. Data are entered by study researchers using secure log-ins. Once recruitment and data collection are complete, the data management service will advise on arrangements for the study team to access the data for analysis.

Once data collection is complete, all paper forms will be transferred to University College London. Data will

be held securely by the study team for up to 1 year after the end of the study, then archived securely in accordance with University College London data protection procedures.

Dissemination

Results will be reported in scientific publications and also disseminated to a wider audience via blogs, social media and direct communication to policy makers. Participants will be offered a summary and they will be communicated directly to participating teams.

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Competing interests None declared.

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