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A 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 for a randomised controlled trial (the CORE self-management trial)

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ABSTRACT

Introduction: Crisis resolution teams 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 throughout most of 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, 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 self-management trial compares the effectiveness of a peer-provided self-management intervention for people leaving crisis resolution team 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 four and at 18 months following trial entry, measured using the Questionnaire on the Process of Recovery (QPR). 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.

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Keywords: Peer support, self-management, crisis resolution teams, home treatment, relapse prevention, randomised controlled trial

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INTRODUCTION

Background and Rationale

Crisis Resolution Teams (CRTs) – sometimes called home treatment or crisis assessment teams - provide rapid assessment in mental health crises and offer intensive home treatment as an alternative to acute psychiatric inpatient admission if feasible[1]. Since being mandated in the NHS Plan (2000)[2], 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[3-7] and healthcare costs[8,9] and increase service user satisfaction with acute care[3,6]. Service users, however, have reported considerable areas of dissatisfaction including continuity of care between services during and following a period of CRT care[10,11]. 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[12,13,14,15]. Thus demand for acute care in England remains very high in the absence of interventions to reduce repeat use[16]. 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[17].

The aim of the present study is to develop and test an intervention intended to achieve this. The SPIRIT 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[13]. 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 following a mental health crisis[18]. 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[19]. 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[20] and the Recovery Workbook[21] 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 NHS services, promoted by initiatives such as the NHS Confederation *Implementing Recovery through Organisational Change* project[22], 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 community mental health teams 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 one year than those in the control intervention receiving treatment as usual enhanced by access to a self-management manual.
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 one 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 to 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.
4. 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 trial with two parallel arms, 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 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 Crisis Resolution and Home Treatment Teams 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. 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.

In order to achieve a study sample which is broadly representative of the general population of Crisis Resolution Team service users, we 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 Crisis Resolution Teams 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 Georges NHS Foundation Trust[23], specifically their Personal Recovery Plan. This was in turn informed by self-management resources such as the Wellness Recovery Action Plan[20] and relapse prevention interventions[24].

Selection and development of the intervention

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

(a) **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.

(b) **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[26].

(c) **Stakeholder focus groups and adaptation of the intervention:** Informed by this work, the Personal Recovery Plan[27] 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 of how to fit this intervention within existing care pathways. The groups usually comprised 6 to 8 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.

(d) **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 four-day training in fundamentals of delivery 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 ten sessions with a peer support worker. 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 wellbeing once a crisis has abated

Meetings take place weekly, with the aim of completing the programme of up to ten sessions within three 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 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 go 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.

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 health care 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 one 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 one year of follow-up

a. Days on the caseload of an acute care service over one year.
b. Time to first relapse (indicated by admission to an acute service)

Measures at interview at 4 and 18 months follow-up

a. *Self-rated recovery,* measured by total score on the Questionnaire on the Process of Recovery[28] (QPR), a 22-item measure of self-rated recovery.
b. *Self-management skills*, rated by score on the Illness Management and Recovery Scale-patient version[29] (IMR) – a 15-item measure of self-reported management of illness and functioning.
c. *Overall satisfaction with mental health services*, rated by total score on the Client Satisfaction Questionnaire[30] (CSQ) – an eight item measure of respondents' satisfaction with mental health services.
d. *Symptom severity*, measured by the Brief Psychiatric Rating Scale[31] (BPRS) – a 24-item interviewer-rated measure of psychiatric symptoms rated by the researcher based on the participant's responses to a structured interview schedule.
e. *Loneliness,* The UCLA Loneliness Scale[32] (ULS-8) – an eight item measure of perceived loneliness.
f. *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[33] – a six item measure of social contact with family and friends.
g. The EuroQol EQ-5D 3 level (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 ask the participant not to disclose this to them. An additional measure, requiring an unblinded researcher, is the Recovery Promoting Relationships Scale[35] – a 24-item patient-report measure of general therapeutic alliance and specific recovery orientation of health service providers. This is administered by 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:

a. Socio-demographic 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 ICD10 classification.
c. The Social Outcomes Index[36] (SIX) as a measure of social circumstances: this four-item measure includes questions on employment, accommodation and social contact.
d. The Health and Lifestyles Survey social capital questionnaire[37] – a six-item measure of neighbourhood social capital.
e. Audit-C[38] – a three item self-report screening measure of alcohol use.
f. DAST-10[39] – a ten item self-report screening measure of drug use.

