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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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4 management intervention to prevent relapse in crisis resolution team users: study protocol for a
5 randomised controlled trial (the CORE self-management trial)
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37

38 **ABSTRACT**

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

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

21
22 **Ethics and dissemination:** The CORE self-management trial was approved by the London Camden
23 and Islington Research Ethics Committee (REC ref: 12/LO/0988). A Trial Steering Committee and
24 Data Monitoring Committee oversee the progress of the study. We will report on the results of the
25 clinical trial, as well as on the characteristics of the participants and their associations with relapse.

26
27 **Trial Registration:** ISRCTN01027104 DOI 10.1186/ISRCTN01027104. Date registered: 11/10/12

28
29 **Keywords:** Peer support, self-management, crisis resolution teams, home treatment, relapse
30 prevention, randomised controlled trial

31
32 **Sponsor:** Camden and Islington NHS Foundation Trust (UK), Bloomsbury Building, St Pancras
33 Hospital, 4 St Pancras Way, London NW1 0PE

34 35 36 37 38 39 40 41 42 43 44 45 **INTRODUCTION**

46 47 **Background and Rationale**

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50 Crisis Resolution Teams (CRTs) – sometimes called home treatment or crisis assessment teams -
51 provide rapid assessment in mental health crises and offer intensive home treatment as an
52 alternative to acute psychiatric inpatient admission if feasible¹. Since being mandated in the NHS
53 Plan (2000)², CRTs have proliferated and are now available in most NHS Trust catchment areas in
54 England. Research evaluations have been mainly positive, suggesting CRTs reduce inpatient
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3 admissions³⁻⁷ and healthcare costs^{8,9} and increase service user satisfaction with acute care^{3,6}. Service
4 users, however, have reported considerable areas of dissatisfaction including continuity of care
5 between services during and following a period of CRT care^{10,11}. Recent policy reports have also
6 criticised CRTs for failings including lack of continuity and integration with other services, and
7 insufficient attention to strategies for maintaining well-being and avoiding future crises^{12,13,14,15}. Thus
8 demand for acute care in England remains very high in the absence of interventions to reduce repeat
9 use¹⁶. A scoping review regarding interventions for mental health crisis care did not find robust
10 evidence on how to prevent repeat crises in people leaving crisis care¹⁷.

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17 The aim of the present study is to develop and test an intervention intended to achieve this. The
18 SPIRIT guidelines are followed in this report of the protocol.

19 20 21 **Choice of comparators**

22 23 **Self-management intervention**

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25 There is substantial evidence for the effectiveness of self-management programmes supporting
26 mental health service users to manage their own illness¹³. These commonly involve learning to
27 anticipate and respond to signs of a crisis and developing skills to manage symptoms or other
28 difficulties. The provision of peer support – support provided by people who have themselves
29 experienced mental ill health - alongside existing aftercare services has also been advocated to
30 improve outcomes for people following a mental health crisis¹⁸. Hypothesised qualities of peer
31 workers include an ability to provide support and encouragement that is particularly warm and
32 empathic due to being rooted in personal experience, and provision of a role model for recovery¹⁹.
33 These qualities suggest that peer workers are a particularly appropriate choice for delivery of
34 programmes aimed at enhancing recovery and proactive behaviours and self-care to remain well.
35 North American trials of peer-provided self-management programmes such as the Wellness
36 Recovery Action Plan²⁰ and the Recovery Workbook²¹ report some promising outcomes for service
37 users, but their impact on admissions or relapse has not been assessed. Our goal in the current study
38 is to develop and test an intervention with a similar self-management focus for people leaving the
39 care of crisis teams, aiming to reduce their subsequent readmission rates and dependence on
40 services. The employment of peer support workers to deliver self-management support to service
41 users is becoming increasingly common within NHS services, promoted by initiatives such as the NHS
42 Confederation *Implementing Recovery through Organisational Change* project²², but thus far the
43 effectiveness of such an intervention in reducing acute care readmission following a crisis has not to
44 our knowledge been tested.
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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

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3 London and St Georges NHS Foundation Trust²³, specifically their Personal Recovery Plan. This was in
4 turn informed by self-management resources such as the Wellness Recovery Action Plan²⁰ and
5 relapse prevention interventions²⁴.
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8 9 *Selection and development of the intervention*

10 The intervention was adapted and selected via the following stages, more fully described in a
11 companion paper:
12

- 13
14 (a) **Initial searches:** Systematic literature searches were carried out to find relevant literature on
15 self-management interventions for people with mental health problems, and on peer
16 support interventions²⁵. A literature and internet search was also carried out and key
17 experts consulted to identify relevant resources for self-management interventions.
18
19 (b) **Individual interviews to inform intervention selection:** In individual interviews with 41
20 consenting service users, their views were explored of the types of intervention that would
21 be feasible and useful following a crisis, how they should be offered and delivered, and the
22 potential benefits and risks of having a peer worker deliver the interventions. These
23 interviews were carried out by service user researchers, and were also used to elicit data
24 relevant to the other Workstream included in the CORE study, involving development and
25 testing of an intervention to improve CRT fidelity²⁶.
26
27 (c) **Stakeholder focus groups and adaptation of the intervention:** Informed by this work, the
28 Personal Recovery Plan²⁷ was identified by the study team and advisory groups of service
29 users and carers, and of clinicians, involved in the study as the most promising basis for the
30 study intervention. A series of stakeholder focus groups was then convened for discussion of
31 how to fit this intervention within existing care pathways. The groups usually comprised 6 to
32 8 participants. Twelve groups of consenting participants were convened in all; five of people
33 with experience of using crisis services, five of CRT staff and two of carers with experience of
34 crisis services. Following this step, the Personal Recovery Plan was adapted with the
35 permission of its authors and under licence from the copyright holders, South West London
36 and St George's Mental Health Trust, to fit the context of the trial, including adaptations to
37 make it as relevant as possible to people who have recently experienced a crisis. A protocol
38 was also developed for peer support worker training, and for delivery of the intervention in
39 the context of the trial.
40
41 (d) **Feasibility study:** Following this, an uncontrolled feasibility study was conducted to test the
42 feasibility and acceptability of the intervention. Four peer support workers were given a
43 four-day training in fundamentals of delivery peer support and in the delivery of our draft
44 self-management intervention: an abbreviated and tailored version of the Nottingham
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3 Institute of Mental Health's accredited peer support worker training. Eleven participants
4 were recruited from an inner city CRT, and gave informed consent to receive the
5 intervention over 10 sessions. Following the intervention period, a group interview was
6 conducted with the Peer Support Workers and individual interviews with the service user
7 participants (n=9). Experiences of the intervention and suggestions for adaptation were
8 explored and further minor modifications introduced throughout the intervention.
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12 *Delivery of the intervention*

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14 The intervention is delivered in a series of up to ten sessions with a peer support worker. The peer
15 support worker offers sympathetic listening and seeks to instil hope through appropriate sharing of
16 skills and coping strategies acquired in their own recovery journey. The intervention is structured
17 round the completion of a Personal Recovery Workbook with the following structured components:
18
19

- 20 • Setting personal recovery goals
- 21 • Help with plans to re-establish community functioning and support networks following a
22 crisis
- 23 • Using the experience of recent crisis to identify early warning signs and an action plan to
24 avoid or attenuate relapse
- 25 • Planning strategies and coping resources to maintain wellbeing once a crisis has abated

26
27 Meetings take place weekly, with the aim of completing the programme of up to ten sessions within
28 three months. The peer support worker encourages the participant to consider involving friends and
29 family in the intervention, by showing them materials from the meetings, eliciting their help with
30 making crisis plans or inviting them to attend a meeting. Unless clinical staff identify any risks
31 necessitating that meetings should take place on NHS premises, they take place in the location
32 preferred by the participants, which can be their homes, an appropriate public space, or NHS
33 premises.
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36 *Peer support workers and their training*

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38 Peer support workers have been recruited and employed by participating NHS Trusts for the study.
39 All are people who have themselves experienced mental health problems and used mental health
40 services. An introductory programme of training has been arranged by the study team. This includes
41 familiarising peer support workers with the study workbook and how to support participants in using
42 it. It also covers more generic issues such as safety, confidentiality, appropriate self-disclosure, roles
43 and boundaries, engagement and listening skills and cultural sensitivity. Additional induction
44 required by participating NHS Trusts has also been attended by peer workers. An experienced peer
45 support worker from the study team additionally met each peer support team during the trial. A
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3 programme of group supervision has also been established by the peer workers, facilitated by
4 clinicians from the employing Trust. Peer support workers have been encouraged to use this
5 additional supervision to discuss general issues arising from using the Personal Recovery Workbook
6 or from their role as a peer supporter (not specific clinical concerns relating to participants, which go
7 are addressed by local NHS supervisors), and to discuss needs for any additional “top-up” training, to
8 be provided as required by the study team.. Standard NHS Trust procedures are followed regarding
9 confidentiality, safety, and lone working.
10

11 Control intervention

12 In the control condition, participants are sent a Personal Recovery Workbook to complete by
13 themselves or with family and friends if they wish: this has the same content as in the Experimental
14 group.
15

16 Discontinuation criteria

17 Participants may withdraw from the intervention at any time without giving a reason. The
18 intervention is also suspended if a participant becomes unwell to the extent that he or she no longer
19 has capacity to consent to continuing the sessions or the ability to cooperate with them.
20

21 Monitoring adherence to the intervention

22 Peer support workers keep a brief anonymised log of the intervention, recording the content of
23 each session and the sections of the workbook completed. Study research staff monitor the
24 completion of this log.
25

26 Concomitant care

27 Otherwise usual care is received, with no treatments withheld from participants in either arm of the
28 trial. In both conditions this may be from a relevant community mental health team to which the
29 CRT has made a referral after discharge or to primary care services, if the threshold for continuing
30 specialist mental health care in the community is not judged to be met. In order to ensure that
31 participants’ trial status did not affect other ongoing care and, in particular, the discharge plans for
32 support arranged by the CRT they were using, neither participants nor CRTs were informed of
33 participants’ trial allocation status until after they had been discharged from the CRT.
34

35 Outcomes

- 36
- 37 1. Primary Outcome: The primary outcome is whether, in one year of follow-up from study
38 entry, participants are readmitted to an acute care setting, including acute inpatient wards,
39 CRTs, crisis houses and acute day care services.
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3 2. Secondary outcomes: The following are measured as secondary outcomes; all are
4 dimensions of outcome on which there are potential mechanisms for an effect from a peer-
5 provided self-management intervention.
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9 Service use measures over one year of follow-up

- 10 a. Days on the caseload of an acute care service over one year.
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12 b. Time to first relapse (indicated by admission to an acute service)
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14 Measures at interview at 4 and 18 months follow-up

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16 a. *Self-rated recovery*, measured by total score on the Questionnaire on the Process of
17 Recovery²⁸ (QPR), a 22-item measure of self-rated recovery.
18
19 b. *Self-management skills*, rated by score on the Illness Management and Recovery Scale-
20 patient version²⁹ (IMR) – a 15-item measure of self-reported management of illness and
21 functioning.
22
23 c. *Overall satisfaction with mental health services*, rated by total score on the Client
24 Satisfaction Questionnaire³⁰ (CSQ) – an eight item measure of respondents' satisfaction with
25 mental health services.
26
27 d. *Symptom severity*, measured by the Brief Psychiatric Rating Scale³¹ (BPRS) – a 24-item
28 interviewer-rated measure of psychiatric symptoms rated by the researcher based on the
29 participant's responses to a structured interview schedule.
30
31 e. *Loneliness*, The UCLA Loneliness Scale³² (ULS-8) – an eight item measure of perceived
32 loneliness.
33
34 f. *Social network* measured by total number of friends and relatives with whom participant has
35 been in contact in the past month according to the Lubben Social Network Scale³³ – a six
36 item measure of social contact with family and friends.
37
38 g. The EuroQol EQ-5D 3 level (EQ-5D-3L) was completed by participants to derive utility scores
39 to calculate QALYs for the health economic evaluation. Structured recording of mental
40 health service use at 1 year was also included for this purpose.
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49 All these measures are administered by a researcher who is blind to study condition and ask the
50 participant not to disclose this to them. An additional measure, requiring an unblinded researcher, is
51 the Recovery Promoting Relationships Scale³⁵ – a 24-item patient-report measure of general
52 therapeutic alliance and specific recovery orientation of health service providers. This is
53 administered by following the initial interview.
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3 Further measures used to characterise the sample and to adjust in secondary analysis for variables
4 known to be associated with the primary outcome include:

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6 a. Socio-demographic and clinical data (including age, gender, ethnicity, accommodation and living
7 situation, employment status, educational attainment and past service use, including admissions
8 and compulsory admissions).
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11 b. Clinical diagnosis as recorded on electronic records using the ICD10 classification.
12
13 c. The Social Outcomes Index³⁶ (SIX) as a measure of social circumstances: this four-item measure
14 includes questions on employment, accommodation and social contact.
15
16 d. The Health and Lifestyles Survey social capital questionnaire³⁷ – a six-item measure of
17 neighbourhood social capital.
18
19 e. Audit-C³⁸ – a three item self-report screening measure of alcohol use.
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21 f. DAST-10³⁹ – a ten item self-report screening measure of drug use.
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26 **Participant timeline**

27 **Table 1 about here**

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29 This is summarised in Table 1. Potential participants are approached by CRT staff initially just prior to
30 or just after discharge from the team. Where potential participants are confirmed as eligible,
31 baseline interviews including all the above measures take place as soon as possible, with a maximum
32 of one month after CRT discharge for entry to the trial. Randomisation (see below) follows baseline
33 interviews, after which participants randomised to the control group are allocated a peer support
34 worker to begin the three month intervention. All participants are contacted at 4 months following
35 entry to the study for an initial follow-up interview. Data on the primary outcome is collected from
36 clinical records at one year, and participants are contacted 18 months following randomisation for a
37 final follow-up interview with the measures above.
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46 **Sample size**

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48 A sample size of 440 is required to detect a difference in admission rates during the follow-up period
49 of 50% in the control group versus 35% in the experimental group, with 80% power and 5%
50 significance. This calculation is based on unequal allocation of 217 in the control arm and 159 in the
51 intervention arm. The intervention arm is then inflated for clustering (peer support worker) using an
52 intraclass correlation coefficient of 0.03, after rounding this gives 220 participants in the
53 intervention arm. The intervention arm is then inflated for clustering (peer support worker) using an
54 intraclass correlation coefficient of 0.03, after rounding this gives 220 participants in the
55 intervention arm and 220 participants in the control arm (a total of 440 participants) from six Crisis
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3 Resolution Teams, all in different NHS Trusts. It is expected that on average, there will be at least
4 four peer support workers within each Crisis Resolution Team, with an average cluster size of 11. Of
5 these 440 participants, 40 were recruited during the internal pilot conducted in one Trust only to
6 establish acceptability of our trial procedures and feasibility of recruitment to a randomised
7 controlled trial of the intervention. It was agreed by the Trial Steering Committee and the study
8 funders that changes to study procedures and to the intervention following this internal pilot were
9 sufficiently minimal for the internal pilot sample to be included within the main study sample.
10

11 **Recruitment strategies**

12
13 Close liaison is maintained by research staff with the participating CRT staff, who have been strongly
14 encouraged to consider every CRT client's eligibility for the trial. Leaflets, a website and a Twitter
15 account are among the methods used to raise awareness of the study among staff and local service
16 users.
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27 **METHODS: ASSIGNMENT OF INTERVENTIONS**

28 **Group allocation**

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

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47 It is not feasible to blind participants to whether they are allocated to the treatment or control
48 group. Data for the study's primary outcome (readmission to acute care during the follow-up period)
49 is provided by administrators from participating NHS Trusts, who are not informed by researchers of
50 participants' treatment allocation. The study data officer or trial manager conducts randomisation,
51 and informs the CRT which treatment group each participant has been allocated to. The data officer,
52 or sometimes in their absence the trial manager, also conducts the section of the follow-up
53 interview with participants in the treatment group which relates to their experience of the
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3 intervention. Study researchers, blind to participants' allocation status, conduct the 4-month and 18-
4 month follow-up interviews. Maintaining blinding of researchers is not likely to be achieved in full
5 for secondary outcomes collected during a follow-up interview, as it is likely some participants may
6 disclose in the course of the follow-up interview whether they have received the peer supported
7 programme. Researchers seek to minimise this by prompting participants not to disclose which trial
8 group they were in, both when setting up interviews and during the interview itself. Data will be
9 analysed blind to allocation with the exception of the RPRS, which will be analysed after the analyses
10 of other outcomes have been checked and agreed.
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18 **METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS**

19 **Data collection**

20 **Baseline interviews**

21
22 Once written consent to participate in the study has been obtained, but before participants are
23 randomly allocated to intervention or control groups, a study researcher completes the study
24 baseline measures with all participants as a structured interview. This interview takes about one
25 hour to complete. It may take place at the participant's home, NHS or university premises, as the
26 participant prefers within any limits advised by CRT clinicians during the recruitment process.
27 Following completion, participants are offered a £20 gift of cash to acknowledge their time and help
28 with the study.
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37 **Follow up interviews at 4 and 18 months**

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

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55 Once all participants from a participating NHS Trust have been recruited into the study, a study
56 researcher contacts the appropriate administrators or informatics team within the Trust regarding
57 collection of data from patient records. The study researchers provide a list of consenting
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3 participants' names, dates of birth and study identification numbers and a standardised schedule of
4 the information required for each patient, with the time period for which data is needed clearly
5 specified. Administrators are then be asked to provide the data to the research team, identifying
6 each patient by study ID number only to avoid data protection risks from transferring identifiable
7 patient data.
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12 One year after all participants from a participating NHS Trust have been recruited into the study (six
13 months and one year for the pilot trial), a study researcher again contacts the Trust's administrators
14 to collect outcomes data, using similar procedures to those described above.
15
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17 **Minimising loss to follow-up**

18 Primary outcome

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20
21 Research Ethics Committee approval allows data on the primary outcome to be collected even if
22 participants are lost to follow-up, minimising missing values on this measure. If service use data
23 relating to the primary study outcome are not available through Trust patient records, study
24 researchers will attempt to collect these data from other NHS Trust or GP records or the participant,
25 in accordance with the written consent provided by the participant.
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30 Follow-up interviews

31
32 Response rate is maximised by making at least 3 attempts to contact each participant, and by
33 obtaining multiple contact details (e.g. email, landline, mobile phone, a close relative's phone) at the
34 time of the baseline to maximise the likelihood of making contact. A £20 honorarium is offered at
35 each interview to thank participants for their time and effort.
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40 **Data entry and management**

41
42 All data recorded on paper forms are stored securely (in locked cabinets in locked offices) on
43 university sites in accordance with university data protection procedures. Data collection forms
44 identify participants only by their study ID. Participant consent forms, contact details and a single
45 master copy linking participants' names and IDs are held separately from other data.
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49
50 Data are entered using a web based system set up by Sealed Envelope⁴. This has been set up so
51 that, it mirrors the data collection sheets in order. It also has range checks, consistency checks and
52 for closed questions gives a number of options plus "other" where appropriate. Assessors who enter
53 data have no access to the group allocation through this system.
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3 With the checks in place, there should not be any issues with illegal values being entered or
4 inconsistent data being entered so necessary cleaning should be minimal. However, data are
5 checked by the Statistician before analysis and any problems reported to the Assistant/ Trial
6 Manager, who rectifies them as appropriate before data analysis.
7
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10 **Data analysis**

11 General principles

12
13 The assumptions underpinning each statistical method will be checked. For example, normality and
14 equality of variances will be checked for t-tests. The use of transformations or non-parametric
15 methods will be considered if assumptions do not hold. Adjusted analyses will be performed if
16 baseline imbalances are observed. The impact of missing data will be explored in all analyses.
17 Supportive analyses will be performed if non-compliance is considered to be a problem.
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23 The primary analyses will be complete case. All analyses will be on an intention to treat basis. Data
24 will be analysed using Stata.
25
26