Participant timeline

Table 1 about here

This is summarised in Table 1**.** Potential participants are approached by CRT staff initially just prior to or just after discharge from the team. Where potential participants are confirmed as eligible, baseline interviews including all the above measures take place as soon as possible, with a maximum of one 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 three month intervention. All participants are contacted at 4 months following entry to the study for an initial follow-up interview. Data on the primary outcome is collected from clinical records at one 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. This calculation is based on unequal l allocation of 217 in the control arm and 159 in the intervention arm. The intervention arm is then inflated for clustering (peer support worker) using an intraclass correlation coefficient of 0.03, after rounding this gives 220 participants in the intervention arm and 220 participants in the control arm (a total of 440 participants) from six Crisis

Resolution Teams, all in different NHS Trusts. It is expected that on average, there will be at least four peer support workers within each Crisis Resolution Team, 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 and the study funders that changes to study procedures and to the intervention following this internal pilot were sufficiently minimal 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 Crisis Resolution Team, 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) is 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. The data officer, or sometimes in their absence the trail 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 one 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.

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 (for example 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 is needed clearly specified. Administrators are then be 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 (six months and one 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 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 3 attempts to contact each participant, and by obtaining multiple contact details (e.g. 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[4]. This has been set up so that, it mirrors the data collection sheets in order. It also has range checks, 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 on an intention to treat basis. Data will be analysed using Stata.

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, SD, 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 deviation will 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 random effects logistic regression, with clustering by peer support worker being modelled using random effects. Those in the control group will be considered to be clusters of size one for analysis purposes. Condition (psychosis versus 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 interval.

Secondary Outcomes

For the analysis of the scales, random effects linear regression will be utilised (with peer support worker as the random effect), controlling for the baseline value of the outcome, condition (psychosis

versus no psychosis) and centre. These will be reported in terms of mean difference in outcome between the two randomised groups with associated 95% confidence intervals.

To assess the total days spent in acute care, we will perform random effects linear regression analysis 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% confidence interval.

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 standard errors will be used. The condition (psychosis versus no psychosis) and centre will be added as fixed effects.

Supportive analyses

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; analyses of outcomes adjusting for non-compliant participants in the treatment group using a dichotomous variable compliant is defined as three or more meetings attended; analyses adjusting 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. The following variables will be reported:

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:

Degree of match between PSW and participant

The proportion of participants who were matched with their PSW will be reported regarding:

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 to control over 1 year for a range of values of willingness to pay for a quality adjusted life year (QALY) gained.

Outcomes

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

Analyses

All analyses will follow the assumptions made in Part I 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.

These will be costed 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]. 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 to control group. The average cost of an admission as calculated from baseline and 12 month data will be applied to any readmissions.

QALYs

We will calculate the mean cost per quality adjusted life year (QALY) gained of peer-provided self-management compared to control over 1 year. QALYs will be calculated using the EQ-5D-3L and the formula developed by Dolan and colleagues[8]. 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[41]. Confidence intervals 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).

Confidence intervals

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

Incremental cost-effectiveness ratio (ICER)

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 to control at 1 year using 1 year modelled QALYs and 1 year costs. An 18 month ICER will be calculated using 18 month QALY data and 18 month modelled cost data.

Cost-effectiveness plane (CEP) and cost-effectiveness acceptability curve (CEAC)

The results of the non-parametric bootstrap will be presented on a CEP. A 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 to 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. Two analyses will be conducted, one including employment and one excluding employment, using the 4 month data only for the 3 variables, each costed using PSSRU and assuming mean national values for wages.
- Testing the impact of a range of assumptions about QALYs over the 4-12 month period.
- Different values for the QALY decrement as a result of an inpatient admission.
- Any sub-group 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 Trial Steering Committee and a Data Monitoring Group. These meet regularly to monitor trial progress and advise on any proposed amendments. No interim analyses are planned, but the Trial Standard Operating Procedures (agreed by the PRIMENT Clinical Trials Unit, who oversee this trial) require all adverse incidents of any kind to be reported in the first place to the Chair of the Trial Steering Committee.

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), who have 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).

Consent

Clinical staff from the CRT (or on occasion clinicians from other services who are known to the patient) contact patients initially to explain briefly 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 answer 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 will be 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 will 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 will be 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 will oversee the development and management of a secure database for all quantitative study data. Participants will be identified only by a study identification number in the database. Data will be 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 one 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.

DECLARATIONS

Ethical approval

The trial received a favourable opinion from the London Camden and Islington Research Ethics Committee (REC ref: 12/LO/0988

The following sites have approved the trial: Camden and Islington NHS Foundation Trust; Surrey and Borders Partnership NHS Foundation Trust; North East London NHS Foundation Trust; South London and Maudsley NHS Foundation Trust; West London Mental Health NHS Trust; Avon and Wiltshire Mental Health Partnership NHS Trust

Competing interests

The authors have no relevant declarations of interest.

Author's contributions

The trial design was developed by SJ, BLE, DH, DO, SP, OM, RG, FN, TW, CH and NM. LM and GA developed the statistical analysis plans and RH the economic analysis plan. AM has led on the development of the intervention. SJ is the Chief Investigator, based at University College London and BLE the project manager. DO provided oversight as a triallist in the PRIMENT Clinical Trials Unit. All authors have contributed and approved this manuscript.