27 Descriptive statistics

28
29 Initial analyses will look at summary statistics for all variables, both overall and by randomised
30 group. Summary statistics for continuous variables will be mean, median, SD, lower quartile, upper
31 quartile, minimum and maximum. These variables will also be plotted to check their distribution. If
32 variables are skewed, then median and interquartile ranges will be reported, otherwise mean and
33 standard deviation will be reported. Summary statistics for categorical variables will be frequency
34 and percentage within each category. No statistical significance tests for baseline characteristics by
35 randomised group will be performed, but balance will be assessed visually.
36
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41 Primary Outcomes

42
43 Data on readmission during the study period will be analysed using random effects logistic
44 regression, with clustering by peer support worker being modelled using random effects. Those in
45 the control group will be considered to be clusters of size one for analysis purposes. Condition
46 (psychosis versus no psychosis) and centre will be entered into the model as fixed effects. This
47 analysis will be reported in terms of an odds ratio and 95% confidence interval.
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51 Secondary Outcomes

52
53 For the analysis of the scales, random effects linear regression will be utilised (with peer support
54 worker as the random effect), controlling for the baseline value of the outcome, condition (psychosis
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3 versus no psychosis) and centre. These will be reported in terms of mean difference in outcome
4 between the two randomised groups with associated 95% confidence intervals.
5
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7 To assess the total days spent in acute care, we will perform random effects linear regression
8 analysis with the peer support worker being entered as a random effect. Centre will be entered into
9 the model as a fixed effect. This analysis will be reported as coefficient and 95% confidence interval.
10
11

12 Time to first readmission during the study period will be analysed using Cox regression frailty model.
13 However, if the frailty model fails to converge, then Cox regression with robust standard errors will
14 be used. The condition (psychosis versus no psychosis) and centre will be added as fixed effects.
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20 21 Supportive analyses

22 Conducted on the primary outcome, adjusting for any marked differences in randomised groups in
23 terms of demographic characteristics, service use in the year preceding entry to the study and scores
24 on outcome measures; amount of improvement for both groups between baseline and follow-up;
25 analyses of outcomes adjusting for non-compliant participants in the treatment group using a
26 dichotomous variable compliant is defined as three or more meetings attended; analyses adjusting
27 for whether peer support schemes were already established in the catchment area or newly
28 introduced for the study. Those in the treatment as usual group will be assigned to the same
29 category as those who are non-compliant in the intervention group.
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39 Participants attending fewer than three meetings with a peer support worker will be defined as non-
40 compliant. Non-compliance will be examined using Complier Average Causal Effect (CACE) analysis.
41 We will look at baseline predictors of attending fewer than three meetings using random effects
42 logistic regression (those in the intervention group only).
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48 Process analysis

49 The following descriptive information will be provided about the content of the intervention and the
50 degree of match between the peer support workers and the participants. The following variables
51 will be reported:
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55 *Use of the Personal Recovery Plan*

56 a) From participant data at follow up: the proportion of participants in the treatment and control
57 groups discussing or reading each of four sections of the recovery plan. A composite score of 0-4 will
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3 be reported for overall extent of awareness of the recovery plan, combining participants' reports of
4 whether they had looked at each section of the workbook.

5
6 b) From participant data at follow-up: the proportion of participants in the treatment and control
7 groups making a written plan for each of four sections of the recovery plan. A composite score of 0-
8 4 will be reported for overall extent of development of a written recovery plan by combining
9 participants' reports of whether they had looked at each section of the workbook.

10
11 c) From a random sample of contact records provided by Peer Support Workers: we will report the
12 proportion of meetings at which: the recovery plan was discussed or a written plan developed, and
13 the frequency with which other informal or professional carers were involved.
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20 21 *Peer Support Workers' style*

22
23 The mean RPRS total and index scores (recovery promoting strategies, and core relationship) and
24 range of mean scores among Peer Support Workers will be reported.

25
26 Degree of match between Peer Support Workers and participant

27
28 The proportion of participants who were matched with their Peer Support Workers will be reported
29 regarding:
30
31

32 33 *Degree of match between PSW and participant*

34
35 The proportion of participants who were matched with their PSW will be reported regarding:

- 36
37 a) Diagnosis
38 b) Experience of hospital admission (ever admitted yes/ no)
39 c) Gender
40 d) Ethnicity
41 e) Age
42
43
44

45 In the event of positive study outcomes, an exploratory regression analysis will be conducted to
46 model the relationship of these process factors to study outcomes.
47
48

49 **Missing data**

50
51 It is not expected that there will be much missing data for the primary outcomes, as these data will
52 come from the trust's informatics department. However, there may be missing data for other
53 outcomes. All items within a scale may be missing, or individual items within a given scale may be
54 missing. Some scales have recognised ways to impute missing items up to a given number of items,
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3 which will be used as appropriate. The extent and patterns of missingness will be evaluated to
4 determine whether it is associated with any of the outcomes. If variables are associated with
5 missingness, these will be controlled for in complete case analysis to maintain the missing at random
6 assumption.
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10 **Analysis plan for the Economic Evaluation**

11 Aim

12
13 The aim of the economic evaluation is to calculate the probability that peer-provided self-
14 management is cost-effective compared to control over 1 year for a range of values of willingness to
15 pay for a quality adjusted life year (QALY) gained.
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20 Outcomes

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

29
30 All analyses will follow the assumptions made in Part I regarding missing data, loss to follow up and
31 clustering. In line with the statistical analysis the primary economic evaluation will be a complete
32 case analysis. Sensitivity analyses will be conducted accounting for loss to follow up and missing data
33 as described below (Sensitivity Analyses).
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40 *Cost of the intervention*

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42 Information on peer support worker costs (salaries and oncosts) and time spent with patients on
43 peer support worker will be used to calculate the average cost per patient of the peer-provided self-
44 management intervention.
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53 *Cost of mental health service use*

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55 Acute and community mental health service use for the intervention and control group will be
56 collected from electronic patient records held by the mental health trust at baseline and 1 year.
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3 These will be costed for each patient using unit costs from the most recent Unit Costs of Health and
4 Social Care published by the Personal Social Services Research Unit⁷. Mean cost per patient at
5 baseline and 1 year for intervention and control groups will be reported by type of service use.
6
7

8
9 To extrapolate 12 month service use to 18 months we will develop a time to event model to predict
10 the probability of acute readmission between 12 months and 18 months for the intervention group
11 compared to control group. The average cost of an admission as calculated from baseline and 12
12 month data will be applied to any readmissions.
13
14

15 16 17 18 *QALYs*

19
20 We will calculate the mean cost per quality adjusted life year (QALY) gained of peer-provided self-
21 management compared to control over 1 year. QALYs will be calculated using the EQ-5D-3L and the
22 formula developed by Dolan and colleagues⁸. We will calculate the mean area under the curve for
23 each group from baseline to 4 months, controlling for any baseline differences using regression
24 analysis⁴¹. Confidence intervals will be constructed using non-parametric bootstrapping. To calculate
25 QALYs over 1 year, we will assume both groups have a linear return to their patient specific baseline
26 EQ-5D at 1 year, unless they have had an acute readmission. Patients with an acute readmission
27 between 4 months and 1 year will have a QALY decrement attributed calculated using regression
28 analysis and 4 month patient data.
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36 Baseline, 4 month and 18 month EQ-5D-3L responses will be used to calculate QALYs over 18
37 months. This will also be calculated as area under the curve adjusting for baseline (Hunter et al
38 2015).
39
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41 42 *Confidence intervals*

43
44 Confidence intervals for mean costs and QALYs will be calculated using non-parametric bootstrap
45 with replacement.
46

47 48 *Incremental cost-effectiveness ratio (ICER)*

49
50 The mean costs and QALYs calculated above will be used to calculate the mean incremental cost per
51 QALY gained of peer-provided self-management compared to control at 1 year using 1 year
52 modelled QALYs and 1 year costs. An 18 month ICER will be calculated using 18 month QALY data
53 and 18 month modelled cost data.
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56 57 *Cost-effectiveness plane (CEP) and cost-effectiveness acceptability curve (CEAC)*

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2
3 The results of the non-parametric bootstrap will be presented on a CEP. A CEAC will also be
4 constructed using the bootstrap data from a range of values of willingness to pay for a QALY gained.
5
6 The probability that the peer-provided self-management is cost-effective compared to control at a
7 willingness to pay for a QALY gained of £20,000 will be reported.
8
9

10 *Supportive Analyses*

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

- 12 • Cost-effectiveness complete case analysis at 4 months.
- 13 • Housing, employment and GP contacts are recorded at baseline and 4 months only. Two
14 analyses will be conducted, one including employment and one excluding employment, using
15 the 4 month data only for the 3 variables, each costed using PSSRU and assuming mean national
16 values for wages.
- 17 • Testing the impact of a range of assumptions about QALYs over the 4-12 month period.
- 18 • Different values for the QALY decrement as a result of an inpatient admission.
- 19 • Any sub-group analyses identified including the ICER for different levels of engagement with the
20 peer-support worker in the intervention group, including CACE analysis.