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Data sharing: We will make data available via the corresponding author with as few restrictions as possible once the main study outputs are published.

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	-1	0	T1	T2	T3
	Enrolment Screening	Allocation Baseline & 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:					
Socio-demographic information		X			
Client Satisfaction Questionnaire (CSQ)		X	X		X
Social Outcomes Index (SIX)		X	X		X
Illness Management and Recovery Questionnaire (IMR)		X	X		X
Questionnaire on the Process of Recovery (QPR)		X	X		X
EuroQol Health Questionnaire (EQ-5D)		X	X		X
UCLA Loneliness Scale (ULS-8)		X	X		X
Lubben Social Network Scale (LSNS-6)		X	X		X
HLS Social Capital Questionnaire		X	X		X
Brief Psychiatric Rating Scale (BPRS)		X	X		X
Alcohol Use Questionnaire (AUDIT-C)		X			
Drug Use Questionnaire (DAST-10)		X			
Recovery Promoting Relationships			X		

Scale (RPRS) (Intervention Group only)					
Information on use of self-management materials			X		X
PATIENT RECORDS DATA (from previous 12 months to timepoint):					
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 diagnosis		X			
Most recent care cluster		X			
CPA status		X			

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

Additional File 1: CORE CRT Service Improvement Programme Trial – Reporting Checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	2
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	20-22
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4-5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5-6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	8

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8-9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10-11
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13-14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15-16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	20
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	20
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	20
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	20
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	21

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	21
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	21
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	21
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" licens

BMJ Open

A 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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A 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 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 throughout most of 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, 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 self-management trial compares the effectiveness of a peer-provided self-management intervention for people leaving crisis resolution team 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 four and at 18 months following trial entry, measured using the Questionnaire on the Process of Recovery (QPR). 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: ISRCTN01027104 DOI 10.1186/ISRCTN01027104. Date registered: 11/10/12

Keywords: Peer support, self-management, crisis resolution teams, home treatment, relapse prevention, randomised controlled trial

Sponsor: Camden and Islington NHS Foundation Trust (UK), Bloomsbury Building, St Pancras Hospital, 4 St Pancras Way, London NW1 0PE

STRENGTHS AND LIMITATIONS OF THE STUDY

- High acute care use and readmissions following a crisis are significant and expensive challenges, yet there is little evidence on how to reduce them: we address this evidence gap.
- Service users have made major contributions to intervention and protocol delivery 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.

INTRODUCTION

Background and Rationale

Crisis Resolution Teams (CRTs) – sometimes called home treatment or crisis assessment teams - provide rapid assessment in mental health crises and offer intensive home treatment as an alternative to acute psychiatric inpatient admission if feasible[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[13,14,15,16]. 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 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 following 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 NHS services, 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 community mental health teams 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 one 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.
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 one 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 to 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 trial with two parallel arms, 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 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 Crisis Resolution and Home Treatment Teams 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 generalizable 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 Crisis Resolution Teams 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 Georges 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:

(a) **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[28]**.** A literature and internet search was also carried out and key experts consulted to identify relevant resources for self-management interventions.

(b) **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].

(c) **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 of how to fit this intervention within existing care pathways. The groups usually comprised 6 to 8 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.

(d) **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 four-day training in fundamentals of delivery 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 ten 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 wellbeing once a crisis has abated

Meetings take place weekly, with the aim of completing the programme of up to ten sessions within three 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, 34]. 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 go 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 health care 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 one 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 one year of follow-up

a. Days on the caseload of an acute care service over one year.
b. Time to first relapse (indicated by admission to an acute service)

Measures at interview at 4 and 18 months follow-up

a. *Self-rated recovery,* measured by total score on the Questionnaire on the Process of Recovery[35] (QPR), a 22-item measure of self-rated recovery.
b. *Self-management skills*, rated by score on the Illness Management and Recovery Scale-patient version[36] (IMR) – a 15-item measure of self-reported management of illness and functioning.
c. *Overall satisfaction with mental health services*, rated by total score on the Client Satisfaction Questionnaire[37] (CSQ) – an eight item measure of respondents' satisfaction with mental health services.
d. *Symptom severity*, measured by the Brief Psychiatric Rating Scale[38] (BPRS) – a 24-item interviewer-rated measure of psychiatric symptoms rated by the researcher based on the participant's responses to a structured interview schedule.
e. *Loneliness,* The UCLA Loneliness Scale[39] (ULS-8) – an eight item measure of perceived loneliness.
f. *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[40] – a six item measure of social contact with family and friends.
g. The EuroQol EQ-5D 3 level[41] (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 ask the participant not to disclose this to them. An additional measure, requiring an unblinded researcher, is the Recovery Promoting Relationships Scale[42] – a 24-item patient-report measure of general

therapeutic alliance and specific recovery orientation of health service providers. This is administered by 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:

a. Socio-demographic 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 ICD10 classification.
c. The Social Outcomes Index[43] (SIX) as a measure of social circumstances: this four-item measure includes questions on employment, accommodation and social contact.
d. The Health and Lifestyles Survey social capital questionnaire[44] – a six-item measure of neighbourhood social capital.
e. Audit-C[45] – a three item self-report screening measure of alcohol use.
f. DAST-10[46] – a ten item self-report screening measure of drug use.

Participant timeline

Table 1 about here

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[47]. 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 one 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 three month intervention. All participants are contacted at 4 months following entry to the study for an initial follow-up interview. Data on the primary outcome is collected from clinical records at one 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, after rounding this gives 220 participants in the intervention arm and 220 participants in the control arm (a total of 440 participants) from six Crisis Resolution Teams, 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 is confirmed as a relatively conservative estimate by a meta-analysis of therapist effects in low-intensity mental health interventions[48]. It is expected that on average, there will be at least four peer support workers within each Crisis Resolution Team, 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 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 Crisis Resolution Team, 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) is 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, 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 one 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.

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 (for example 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 is needed clearly specified. Administrators are then be 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 (six months and one 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 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 3 attempts to contact each participant, and by obtaining multiple contact details (e.g. 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, 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.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, SD, 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 deviation will 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 one for analysis purposes. Condition (psychosis versus 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 interval.

Secondary Outcomes

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

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% confidence interval.

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 standard errors will be used. The condition (psychosis versus no psychosis) and centre will be added as fixed effects.

Supportive analyses

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; analyses of outcomes adjusting for non-compliant participants in the treatment group using a dichotomous variable compliant is defined as three or more meetings attended; analyses adjusting 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. The following variables will be reported:

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:

Degree of match between peer support worker and participant

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

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 to control over 1 year for a range of values of willingness to pay for a quality adjusted life year (QALY) gained. The cost perspective is in alignment with the National Institute for Health and Care Excellence (NICE) Technology Assessment Guidance which provides guidance on the implementation of new health care technologies in the English National Health Service (NHS)

Outcomes

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

Analyses

All analyses will follow the assumptions made in Part I 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. These will be costed 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]. 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 to control group. The average cost of an admission as calculated from baseline and 12 month data will be applied to any readmissions.

QALYs

We will calculate the mean cost per quality adjusted life year (QALY) gained of peer-provided self-management compared to control over 1 year. QALYs will be calculated using the EQ-5D-3L and the formula developed by Dolan and colleagues[49]. 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[50]. Confidence intervals 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).

Confidence intervals

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

Incremental cost-effectiveness ratio (ICER)

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 to control at 1 year using 1 year modelled QALYs and 1 year costs. An 18 month ICER will be calculated using 18 month QALY data and 18 month modelled cost data.

Cost-effectiveness plane (CEP) and cost-effectiveness acceptability curve (CEAC)

The results of the non-parametric bootstrap will be presented on a CEP. A 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 to 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 health care 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 3 variables, each costed using PSSRU and assuming mean national values for wages.
- Testing the impact of a range of assumptions about QALYs over the 4-12 month period.
- Different values for the QALY decrement as a result of an inpatient admission.
- Any sub-group 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 Trial Steering Committee and a Data Monitoring Group. These meet regularly to monitor trial progress and advise on any proposed amendments. No interim analyses are planned, but the Trial Standard Operating Procedures (agreed by the PRIMENT Clinical Trials Unit, who oversee this trial) require all adverse incidents of any kind to be reported in the first place to the Chair of the Trial Steering Committee.

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), who have 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).

Consent

Clinical staff from the CRT (or on occasion clinicians from other services who are known to the patient) contact patients initially to explain briefly 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 answer 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 will be 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 will 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 will be 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 will oversee the development and management of a secure database for all quantitative study data. Participants will be identified only by a study identification number in the database. Data will be 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 one 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.

DECLARATIONS

Ethical approval

The trial received a favourable opinion from the London Camden and Islington Research Ethics Committee (REC ref: 12/LO/0988F

The following sites have approved the trial: Camden and Islington NHS Foundation Trust; Surrey and Borders Partnership NHS Foundation Trust; North East London NHS Foundation Trust; South London and Maudsley NHS Foundation Trust; West London Mental Health NHS Trust; Avon and Wiltshire Mental Health Partnership NHS Trust

Competing interests

The authors have no relevant declarations of interest.

Author's contributions

The trial design was developed by SJ, BLE, DH, DO, SP, OM, RG, FN, TW, CH and NM. LM and GA developed the statistical analysis plans and RH the economic analysis plan. AM has led on the development of the intervention. SJ is the Chief Investigator, based at University College London and BLE the project manager. DO provided oversight as a triallist in the PRIMENT Clinical Trials Unit. All authors have contributed and approved this manuscript.