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22 If any key assumptions become apparent during the analysis these will also be tested for as part of
23 the sensitivity analyses.
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35 **METHODS: MONITORING AND APPROVALS**

36 **Monitoring**

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38 The trial is overseen throughout by a Trial Steering Committee and a Data Monitoring Group. These
39 meet regularly to monitor trial progress and advise on any proposed amendments. No interim
40 analyses are planned, but the Trial Standard Operating Procedures (agreed by the PRIMENT Clinical
41 Trials Unit, who oversee this trial) require all adverse incidents of any kind to be reported in the first
42 place to the Chair of the Trial Steering Committee.
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48 **Auditing**

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50 The trial sponsor regularly audits a sample of their sponsored trials, including inspection of processes
51 and procedures for storing data.
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55 **Ethics and dissemination**

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57 Ethical approval
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3 Ethical approval has been obtained from the London Camden and Islington Research Ethics
4 Committee (REC ref: 12/LO/0988), who have approved all amendments to protocol. The main
5 substantial amendment since the study was originally approved has been the addition of a follow-
6 up interview at 18 months (also approved by the Research Ethics Committee).
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10 11 12 Consent

13 Clinical staff from the CRT (or on occasion clinicians from other services who are known to the
14 patient) contact patients initially to explain briefly the study briefly and ask if patients are willing to
15 be contacted by a study researcher to discuss participation further. At this stage, clinicians will
16 screen out service users who are unwilling participate in the study, who pose a serious risk of harm
17 to others or who clearly lack capacity to provide consent. Clinicians note this willingness to be
18 contacted in clinical records and then pass on names and contact details to researchers. A study
19 researcher contacts potential participants to explain what the study involves and answer any
20 questions. For those still willing to participate, the researcher sends a written information sheet
21 about the study, and arranges a time to meet potential participants to seek written, informed
22 consent. Research staff seeking consent provide both a written patient information sheet and a
23 verbal explanation of the study and establish that participants understand the trial and intervention
24 procedures before seeking written informed consent.
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33 34 Confidentiality

35 All data recorded on paper forms will be stored securely at University College London or the
36 University of the West of England (for data collected by a study researcher based there) in
37 accordance with university data protection procedures. Data collection forms will identify
38 participants only by their study ID. Participant consent forms, contact details and a single master
39 copy linking participants' names and IDs will be held separately from other data. All data will be held
40 in locked filing cabinets in locked offices within university buildings.
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46 An independent data management service (Sealed Envelope) commissioned by the Priment Clinical
47 Trials Unit will oversee the development and management of a secure database for all quantitative
48 study data. Participants will be identified only by a study identification number in the database. Data
49 will be entered by study researchers using secure log-ins. Once recruitment and data collection are
50 complete, the data management service will advise on arrangements for the study team to access
51 the data for analysis.
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3 Once data collection is complete, all paper forms will be transferred to University College London.
4 Data will be held securely by the study team for up to one year after the end of the study, then
5 archived securely in accordance with University College London data protection procedures.
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8 9 **Dissemination**

10 Results will be reported in scientific publications and also disseminated to a wider audience via
11 blogs, social media and direct communication to policy makers. Participants will be offered a
12 summary and they will be communicated directly to participating teams.
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15 16 **DECLARATIONS**

17 18 **Ethical approval**

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20 The trial received a favourable opinion from the London Camden and Islington Research Ethics
21 Committee (REC ref: 12/LO/0988)
22
23

24 The following sites have approved the trial: Camden and Islington NHS Foundation Trust; Surrey and
25 Borders Partnership NHS Foundation Trust; North East London NHS Foundation Trust; South London
26 and Maudsley NHS Foundation Trust; West London Mental Health NHS Trust; Avon and Wiltshire
27 Mental Health Partnership NHS Trust
28
29
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31 32 **Competing interests**

33
34 The authors have no relevant declarations of interest.
35
36

37 38 **Author's contributions**

39 The trial design was developed by SJ, BLE, DH, DO, SP, OM, RG, FN, TW, CH and NM. LM and GA
40 developed the statistical analysis plans and RH the economic analysis plan. AM has led on the
41 development of the intervention. SJ is the Chief Investigator, based at University College London and
42 BLE the project manager. DO provided oversight as a triallist in the PRIMENT Clinical Trials Unit. All
43 authors have contributed and approved this manuscript.
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47

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52 their help and advice with developing the Peer Support Worker training programme for our trial. We
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4 Scale and advice regarding its use.
5
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12 expressed in this paper are those of the authors and not necessarily those of the NHS, the NIHR or
13 the Department of Health.
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19 Data sharing: We will make data available via the corresponding author with as few restrictions as
20 possible once the main study outputs are published.
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For peer review only

	-1	0	T1	T2	T3
	Enrolment Screening	Allocation Baseline & Randomisation	Follow- up 4 month s	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



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	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

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6	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
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Introduction

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15			
16	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
17			3-4
18		6b	Explanation for choice of comparators
19			4
20	Objectives	7	Specific objectives or hypotheses
21			4-5
22	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)
23			5
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Methods: Participants, interventions, and outcomes

27			
28	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
29			5
30	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)
31			5-6
32	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
33			6-7
34		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)
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6		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8-9
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9		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
10				
11	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
12				
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16	Participant	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
17	timeline			
18				
19	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
20				
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22	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11
23				
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Methods: Assignment of interventions (for controlled trials)

Allocation:

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29	Sequence	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
30	generation			
31				
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34	Allocation	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
35	concealment			
36	mechanism			
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38	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
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5	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
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8		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
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13	Methods: Data collection, management, and analysis			
14	Data collection	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
15	methods			
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18		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
19				
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21	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
22				
23				
24	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
25				
26		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15-16
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28		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
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37	Methods: Monitoring			
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6	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
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11		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
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14	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
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17	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	20
18				
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21	Ethics and dissemination			
22				
23	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20
24				
25				
26	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
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30	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	20
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33		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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36	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
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6	Declaration of	28	Financial and other competing interests for principal investigators for the overall trial and each	21
7	interests		study site	
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9	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual	21
10			agreements that limit such access for investigators	
11				
12	Ancillary and post-	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm	N/A
13	trial care		from trial participation	
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16	Dissemination	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare	21
17	policy		professionals, the public, and other relevant groups (eg, via publication, reporting in results	
18			databases, or other data sharing arrangements), including any publication restrictions	
19				
20		31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
21				
22		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical	N/A
23			code	
24				
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26	Appendices			
27				
28	Informed consent	32	Model consent form and other related documentation given to participants and authorised	
29	materials		surrogates	
30				
31	Biological	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or	N/A
32	specimens		molecular analysis in the current trial and for future use in ancillary studies, if applicable	

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34 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification
35 on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the
36 Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" licens
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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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-015665.R1
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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research
Keywords:	MENTAL HEALTH, Peer support, Self management, Relapse prevention

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Manuscripts

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3 A randomised controlled trial of the clinical and cost-effectiveness of a peer delivered self-
4 management intervention to prevent relapse in crisis resolution team users: study protocol
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43 **Word Count: 6,633**

44 45 **ABSTRACT**

46 **Introduction:** Crisis resolution teams provide assessment and intensive home treatment in a crisis,
47 aiming to offer an alternative for people who would otherwise require a psychiatric inpatient
48 admission. They are available throughout most of England. Despite some evidence for their clinical
49 and cost-effectiveness, recurrent concerns are expressed regarding discontinuity with other services
50 and lack of focus on preventing future relapse and readmission to acute care. Currently evidence on
51 how to prevent readmissions to acute care is limited. Self-management interventions, involving
52 supporting service users in recognising and managing signs of their own illness, have some
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3 supporting evidence, but have not been tested as a means of preventing readmission to acute care
4 in people leaving community crisis care. We thus proposed the current study to test the
5 effectiveness of such an intervention. We selected peer support workers as the preferred staff to
6 deliver such an intervention, as they are well-placed to model and encourage active and
7 autonomous recovery from mental health problems.
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11 **Methods and analysis:** The CORE self-management trial compares the effectiveness of a peer-
12 provided self-management intervention for people leaving crisis resolution team care, with
13 treatment as usual supplemented by a booklet on self-management. The planned sample is 440
14 participants, including 40 participants in an internal pilot. The primary outcome measure is whether
15 participants are readmitted to acute care over 1 year of follow-up following entry to the trial.
16 Secondary outcomes include self-rated recovery at four and at 18 months following trial entry,
17 measured using the Questionnaire on the Process of Recovery (QPR). Analysis will follow an
18 intention to treatment principle. Random effects logistic regression modelling with adjustment for
19 clustering by peer support worker will be used to test the primary hypothesis.
20

21
22 **Ethics and dissemination:** The CORE self-management trial was approved by the London Camden
23 and Islington Research Ethics Committee (REC ref: 12/LO/0988). A Trial Steering Committee and
24 Data Monitoring Committee oversee the progress of the study. We will report on the results of the
25 clinical trial, as well as on the characteristics of the participants and their associations with relapse.
26

27
28 **Trial Registration:** ISRCTN01027104 DOI 10.1186/ISRCTN01027104. Date registered: 11/10/12
29

30
31 **Keywords:** Peer support, self-management, crisis resolution teams, home treatment, relapse
32 prevention, randomised controlled trial
33

34
35 **Sponsor:** Camden and Islington NHS Foundation Trust (UK), Bloomsbury Building, St Pancras
36 Hospital, 4 St Pancras Way, London NW1 0PE
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38 39 40 41 STRENGTHS AND LIMITATIONS OF THE STUDY

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- 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 feasible¹. 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 practice². 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 admissions⁴⁻⁸ 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 year¹⁷. Thus demand for acute care in England remains very high in the absence of interventions to reduce repeat use¹⁸. 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 care¹⁹.