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Data sharing: We will make data available via the corresponding author with as few restrictions as possible once the main study outputs are published.

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	-1	0	T1	T2	T3
	Enrolment Screening	Allocation Baseline & 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:					
Socio-demographic information		X			
Client Satisfaction Questionnaire (CSQ)		X	X		X
Social Outcomes Index (SIX)		X	X		X
Illness Management and Recovery Questionnaire (IMR)		X	X		X
Questionnaire on the Process of Recovery (QPR)		X	X		X
EuroQol Health Questionnaire (EQ-5D)		X	X		X
UCLA Loneliness Scale (ULS-8)		X	X		X
Lubben Social Network Scale (LSNS-6)		X	X		X
HLS Social Capital Questionnaire		X	X		X
Brief Psychiatric Rating Scale (BPRS)		X	X		X
Alcohol Use Questionnaire (AUDIT-C)		X			
Drug Use Questionnaire (DAST-10)		X			
Recovery Promoting Relationships			X		

Scale (RPRS) (Intervention Group only)					
Information on use of self-management materials			X		X
PATIENT RECORDS DATA (from previous 12 months to timepoint):					
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 diagnosis		X			
Most recent care cluster		X			
CPA status		X			

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

Additional File 1: CORE CRT Service Improvement Programme Trial – Reporting Checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	2
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	20-22
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4-5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	5-6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	8

	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8-9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9-10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10-11
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	12-13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	13-14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14-19
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15-16
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	20
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	20
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	20
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	20
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	20
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	21

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	21
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	21
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	21
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" licens

BMJ Open

A 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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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research
Keywords:	MENTAL HEALTH, Peer support, Self management, Relapse prevention

A 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 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 throughout most of 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, 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 self-management trial compares the effectiveness of a peer-provided self-management intervention for people leaving crisis resolution team 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 four and at 18 months following trial entry, measured using the Questionnaire on the Process of Recovery (QPR). 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.

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Keywords: Peer support, self-management, crisis resolution teams, home treatment, relapse prevention, randomised controlled trial

Sponsor: Camden and Islington NHS Foundation Trust (UK), Bloomsbury Building, St Pancras Hospital, 4 St Pancras Way, London NW1 0PE

STRENGTHS AND LIMITATIONS OF THE STUDY

- High 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 delivery 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 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.
- Readmission to acute care is used as a proxy measure for relapse: this is likely to result in high follow-up rates, but will miss some crises not resulting in readmission to acute care.

INTRODUCTION

Background and Rationale

Crisis Resolution Teams (CRTs) – sometimes called home treatment or crisis assessment teams - provide rapid assessment in mental health crises and offer intensive home treatment as an alternative to acute psychiatric inpatient admission if feasible[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[13,14,15,16]. 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 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 following 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 NHS services, 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 community mental health teams 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 one 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.
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 one 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 to 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 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 Crisis Resolution and Home Treatment Teams 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 generalizable 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 Crisis Resolution Teams 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 Georges 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:

(a) **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[28]**.** A literature and internet search was also carried out and key experts consulted to identify relevant resources for self-management interventions.

(b) **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].

(c) **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 of how to fit this intervention within existing care pathways. The groups usually comprised 6 to 8 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.

(d) **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 four-day training in fundamentals of delivery 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 ten 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 wellbeing once a crisis has abated

Meetings take place weekly, with the aim of completing the programme of up to ten sessions within three 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, 34]. 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 go 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 health care 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 one 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 one year of follow-up

a. Days on the caseload of an acute care service over one year.
b. Time to first relapse (indicated by admission to an acute service)

Measures at interview at 4 and 18 months follow-up

a. *Self-rated recovery,* measured by total score on the Questionnaire on the Process of Recovery[35] (QPR), a 22-item measure of self-rated recovery.
b. *Self-management skills*, rated by score on the Illness Management and Recovery Scale-patient version[36] (IMR) – a 15-item measure of self-reported management of illness and functioning.
c. *Overall satisfaction with mental health services*, rated by total score on the Client Satisfaction Questionnaire[37] (CSQ) – an eight item measure of respondents' satisfaction with mental health services.
d. *Symptom severity*, measured by the Brief Psychiatric Rating Scale[38] (BPRS) – a 24-item interviewer-rated measure of psychiatric symptoms rated by the researcher based on the participant's responses to a structured interview schedule.
e. *Loneliness,* The UCLA Loneliness Scale[39] (ULS-8) – an eight item measure of perceived loneliness.
f. *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[40] – a six item measure of social contact with family and friends.
g. The EuroQol EQ-5D 3 level[41] (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 ask the participant not to disclose this to them. An additional measure, requiring an unblinded researcher, is the Recovery Promoting Relationships Scale[42] – a 24-item patient-report measure of general

therapeutic alliance and specific recovery orientation of health service providers. This is administered by 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:

a. Socio-demographic 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 ICD10 classification.
c. The Social Outcomes Index[43] (SIX) as a measure of social circumstances: this four-item measure includes questions on employment, accommodation and social contact.
d. The Health and Lifestyles Survey social capital questionnaire[44] – a six-item measure of neighbourhood social capital.
e. Audit-C[45] – a three item self-report screening measure of alcohol use.
f. DAST-10[46] – a ten item self-report screening measure of drug use.

Participant timeline

Table 1 about here

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[47]. 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 one 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 three month intervention. All participants are contacted at 4 months following entry to the study for an initial follow-up interview. Data on the primary outcome is collected from clinical records at one 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, after rounding this gives 220 participants in the intervention arm and 220 participants in the control arm (a total of 440 participants) from six Crisis Resolution Teams, 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 is confirmed as a relatively conservative estimate by a meta-analysis of therapist effects in low-intensity mental health interventions[48]. It is expected that on average, there will be at least four peer support workers within each Crisis Resolution Team, 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 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 Crisis Resolution Team, 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) is 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, 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 one 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 (for example 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 is needed clearly specified. Administrators are then be 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 (six months and one 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 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 3 attempts to contact each participant, and by obtaining multiple contact details (e.g. 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, 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. 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, SD, 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 deviation will 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 one for analysis purposes. Condition (psychosis versus 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 interval.

Secondary Outcomes

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

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% confidence interval.

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 standard errors will be used. The condition (psychosis versus no psychosis) and centre will be added as fixed effects.

Supportive analyses

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;

analyses of outcomes adjusting for non-compliant participants in the treatment group using a dichotomous variable compliant is defined as three or more meetings attended; analyses adjusting 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. The following variables will be reported:

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:

Degree of match between peer support worker and participant

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

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 to control over 1 year for a range of values of willingness to pay for a quality adjusted life year (QALY) gained. The cost perspective is in alignment with the National Institute for Health and Care Excellence (NICE) Technology Assessment Guidance which provides guidance on the implementation of new health care technologies in the English National Health Service (NHS)

Outcomes

- Mental health service use (community and acute services) during one year follow up period.

- EQ-5D-3L at baseline and 4 months and 18 months.

Analyses

All analyses will follow the assumptions made in Part I 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. These will be costed 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]. 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 to control group. The average cost of an admission as calculated from baseline and 12 month data will be applied to any readmissions.

QALYs

We will calculate the mean cost per quality adjusted life year (QALY) gained of peer-provided self-management compared to control over 1 year. QALYs will be calculated using the EQ-5D-3L and the formula developed by Dolan and colleagues[49]. 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[50]. Confidence intervals 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).

Confidence intervals

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

Incremental cost-effectiveness ratio (ICER)

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 to control at 1 year using 1 year modelled QALYs and 1 year costs. An 18 month ICER will be calculated using 18 month QALY data and 18 month modelled cost data.

Cost-effectiveness plane (CEP) and cost-effectiveness acceptability curve (CEAC)

The results of the non-parametric bootstrap will be presented on a CEP. A 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 to 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 health care 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 3 variables, each costed using PSSRU and assuming mean national values for wages.
- Testing the impact of a range of assumptions about QALYs over the 4-12 month period.
- Different values for the QALY decrement as a result of an inpatient admission.

- Any sub-group 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 Trial Steering Committee and a Data Monitoring Committee. These meet regularly to monitor trial progress and advise on any proposed amendments. The Data Monitoring Committee (DMC) comprises three senior academics with experience of trials and mental health services research: a clinical academic psychologist who chaires 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 will be sent by the DMC Chair to the Chair of the Independent Trial Steering Committee (TSC) in advance of TSC meetings.

No interim analyses are planned, but the Trial Standard Operating Procedures (agreed by the PRIMENT Clinical Trials Unit, who oversee this trial) require all adverse incidents of any kind to be reported in the first place to the Chair of the Trial Steering Committee. Criteria for defining adverse events are agreed with the overseeing Clinical Trials Unit. Adverse events will be 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 will be recorded on a standard form by the study data officer, with information provided by an involved clinician from the NHS site. Adverse events will then be 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 Trial Steering Committee, who acts as an independent clinical reviewer, who will make the final judgement about study-relatedness and any need to alert the DMC immediately. Participant deaths will be additionally 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 will be 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), who have 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 Version 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 Version 3, 17/11/2013. The consent form used during participant recruitment was V2, 17/11/13. An updated consent form used to reconfirm consent for 18-month follow up interviews was V4, 04/11/15. Both consent forms are included as 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 briefly 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 answer 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 will be 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 will 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 will be 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 will oversee the development and management of a secure database for all quantitative study data. Participants will be identified only by a study identification number in the database. Data will be 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 one 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.