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 illness¹⁴. 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

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3 improve outcomes for people following a mental health crisis²⁰. Hypothesised qualities of peer
4 workers include an ability to provide support and encouragement that is particularly warm and
5 empathic due to being rooted in personal experience, and provision of a role model for recovery²¹.
6 These qualities suggest that peer workers are a particularly appropriate choice for delivery of
7 programmes aimed at enhancing recovery and proactive behaviours and self-care to remain well.
8 North American trials of peer-provided self-management programmes such as the Wellness
9 Recovery Action Plan²² and the Recovery Workbook²³ report some promising outcomes for service
10 users, but their impact on admissions or relapse has not been assessed. Our goal in the current study
11 is to develop and test an intervention with a similar self-management focus for people leaving the
12 care of crisis teams, aiming to reduce their subsequent readmission rates and dependence on
13 services. The employment of peer support workers to deliver self-management support to service
14 users is becoming increasingly common within NHS services, promoted by initiatives such as the NHS
15 Confederation *Implementing Recovery through Organisational Change* project²⁴, but thus far the
16 effectiveness of such an intervention in reducing acute care readmission following a crisis has not to
17 our knowledge been tested.
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28 **Control intervention**

29 Specific interventions to prevent relapse and promote recovery following a crisis are not currently
30 routinely delivered in NHS settings: we are thus aiming to test whether investing in delivery of such
31 an intervention is more effective than just providing service users with a simple resource to help
32 them manage their mental health and recovery themselves. The control condition was therefore
33 treatment as usual from community mental health teams with participants also being sent the self-
34 management manual on which the experimental intervention was based. This manual gives details
35 of how to develop plans for relapse prevention and for setting recovery goals.
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42 **Hypotheses/Objectives**

- 43
44 1. The primary hypothesis to be tested is that service users receiving the experimental
45 intervention will be less likely to relapse (indicated by readmission to acute care) over one
46 year than those in the control intervention receiving treatment as usual enhanced by access
47 to a self-management manual. *The anticipated admission rates at 1 year follow-up on which
48 study power calculation was based were 50% for control and 35% for intervention.*
- 49
50 2. Secondary hypotheses are to test whether being in the experimental rather than the control
51 condition is associated with longer time to first admission to acute care and fewer days in
52 acute care over one year, and also in better perceived recovery and illness management;
53 greater satisfaction with services; fewer symptoms; less loneliness; enhanced social
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3 networks, and greater social inclusion at the 4 month and the 18 month follow-up interviews
4 than participants in the control condition.

- 5
6 3. A further objective was to conduct a health economic evaluation to calculate the probability
7 that peer-provided self-management is cost-effective compared to control over 1 year for a
8 range of values of willingness to pay for a quality adjusted life year (QALY) gained. A
9 secondary analysis will calculate cost per QALY gained over 18 months.
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13 A planned secondary use of the data is to investigate a set of hypotheses regarding loneliness,
14 social isolation and social capital and outcomes following a crisis: these will be separately
15 reported and disseminated.
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18 19 **Trial Design**

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21 The CORE (CRT Optimisation and Relapse Prevention) trial of a peer-provided self-management
22 intervention is a rater-blind, randomised controlled trial with two parallel arms, designed to test the
23 hypotheses above. The trial is powered on the primary outcome, with adjustment for clustering by
24 peer support worker.
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31 **METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES**

32 33 **Setting**

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35 All participants are identified from the caseload of Crisis Resolution and Home Treatment Teams in
36 six NHS Trusts. Four are in London, one in the South East of England and one in the South-West.
37 Areas include inner city, suburban, mixed and rural catchment areas. All the Crisis Resolution and
38 Home Treatment Teams aim to operate according to the standard NHS model. All teams are
39 contactable 24 hours a day and see service users primarily in their homes, offering short term care
40 during the crisis before discharge to other secondary or primary care services as appropriate for
41 further management. Structured self-management interventions are not widely implemented in
42 these catchment areas²⁵, so that both control and experimental arms are receiving an additional
43 intervention. A list of participating sites is available from the authors.
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51 **Eligibility criteria**

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54 Inclusion criteria
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- 3 1. On the caseload for at least a week of one of the participating CRTs because of a mental
- 4 health crisis (including both participants treated only by the CRT during the crisis and those
- 5 initially admitted to hospital or a crisis house and then discharged to the CRT).
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- 8 2. Capacity and willingness to give informed consent to participate in the study.
- 9
- 10 3. Consented to enter the trial within a month of discharge from the CRT.

11 Exclusion criteria

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- 13 1. People presenting such a high risk to others that the CRT judged that it would be unsafe for
- 14 peer support workers to meet with them even in a mental health service setting.
- 15
- 16 2. People who are discharged to addresses outside the catchment area.
- 17
- 18 3. People who cannot understand the intervention when delivered in English.
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21 Criteria were deliberately broad in order to reach conclusions generalizable to the full range of CRT
22 users. With this aim of achieving broad representativeness of CRT service users, we also set a
23 threshold at each study site of at least 50% of participants to be identified at screening as having
24 schizophrenia or other psychosis, or bipolar disorder. Within this stipulation, participation has been
25 offered to all eligible service users in participating Crisis Resolution Teams until the recruitment
26 target for the service has been reached.
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30 31 **Interventions**

32 Experimental group intervention

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36 The peer-provided self-management intervention tested in the study has been adapted from
37 recovery resources compiled by Dr Rachel Perkins, Dr Julie Repper and colleagues at South West
38 London and St Georges NHS Foundation Trust²⁶, specifically their Personal Recovery Plan. This was in
39 turn informed by self-management resources such as the Wellness Recovery Action Plan²² and
40 relapse prevention interventions²⁷.
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45 *Selection and development of the intervention*

46 The intervention was adapted and selected via the following stages, more fully described in a
47 companion paper:
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- 50 (a) **Initial searches:** Systematic literature searches were carried out to find relevant literature on
51 self-management interventions for people with mental health problems, and on peer
52 support interventions²⁸. A literature and internet search was also carried out and key
53 experts consulted to identify relevant resources for self-management interventions.
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3 (b) **Individual interviews to inform intervention selection:** In individual interviews with 41
4 consenting service users, their views were explored of the types of intervention that would
5 be feasible and useful following a crisis, how they should be offered and delivered, and the
6 potential benefits and risks of having a peer worker deliver the interventions. These
7 interviews were carried out by service user researchers, and were also used to elicit data
8 relevant to the other Workstream included in the CORE study, involving development and
9 testing of an intervention to improve CRT fidelity²⁹.
10
11 (c) **Stakeholder focus groups and adaptation of the intervention:** Informed by this work, the
12 Personal Recovery Plan^{30, 31} was identified by the study team and advisory groups of service
13 users and carers, and of clinicians, involved in the study as the most promising basis for the
14 study intervention. A series of stakeholder focus groups was then convened for discussion of
15 how to fit this intervention within existing care pathways. The groups usually comprised 6 to
16 8 participants. Twelve groups of consenting participants were convened in all; five of people
17 with experience of using crisis services, five of CRT staff and two of carers with experience of
18 crisis services. Following this step, the Personal Recovery Plan was adapted with the
19 permission of its authors and under licence from the copyright holders, South West London
20 and St George's Mental Health Trust, to fit the context of the trial, including adaptations to
21 make it as relevant as possible to people who have recently experienced a crisis. A protocol
22 was also developed for peer support worker training, and for delivery of the intervention in
23 the context of the trial.
24
25 (d) **Feasibility study:** Following this, an uncontrolled feasibility study was conducted to test the
26 feasibility and acceptability of the intervention. Four peer support workers were given a
27 four-day training in fundamentals of delivery peer support and in the delivery of our draft
28 self-management intervention: an abbreviated and tailored version of the Nottingham
29 Institute of Mental Health's accredited peer support worker training. Eleven participants
30 were recruited from an inner city CRT, and gave informed consent to receive the
31 intervention over 10 sessions. Following the intervention period, a group interview was
32 conducted with the Peer Support Workers and individual interviews with the service user
33 participants (n=9). Experiences of the intervention and suggestions for adaptation were
34 explored and further minor modifications introduced throughout the intervention.
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Delivery of the intervention

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54 The intervention is delivered in a series of up to ten sessions with a peer support worker. Each trial
55 participant is allocated to one peer support worker. If participants specifically requested a peer
56 support worker of their own gender, this is arranged, but no attempt beyond this is made to match
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3 peer support workers and participants. There is no consensus in the literature³² on whether, and on
4 the basis of which characteristics, peer support workers and clients need to be matched. In practice,
5 with three peer support workers available in each CRT, we anticipated being unable to match on
6 many characteristics, and felt that attempting to do so may restrict generalisability to routine NHS
7 settings, where matching is often not feasible. The peer support worker offers sympathetic listening
8 and seeks to instil hope through appropriate sharing of skills and coping strategies acquired in their
9 own recovery journey. The intervention is structured round the completion of a Personal Recovery
10 Workbook with the following structured components:
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- 16 • Setting personal recovery goals
- 17 • Help with plans to re-establish community functioning and support networks following a
18 crisis
- 19 • Using the experience of recent crisis to identify early warning signs and an action plan to
20 avoid or attenuate relapse
- 21 • Planning strategies and coping resources to maintain wellbeing once a crisis has abated

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25 Meetings take place weekly, with the aim of completing the programme of up to ten sessions within
26 three months. The peer support worker encourages the participant to consider involving friends and
27 family in the intervention, by showing them materials from the meetings, eliciting their help with
28 making crisis plans or inviting them to attend a meeting. Unless clinical staff identify any risks
29 necessitating that meetings should take place on NHS premises, they take place in the location
30 preferred by the participants, which can be their homes, an appropriate public space, or NHS
31 premises.
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37 38 *Peer support workers and their training*

39 Peer support workers have been recruited and employed by participating NHS Trusts for the study.
40 All are people who have themselves experienced mental health problems and used mental health
41 services, an agreed essential requirement for a mental health peer support worker^{33, 34}. We did not
42 require CRT use, as we were not aiming for a high level of matching of participant and peer support
43 worker experiences. More restrictive criteria might also have resulted in difficulty in prompt
44 recruitment of people with the required personal skills as well as experience. An introductory
45 programme of training has been arranged by the study team. This includes familiarising peer support
46 workers with the study workbook and how to support participants in using it. It also covers more
47 generic issues such as safety, confidentiality, appropriate self-disclosure, roles and boundaries,
48 engagement and listening skills and cultural sensitivity. Additional induction required by
49 participating NHS Trusts has also been attended by peer workers. An experienced peer support
50 worker from the study team additionally met each peer support team during the trial. A programme
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3 of group supervision has also been established by the peer workers, facilitated by clinicians from the
4 employing Trust. Peer support workers have been encouraged to use this additional supervision to
5 discuss general issues arising from using the Personal Recovery Workbook or from their role as a
6 peer supporter (not specific clinical concerns relating to participants, which go are addressed by
7 local NHS supervisors), and to discuss needs for any additional “top-up” training, to be provided as
8 required by the study team. Standard NHS Trust procedures are followed regarding confidentiality,
9 safety, and lone working for both peer support workers and researchers, including seeing service
10 users on NHS premises when there are safety concerns and checking researchers are safe following
11 all contacts.
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18 Control intervention

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20 In the control condition, participants are sent a Personal Recovery Workbook to complete by
21 themselves or with family and friends if they wish: this has the same content as in the Experimental
22 group.
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24

25 Discontinuation criteria

26
27 Participants may withdraw from the intervention at any time without giving a reason. The
28 intervention is also suspended if a participant becomes unwell to the extent that he or she no longer
29 has capacity to consent to continuing the sessions or the ability to cooperate with them.
30
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33 Monitoring adherence to the intervention

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

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

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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 Recovery³⁵ (QPR), a 22-item measure of self-rated recovery.
- b. *Self-management skills*, rated by score on the Illness Management and Recovery Scale-patient version³⁶ (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 Questionnaire³⁷ (CSQ) – an eight item measure of respondents' satisfaction with mental health services.
- d. *Symptom severity*, measured by the Brief Psychiatric Rating Scale³⁸ (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 Scale³⁹ (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 Scale⁴⁰ – a six item measure of social contact with family and friends.
- g. The EuroQol EQ-5D 3 level⁴¹ (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 Scale⁴² – 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 Index⁴³ (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 questionnaire⁴⁴ – a six-item measure of neighbourhood social capital.
- e. Audit-C⁴⁵ – a three item self-report screening measure of alcohol use.
- f. DAST-10⁴⁶ – 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 guidance⁴⁷. 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

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3 A sample size of 440 is required to detect a difference in admission rates during the follow-up period
4 of 50% in the control group versus 35% in the experimental group, with 80% power and 5%
5 significance. We have based group allocation on an initial allocation rate of 1: 1.37 prior to
6 adjustment for clustering, resulting in 159 in the intervention arm and 217 in the control arm. The
7 intervention arm is then inflated for clustering (peer support worker) using an intraclass correlation
8 coefficient of 0.03, after rounding this gives 220 participants in the intervention arm and 220
9 participants in the control arm (a total of 440 participants) from six Crisis Resolution Teams, all in
10 different NHS Trusts. Thus our initial allocation rate has been selected so as to result in equal
11 numbers following inflation for clustering, making trial randomisation logistically more
12 straightforward. An intraclass correlation coefficient is confirmed as a relatively conservative
13 estimate by a meta-analysis of therapist effects in low-intensity mental health interventions⁴⁸. It is
14 expected that on average, there will be at least four peer support workers within each Crisis
15 Resolution Team, with an average cluster size of 11. Of these 440 participants, 40 were recruited
16 during the internal pilot conducted in one Trust only to establish acceptability of our trial procedures
17 and feasibility of recruitment to a randomised controlled trial of the intervention. It was agreed by
18 the Trial Steering Committee and the study funders that changes to study procedures and to the
19 intervention following this internal pilot were sufficiently minimal (increased support for Peer
20 Support Workers; addition of measures of loneliness, social network, social capital and social
21 outcome) for the internal pilot sample to be included within the main study sample.
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34 **Recruitment strategies**

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

47 **Group allocation**

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52 Following baseline assessment, consenting clients are block randomised into treatment and control
53 groups, stratified by site. Randomisation is conducted by the study data officer or trial manager
54 using an independent randomisation service, "Sealed Envelope" commissioned by the Priment
55 Clinical Trials Unit. Once the data officer learns from "Sealed Envelope" which group participants
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3 have been allocated to, and once the participant has been discharged from the Crisis Resolution
4 Team, the data officer contacts participants to let them know and, for those in the treatment group,
5 to confirm arrangements that a peer support worker will contact them.
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7

8 **Blinding**

9
10
11 It is not feasible to blind participants to whether they are allocated to the treatment or control
12 group. Data for the study's primary outcome (readmission to acute care during the follow-up period)
13 is provided by administrators from participating NHS Trusts, who are not informed by researchers of
14 participants' treatment allocation. The study data officer or trial manager conducts randomisation,
15 and informs the CRT which treatment group each participant has been allocated to. To avoid
16 discharge plans being influenced by the availability of a peer support, we delay disclosing group
17 allocation until the point of CRT discharge. Blinding of other clinicians involved in care following
18 discharge is not feasible as Trust clinical procedures require peer support workers to record visits in
19 electronic records. The data officer, or sometimes in their absence the trial manager, also conducts
20 the section of the follow-up interview with participants in the treatment group which relates to their
21 experience of the intervention. Study researchers, blind to participants' allocation status, conduct
22 the 4-month and 18-month follow-up interviews. Maintaining blinding of researchers is not likely to
23 be achieved in full for secondary outcomes collected during a follow-up interview, as it is likely some
24 participants may disclose in the course of the follow-up interview whether they have received the
25 peer supported programme. Researchers seek to minimise this by prompting participants not to
26 disclose which trial group they were in, both when setting up interviews and during the interview
27 itself. Data will be analysed blind to allocation with the exception of the RPRS, which will be analysed
28 after the analyses of other outcomes have been checked and agreed.
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43 **METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS**

44 **Data collection**

45 **Baseline interviews**

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48 Once written consent to participate in the study has been obtained, but before participants are
49 randomly allocated to intervention or control groups, a study researcher completes the study
50 baseline measures with all participants as a structured interview. This interview takes about one
51 hour to complete. It may take place at the participant's home, NHS or university premises, as the
52 participant prefers within any limits advised by CRT clinicians during the recruitment process.
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3 Following completion, participants are offered a £20 gift of cash to acknowledge their time and help
4 with the study.
5

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7 Follow up interviews at 4 and 18 months

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9 At these time points, researchers contact participants again using their preferred contact details.
10 They remind participants of the study details, and ask if they are willing to meet to complete the
11 follow-up. If so, the researcher sends another copy of the study information sheet and arranges a
12 time and place to meet. At this meeting, the researcher again seeks written informed consent from
13 the participant to complete the follow up research interview, and completes an interview if this is
14 obtained. If for any reason (for example a move to a distant part of the country) a participant is
15 willing but a face to face interview is not feasible, a phone interview is offered, but the BPRS not
16 completed as this depends on observer ratings.
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21
22 Data from patient records

23
24 Once all participants from a participating NHS Trust have been recruited into the study, a study
25 researcher contacts the appropriate administrators or informatics team within the Trust regarding
26 collection of data from patient records. The study researchers provide a list of consenting
27 participants' names, dates of birth and study identification numbers and a standardised schedule of
28 the information required for each patient, with the time period for which data is needed clearly
29 specified. Administrators are then be asked to provide the data to the research team, identifying
30 each patient by study ID number only to avoid data protection risks from transferring identifiable
31 patient data.
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38 One year after all participants from a participating NHS Trust have been recruited into the study (six
39 months and one year for the pilot trial), a study researcher again contacts the Trust's administrators
40 to collect outcomes data, using similar procedures to those described above.
41
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43 **Minimising loss to follow-up**

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46 Primary outcome

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48 Research Ethics Committee approval allows data on the primary outcome to be collected even if
49 participants are lost to follow-up, minimising missing values on this measure. If service use data
50 relating to the primary study outcome are not available through Trust patient records, study
51 researchers will attempt to collect these data from other NHS Trust or GP records or the participant,
52 in accordance with the written consent provided by the participant.
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56 Follow-up interviews
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3 Response rate is maximised by making at least 3 attempts to contact each participant, and by
4 obtaining multiple contact details (e.g. email, landline, mobile phone, a close relative's phone) at the
5 time of the baseline to maximise the likelihood of making contact. A £20 honorarium is offered at
6 each interview to thank participants for their time and effort.
7
8

9 10 **Data entry and management**

11
12 All data recorded on paper forms are stored securely (in locked cabinets in locked offices) on
13 university sites in accordance with university data protection procedures. Data collection forms
14 identify participants only by their study ID. Participant consent forms, contact details and a single
15 master copy linking participants' names and IDs are held separately from other data.
16
17

18
19 Data are entered using a web based system set up by Sealed Envelope. This has been set up so that,
20 it mirrors the data collection sheets in order. It also has range checks, consistency checks and for
21 closed questions gives a number of options plus "other" where appropriate. Assessors who enter
22 data have no access to the group allocation through this system.
23
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25
26 With the checks in place, there should not be any issues with illegal values being entered or
27 inconsistent data being entered so necessary cleaning should be minimal. However, data are
28 checked by the Statistician before analysis and any problems reported to the Assistant/ Trial
29 Manager, who rectifies them as appropriate before data analysis.
30
31
32

33 **Data analysis**

34 35 36 37 General principles

38
39 The assumptions underpinning each statistical method will be checked. For example, normality and
40 equality of variances will be checked for t-tests. The use of transformations or non-parametric
41 methods will be considered if assumptions do not hold. Adjusted analyses will be performed if
42 baseline imbalances are observed. The impact of missing data will be explored in all analyses.
43 Supportive analyses will be performed if non-compliance is considered to be a problem.
44
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48 *The primary analyses will be complete case. All analyses will be performed according to the original*
49 *assigned randomisation groups. Data will be analysed using Stata.* Descriptive statistics

50
51 Initial analyses will look at summary statistics for all variables, both overall and by randomised
52 group. Summary statistics for continuous variables will be mean, median, SD, lower quartile, upper
53 quartile, minimum and maximum. These variables will also be plotted to check their distribution. If
54 variables are skewed, then median and interquartile ranges will be reported, otherwise mean and
55 standard deviation will be reported. Summary statistics for categorical variables will be frequency
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3 and percentage within each category. No statistical significance tests for baseline characteristics by
4 randomised group will be performed, but balance will be assessed visually.
5
6

7 Primary Outcomes

8 Data on readmission during the study period will be analysed using logistic regression with random
9 intercepts, with clustering by peer support worker being modelled using random effects. Those in
10 the control group will be considered to be clusters of size one for analysis purposes. Condition
11 (psychosis versus no psychosis) and centre will be entered into the model as fixed effects. This
12 analysis will be reported in terms of an odds ratio and 95% confidence interval.
13
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17 Secondary Outcomes