DECLARATIONS

Ethical approval

The trial received a favourable opinion from the London Camden and Islington Research Ethics Committee (REC ref: 12/LO/0988F). Consent forms are in supplemental files 1 and 2.

The following sites have approved the trial: Camden and Islington NHS Foundation Trust; Surrey and Borders Partnership NHS Foundation Trust; North East London NHS Foundation Trust; South London and Maudsley NHS Foundation Trust; West London Mental Health NHS Trust; Avon and Wiltshire Mental Health Partnership NHS Trust

Competing interests

The authors have no relevant declarations of interest.

Author's contributions

The trial design was developed by SJ, BLE, DH, DO, SP, OM, RG, FN, TW, CH and NM. LM and GA developed the statistical analysis plans and RH the economic analysis plan. AM has led on the development of the intervention. SJ is the Chief Investigator, based at University College London and

BLE the project manager. DO provided oversight as a triallist in the PRIMENT Clinical Trials Unit. All authors have contributed and approved this manuscript.

Acknowledgements: We are grateful for the help and advice of Rachel Perkins and Julie Repper with the adaptation of the Personal Recovery Plan resource for use in this trial, and to South West London and St George's Mental Health NHS Trust for licensing its adaptation and use in the trial. We are grateful to Marisa Lambert and colleagues from the Nottingham Institute of Mental Health for their help and advice with developing the Peer Support Worker training programme for our trial. We are grateful to Dr Zlatka Russinova for her help with access to the Recovery Promoting Relationships Scale and advice regarding its use.

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Data sharing: We will make data available via the corresponding author with as few restrictions as possible once the main study outputs are published.

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	-1	0	T1	T2	T3
	Enrolment Screening	Allocation Baseline & 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:					
Socio-demographic information		X			
Client Satisfaction Questionnaire (CSQ)		X	X		X
Social Outcomes Index (SIX)		X	X		X
Illness Management and Recovery Questionnaire (IMR)		X	X		X
Questionnaire on the Process of Recovery (QPR)		X	X		X
EuroQol Health Questionnaire (EQ-5D)		X	X		X
UCLA Loneliness Scale (ULS-8)		X	X		X
Lubben Social Network Scale (LSNS-6)		X	X		X
HLS Social Capital Questionnaire		X	X		X
Brief Psychiatric Rating Scale (BPRS)		X	X		X
Alcohol Use Questionnaire (AUDIT-C)		X			
Drug Use Questionnaire (DAST-10)		X			
Recovery Promoting Relationships			X		

Scale (RPRS) (Intervention Group only)					
Information on use of self-management materials			X		X
PATIENT RECORDS DATA (from previous 12 months to timepoint):					
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 diagnosis		X			
Most recent care cluster		X			
CPA status		X			

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

Camden and Islington NHS
NHS Foundation Trust

CORE Phase 3: consent form for participation in randomised controlled trial of a peer-provided, self-management intervention for people leaving Crisis Resolution Teams

Version 2: 17.11.13

Study Title: CORE: Crisis Team Optimisation and Relapse Prevention – Phase 3

Principal Investigator: Professor Sonia Johnson, UCL,
Research worker:

1. I have read and understood the study information sheet dated 17/11/2013 ☐
2. I have had the opportunity to ask questions about the study ☐
3. I understand that my participation is voluntary and that I can withdraw at any time, without giving any reason, without the services provided to me being affected. ☐
4. I understand that the Crisis Resolution Team (CRT) which supported me will be informed that I am taking part in the study. I understand that if I am allocated to receive support from a peer support worker, a record of their meetings with me will be kept in my patient notes. ☐
5. I agree to my GP being informed of my participation in the study ☐
6. I consent to a researcher contacting me to arrange an initial and a follow-up research interview for the study. ☐
7. I consent to a researcher contacting a family member or a member of staff, if I have named them below, if this is necessary to make contact with me for the 4 month study follow-up interview. ☐

8. I consent to the information collected about me for this study being stored securely at University College London ☐

9. I understand that I will be offered a £20 gift in cash for my participation in the research interview, once I have taken part in it. ☐

10. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities and/or the NHS Foundation Trust where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records. ☐

11. I consent to the research team having access to information about my diagnosis and my use of mental health services from my electronic patient records. If information about my use of services is not available from my electronic patient records in the NHS Trust whose services I am currently using, I consent to study researchers collecting this information where possible from other NHS services. ☐

12. I consent to a researcher contacting me up to 18 months after my follow-up interview to ask me about taking part in a further research interview for this study, or a separate follow-on study relating to this one. ☐

13. I agree to take part in the study ☐

My preferred contact details:

Name:

Address:

Phone number(s):

E-mail address:

Preferred method of contact:

☐ Phone
☐ E-mail
☐ Letter

Contact details of family members or carers I am happy for a researcher to contact if necessary to contact me for a follow-up interview:

(If possible, please provide details of any family members or carers whom researchers could contact if unable to contact you directly for a follow-up interview.)

	Family contact #1	Family contact #2
Name		
Relationship to participant		
Address		
Phone number(s)		
email		

Contact details of mental health staff working with me I am happy for a researcher to contact if necessary to contact me for a follow-up interview:

(If possible, please provide details of any mental health staff whom researchers could contact if unable to contact you directly for a follow-up interview.)

Name:

Job title:

Service:

Contact details (if known)

I would like a copy of a report with the study findings when the study is over:

☐ Yes
☐ No

Please sign this consent form below to confirm your consent to take part in the study

_____	_____	_____
Name of participant	Date	Signature

_____	_____	_____
Name of researcher	Date	Signature

Camden and Islington NHS
NHS Foundation Trust

CORE Phase 3: consent form for participation in randomised controlled trial of a peer-provided, self-management intervention for people leaving Crisis Resolution Teams

Version 4: 04 November 2015

Study Title: CORE: Crisis Team Optimisation and Relapse Prevention – Phase 3

Principal Investigator: Professor Sonia Johnson, UCL,
Research worker:

1. I have read and understood the study information sheet dated 04 November 2015 ☐
2. I have had the opportunity to ask questions about the study ☐
3. I understand that my participation is voluntary and that I can withdraw at any time, without giving any reason, without the services provided to me being affected. ☐
4. I understand that the Crisis Resolution Team (CRT) which supported me will be informed that I am taking part in the study. ☐
5. I agree to my GP being informed of my participation in the study
6. I consent to a researcher contacting a family member or a member of staff, if I have named them below, if this is necessary to make contact with me for tha study follow-up interview. ☐
7. I consent to the information collected about me for this study being stored securely at University College London ☐
8. I understand that I will be offered a £20 gift in cash for my participation in the research interview, once I have taken part in it. ☐

9. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities and/or the NHS Foundation Trust where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records. ☐

10. I consent to the research team having access to information about my diagnosis and my use of mental health services from my electronic patient records. If information about my use of services is not available from my electronic patient records in the NHS Trust whose services I am currently using, I consent to study researchers collecting this information where possible from other NHS services. ☐

11. I consent to a researcher contacting me up to 2 years after my follow-up interview to ask me about taking part in a further research interview for this study, or a separate follow-on study relating to this one. ☐

12. I agree to take part in the study ☐

My preferred contact details:

Name:

Address:

Phone number(s):

E-mail address:

Preferred method of contact:
☐ Phone
☐ E-mail
☐ Letter

Contact details of family members or carers I am happy for a researcher to contact if necessary to contact me for a follow-up interview:
(If possible, please provide details of any family members or carers whom researchers could contact if unable to contact you directly for a follow-up interview.)

	Family contact #1	Family contact #2
Name		
Relationship to participant		
Address		
Phone number(s)		
email		

Contact details of mental health staff working with me I am happy for a researcher to contact if necessary to contact me for a follow-up interview:

(If possible, please provide details of any mental health staff whom researchers could contact if unable to contact you directly for a follow-up interview.)

Name:

Job title:

Service:

Contact details (if known)

I would like a copy of a report with the study findings when the study is over:

☐ Yes
☐ No

Please sign this consent form below to confirm your consent to take part in the study

_____	_____	_____
Name of participant	Date	Signature

_____	_____	_____
Name of researcher	Date	Signature

Additional File 1: CORE CRT Service Improvement Programme Trial – Reporting Checklist

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	1-2~~N/A~~
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	24~~22~~
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 23-24
	5b	Name and contact information for the trial sponsor	2
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	24~~22~~

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	21-23~~20-22~~
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-4
	6b	Explanation for choice of comparators	4
Objectives	7	Specific objectives or hypotheses	4-5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6, 8~~5-6~~
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6-9, 29~~6-7~~
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	9~~8~~
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9~~8-9~~

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-11, 30-319 10
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11, 30-3110 11
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	1211
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	1211
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12-13
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12-13
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12-13
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	1312

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13~~12~~
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol. - The structured interview schedule and scoring guidance provided to researchers for using the BPRS are available from the corresponding author on request.	13-14~~12-13~~
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14-15~~13-14~~
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15~~14~~
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15-16~~14-19~~
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16-21~~15-16~~
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17-18
Methods: Monitoring			

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	21~~20~~
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	21~~20~~
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	22~~20~~
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	22~~20~~
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	22~~20~~
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	22~~20~~
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	22-23~~21~~

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	2321
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	2321
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	2321
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Included as supplementary files
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license