18 For the analysis of the scales, linear regression with random intercepts will be utilised (with peer
19 support worker as the random effect), controlling for the baseline value of the outcome, condition
20 (psychosis versus no psychosis) and centre. These will be reported in terms of mean difference in
21 outcome between the two randomised groups with associated 95% confidence intervals.
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26 To assess the total days spent in acute care, we will perform Poisson regression analysis with
27 random intercepts, with the peer support worker being entered as a random effect. Centre will be
28 entered into the model as a fixed effect. This analysis will be reported as coefficient and 95%
29 confidence interval.
30
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33 Time to first readmission during the study period will be analysed using Cox regression frailty model.
34 However, if the frailty model fails to converge, then Cox regression with robust standard errors will
35 be used. The condition (psychosis versus no psychosis) and centre will be added as fixed effects.
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41 Supportive analyses

42 Conducted on the primary outcome, adjusting for any marked differences in randomised groups in
43 terms of demographic characteristics, service use in the year preceding entry to the study and scores
44 on outcome measures; amount of improvement for both groups between baseline and follow-up;
45 analyses of outcomes adjusting for non-compliant participants in the treatment group using a
46 dichotomous variable compliant is defined as three or more meetings attended; analyses adjusting
47 for whether peer support schemes were already established in the catchment area or newly
48 introduced for the study. Those in the treatment as usual group will be assigned to the same
49 category as those who are non-compliant in the intervention group.
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3 Participants attending fewer than three meetings with a peer support worker will be defined as non-
4 compliant. Non-compliance will be examined using Complier Average Causal Effect (CACE) analysis.
5
6 We will look at baseline predictors of attending fewer than three meetings using random effects
7
8 logistic regression (those in the intervention group only).
9

10 11 12 Process analysis

13 The following descriptive information will be provided about the content of the intervention and the
14 degree of match between the peer support workers and the participants. The following variables
15 will be reported:
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17

18 19 *Use of the Personal Recovery Plan*

20 a) From participant data at follow up: the proportion of participants in the treatment and control
21 groups discussing or reading each of four sections of the recovery plan. A composite score of 0-4 will
22 be reported for overall extent of awareness of the recovery plan, combining participants' reports of
23 whether they had looked at each section of the workbook.
24

25 b) From participant data at follow-up: the proportion of participants in the treatment and control
26 groups making a written plan for each of four sections of the recovery plan. A composite score of 0-
27 4 will be reported for overall extent of development of a written recovery plan by combining
28 participants' reports of whether they had looked at each section of the workbook.
29

30 c) From a random sample of contact records provided by Peer Support Workers: we will report the
31 proportion of meetings at which: the recovery plan was discussed or a written plan developed, and
32 the frequency with which other informal or professional carers were involved.
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42 *Peer Support Workers' style*

43 The mean RPRS total and index scores (recovery promoting strategies, and core relationship) and
44 range of mean scores among Peer Support Workers will be reported.
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48 Degree of match between Peer Support Workers and participant

49 The proportion of participants who were matched with their Peer Support Workers will be reported
50 regarding:
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53 *Degree of match between peer support worker and participant*

54 The proportion of participants who were matched with their peer support worker will be reported
55 regarding:
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- 3 a) Diagnosis
- 4 b) Experience of hospital admission (ever admitted yes/ no)
- 5
- 6 c) Gender
- 7
- 8 d) Ethnicity
- 9
- 10 e) Age

11 In the event of positive study outcomes, an exploratory regression analysis will be conducted to
12 model the relationship of these process factors to study outcomes.
13

14 **Missing data**

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16 It is not expected that there will be much missing data for the primary outcomes, as these data will
17 come from the trust's informatics department. However, there may be missing data for other
18 outcomes. All items within a scale may be missing, or individual items within a given scale may be
19 missing. Some scales have recognised ways to impute missing items up to a given number of items,
20 which will be used as appropriate. The extent and patterns of missingness will be evaluated to
21 determine whether it is associated with any of the outcomes. If variables are associated with
22 missingness, these will be controlled for in complete case analysis to maintain the missing at random
23 assumption.
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31 **Analysis plan for the Economic Evaluation**

32 **Aim**

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34 The aim of the economic evaluation is to calculate the probability that peer-provided self-
35 management is cost-effective compared to control over 1 year for a range of values of willingness to
36 pay for a quality adjusted life year (QALY) gained. The cost perspective is in alignment with the
37 National Institute for Health and Care Excellence (NICE) Technology Assessment Guidance which
38 provides guidance on the implementation of new health care technologies in the English National
39 Health Service (NHS)
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45 **Outcomes**

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

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56 All analyses will follow the assumptions made in Part I regarding missing data, loss to follow up and
57 clustering. In line with the statistical analysis the primary economic evaluation will be a complete
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3 case analysis. Sensitivity analyses will be conducted accounting for loss to follow up and missing data
4 as described below (Sensitivity Analyses).
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10 *Cost of the intervention*

11 Information on peer support worker costs (salaries and oncosts) and time spent with patients on
12 peer support worker will be used to calculate the average cost per patient of the peer-provided self-
13 management intervention.
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20 *Cost of mental health service use*

21 Acute and community mental health service use for the intervention and control group will be
22 collected from electronic patient records held by the mental health trust at baseline and 1 year.
23 These will be costed for each patient using unit costs from the most recent Unit Costs of Health and
24 Social Care published by the Personal Social Services Research Unit⁷. Mean cost per patient at
25 baseline and 1 year for intervention and control groups will be reported by type of service use.
26
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29

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

42 We will calculate the mean cost per quality adjusted life year (QALY) gained of peer-provided self-
43 management compared to control over 1 year. QALYs will be calculated using the EQ-5D-3L and the
44 formula developed by Dolan and colleagues⁴⁹. We will calculate the mean area under the curve for
45 each group from baseline to 4 months, controlling for any baseline differences using regression
46 analysis⁵⁰. Confidence intervals will be constructed using non-parametric bootstrapping. To calculate
47 QALYs over 1 year, we will assume both groups have a linear return to their patient specific baseline
48 EQ-5D at 1 year, unless they have had an acute readmission. Patients with an acute readmission
49 between 4 months and 1 year will have a QALY decrement attributed calculated using regression
50 analysis and 4 month patient data.
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3 Baseline, 4 month and 18 month EQ-5D-3L responses will be used to calculate QALYs over 18
4 months. This will also be calculated as area under the curve adjusting for baseline (Hunter et al
5 2015).
6
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8 *Confidence intervals*

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10 95% confidence intervals for mean costs and QALYs will be calculated using non-parametric
11 bootstrap with replacement.
12

13 *Incremental cost-effectiveness ratio (ICER)*

14
15 The mean costs and QALYs calculated above will be used to calculate the mean incremental cost per
16 QALY gained of peer-provided self-management compared to control at 1 year using 1 year
17 modelled QALYs and 1 year costs. An 18 month ICER will be calculated using 18 month QALY data
18 and 18 month modelled cost data.
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23 *Cost-effectiveness plane (CEP) and cost-effectiveness acceptability curve (CEAC)*

24
25 The results of the non-parametric bootstrap will be presented on a CEP. A CEAC will also be
26 constructed using the bootstrap data from a range of values of willingness to pay for a QALY gained.
27 The probability that the peer-provided self-management is cost-effective compared to control at a
28 willingness to pay for a QALY gained of £20,000 will be reported.
29
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31

32 *Supportive Analyses*

33
34 The following sensitivity analyses will be conducted and the new ICER and CEAC reported:

- 35 • Cost-effectiveness complete case analysis at 4 months.
- 36 • Housing, employment and GP contacts are recorded at baseline and 4 months only. No other
37 health care contacts or societal costs were collected so as to minimise patient burden when
38 completing questionnaires. Two analyses will be conducted, one including employment and one
39 excluding employment, using the 4 month data only for the 3 variables, each costed using PSSRU
40 and assuming mean national values for wages.
- 41 • Testing the impact of a range of assumptions about QALYs over the 4-12 month period.
- 42 • Different values for the QALY decrement as a result of an inpatient admission.
- 43 • Any sub-group analyses identified including the ICER for different levels of engagement with the
44 peer-support worker in the intervention group, including CACE analysis.
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52 If any key assumptions become apparent during the analysis these will also be tested for as part of
53 the sensitivity analyses.
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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 month s	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.

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



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	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

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	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
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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

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6		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8-9
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9		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9
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11	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
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16	Participant	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
17	timeline			
18				
19	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
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22	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	11
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Methods: Assignment of interventions (for controlled trials)

Allocation:

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29	Sequence	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
30	generation			
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34	Allocation	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
35	concealment			
36	mechanism			
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38	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
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5	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
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8		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
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Methods: Data collection, management, and analysis

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14	Data collection	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
15	methods		12-13
16			
17		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
18			13-14
19			
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21	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
22			14
23			
24	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
25			14-19
26		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
27			15-16
28		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)
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Methods: Monitoring

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6	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
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11		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
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14	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
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17	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	20
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21	Ethics and dissemination			
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23	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20
24				
25				
26	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
27				
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29				
30	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	20
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33		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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35				
36	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
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6	Declaration of	28	Financial and other competing interests for principal investigators for the overall trial and each	21
7	interests		study site	
8				
9	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual	21
10			agreements that limit such access for investigators	
11				
12	Ancillary and post-	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm	N/A
13	trial care		from trial participation	
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16	Dissemination	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare	21
17	policy		professionals, the public, and other relevant groups (eg, via publication, reporting in results	
18			databases, or other data sharing arrangements), including any publication restrictions	
19				
20		31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
21				
22		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical	N/A
23			code	
24				
25				
26	Appendices			
27				
28	Informed consent	32	Model consent form and other related documentation given to participants and authorised	
29	materials		surrogates	
30				
31	Biological	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or	N/A
32	specimens		molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*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](https://creativecommons.org/licenses/by-nc-nd/3.0/)" 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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Manuscripts

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3 A randomised controlled trial of the clinical and cost-effectiveness of a peer delivered self-
4 management intervention to prevent relapse in crisis resolution team users: study protocol
5
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27 **Word Count: 7,656**

28 **ABSTRACT**

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

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

15
16 **Ethics and dissemination:** The CORE self-management trial was approved by the London Camden
17 and Islington Research Ethics Committee (REC ref: 12/LO/0988). A Trial Steering Committee and
18 Data Monitoring Committee oversee the progress of the study. We will report on the results of the
19 clinical trial, as well as on the characteristics of the participants and their associations with relapse.

20
21 **Trial Registration:** ISRCTN01027104 DOI 10.1186/ISRCTN01027104. Date registered: 11/10/12

22
23 **Keywords:** Peer support, self-management, crisis resolution teams, home treatment, relapse
24 prevention, randomised controlled trial

25
26 **Sponsor:** Camden and Islington NHS Foundation Trust (UK), Bloomsbury Building, St Pancras
27 Hospital, 4 St Pancras Way, London NW1 OPE

28 29 STRENGTHS AND LIMITATIONS OF THE STUDY

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- 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 feasible¹. 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 practice². 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 admissions⁴⁻⁸ 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 year¹⁷. Thus demand for acute care in England remains very high in the absence of interventions to reduce repeat use¹⁸. 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 care¹⁹.

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 illness¹⁴. 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

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3 improve outcomes for people following a mental health crisis²⁰. Hypothesised qualities of peer
4 workers include an ability to provide support and encouragement that is particularly warm and
5 empathic due to being rooted in personal experience, and provision of a role model for recovery²¹.
6 These qualities suggest that peer workers are a particularly appropriate choice for delivery of
7 programmes aimed at enhancing recovery and proactive behaviours and self-care to remain well.
8 North American trials of peer-provided self-management programmes such as the Wellness
9 Recovery Action Plan²² and the Recovery Workbook²³ report some promising outcomes for service
10 users, but their impact on admissions or relapse has not been assessed. Our goal in the current study
11 is to develop and test an intervention with a similar self-management focus for people leaving the
12 care of crisis teams, aiming to reduce their subsequent readmission rates and dependence on
13 services. The employment of peer support workers to deliver self-management support to service
14 users is becoming increasingly common within NHS services, promoted by initiatives such as the NHS
15 Confederation *Implementing Recovery through Organisational Change* project²⁴, but thus far the
16 effectiveness of such an intervention in reducing acute care readmission following a crisis has not to
17 our knowledge been tested.
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28 **Control intervention**

29 Specific interventions to prevent relapse and promote recovery following a crisis are not currently
30 routinely delivered in NHS settings: we are thus aiming to test whether investing in delivery of such
31 an intervention is more effective than just providing service users with a simple resource to help
32 them manage their mental health and recovery themselves. The control condition was therefore
33 treatment as usual from community mental health teams with participants also being sent the self-
34 management manual on which the experimental intervention was based. This manual gives details
35 of how to develop plans for relapse prevention and for setting recovery goals.
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42 **Hypotheses/Objectives**

- 44 1. The primary hypothesis to be tested is that service users receiving the experimental
45 intervention will be less likely to relapse (indicated by readmission to acute care) over one
46 year than those in the control intervention receiving treatment as usual enhanced by access
47 to a self-management manual. *The anticipated admission rates at 1 year follow-up on which
48 study power calculation was based were 50% for control and 35% for intervention.*
- 49 2. Secondary hypotheses are to test whether being in the experimental rather than the control
50 condition is associated with longer time to first admission to acute care and fewer days in
51 acute care over one year, and also in better perceived recovery and illness management;
52 greater satisfaction with services; fewer symptoms; less loneliness; enhanced social
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3 networks, and greater social inclusion at the 4 month and the 18 month follow-up interviews
4 than participants in the control condition.

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6 3. A further objective was to conduct a health economic evaluation to calculate the probability
7 that peer-provided self-management is cost-effective compared to control over 1 year for a
8 range of values of willingness to pay for a quality adjusted life year (QALY) gained. A
9 secondary analysis will calculate cost per QALY gained over 18 months.
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13 A planned secondary use of the data is to investigate a set of hypotheses regarding loneliness,
14 social isolation and social capital and outcomes following a crisis: these will be separately
15 reported and disseminated.
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18 19 **Trial Design**

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21 The CORE (CRT Optimisation and Relapse Prevention) trial of a peer-provided self-management
22 intervention is a rater-blind, randomised controlled superiority trial with two parallel arms
23 (allocation ratio 1:1), designed to test the hypotheses above. The trial is powered on the primary
24 outcome, with adjustment for clustering by peer support worker.
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29 30 31 **METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES**

32 33 **Setting**

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35 All participants are identified from the caseload of Crisis Resolution and Home Treatment Teams in
36 six NHS Trusts. Four are in London, one in the South East of England and one in the South-West.
37 Areas include inner city, suburban, mixed and rural catchment areas. All the Crisis Resolution and
38 Home Treatment Teams aim to operate according to the standard NHS model. All teams are
39 contactable 24 hours a day and see service users primarily in their homes, offering short term care
40 during the crisis before discharge to other secondary or primary care services as appropriate for
41 further management. Structured self-management interventions are not widely implemented in
42 these catchment areas²⁵, so that both control and experimental arms are receiving an additional
43 intervention. A list of participating sites is available from the authors.
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51 52 **Eligibility criteria**

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54 Inclusion criteria
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- 3 1. On the caseload for at least a week of one of the participating CRTs because of a mental
- 4 health crisis (including both participants treated only by the CRT during the crisis and those
- 5 initially admitted to hospital or a crisis house and then discharged to the CRT).
- 6
- 7
- 8 2. Capacity and willingness to give informed consent to participate in the study.
- 9
- 10 3. Consented to enter the trial within a month of discharge from the CRT.

11 Exclusion criteria

- 12
- 13 1. People presenting such a high risk to others that the CRT judged that it would be unsafe for
- 14 peer support workers to meet with them even in a mental health service setting.
- 15
- 16 2. People who are discharged to addresses outside the catchment area.
- 17
- 18 3. People who cannot understand the intervention when delivered in English.
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21 Criteria were deliberately broad in order to reach conclusions generalizable to the full range of CRT
22 users. With this aim of achieving broad representativeness of CRT service users, we also set a
23 threshold at each study site of at least 50% of participants to be identified at screening as having
24 schizophrenia or other psychosis, or bipolar disorder. Within this stipulation, participation has been
25 offered to all eligible service users in participating Crisis Resolution Teams until the recruitment
26 target for the service has been reached.
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31 Interventions

32 Experimental group intervention

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36 The peer-provided self-management intervention tested in the study has been adapted from
37 recovery resources compiled by Dr Rachel Perkins, Dr Julie Repper and colleagues at South West
38 London and St Georges NHS Foundation Trust²⁶, specifically their Personal Recovery Plan. This was in
39 turn informed by self-management resources such as the Wellness Recovery Action Plan²² and
40 relapse prevention interventions²⁷.
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45 *Selection and development of the intervention*

46 The intervention was adapted and selected via the following stages, more fully described in a
47 companion paper:
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- 50 (a) **Initial searches:** Systematic literature searches were carried out to find relevant literature on
51 self-management interventions for people with mental health problems, and on peer
52 support interventions²⁸. A literature and internet search was also carried out and key
53 experts consulted to identify relevant resources for self-management interventions.
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3 (b) **Individual interviews to inform intervention selection:** In individual interviews with 41
4 consenting service users, their views were explored of the types of intervention that would
5 be feasible and useful following a crisis, how they should be offered and delivered, and the
6 potential benefits and risks of having a peer worker deliver the interventions. These
7 interviews were carried out by service user researchers, and were also used to elicit data
8 relevant to the other Workstream included in the CORE study, involving development and
9 testing of an intervention to improve CRT fidelity²⁹.
10
11 (c) **Stakeholder focus groups and adaptation of the intervention:** Informed by this work, the
12 Personal Recovery Plan^{30, 31} was identified by the study team and advisory groups of service
13 users and carers, and of clinicians, involved in the study as the most promising basis for the
14 study intervention. A series of stakeholder focus groups was then convened for discussion of
15 how to fit this intervention within existing care pathways. The groups usually comprised 6 to
16 8 participants. Twelve groups of consenting participants were convened in all; five of people
17 with experience of using crisis services, five of CRT staff and two of carers with experience of
18 crisis services. Following this step, the Personal Recovery Plan was adapted with the
19 permission of its authors and under licence from the copyright holders, South West London
20 and St George's Mental Health Trust, to fit the context of the trial, including adaptations to
21 make it as relevant as possible to people who have recently experienced a crisis. A protocol
22 was also developed for peer support worker training, and for delivery of the intervention in
23 the context of the trial.
24
25 (d) **Feasibility study:** Following this, an uncontrolled feasibility study was conducted to test the
26 feasibility and acceptability of the intervention. Four peer support workers were given a
27 four-day training in fundamentals of delivery peer support and in the delivery of our draft
28 self-management intervention: an abbreviated and tailored version of the Nottingham
29 Institute of Mental Health's accredited peer support worker training. Eleven participants
30 were recruited from an inner city CRT, and gave informed consent to receive the
31 intervention over 10 sessions. Following the intervention period, a group interview was
32 conducted with the Peer Support Workers and individual interviews with the service user
33 participants (n=9). Experiences of the intervention and suggestions for adaptation were
34 explored and further minor modifications introduced throughout the intervention.
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Delivery of the intervention

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54 The intervention is delivered in a series of up to ten sessions with a peer support worker. Each trial
55 participant is allocated to one peer support worker. If participants specifically requested a peer
56 support worker of their own gender, this is arranged, but no attempt beyond this is made to match
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3 peer support workers and participants. There is no consensus in the literature³² on whether, and on
4 the basis of which characteristics, peer support workers and clients need to be matched. In practice,
5 with three peer support workers available in each CRT, we anticipated being unable to match on
6 many characteristics, and felt that attempting to do so may restrict generalisability to routine NHS
7 settings, where matching is often not feasible. The peer support worker offers sympathetic listening
8 and seeks to instil hope through appropriate sharing of skills and coping strategies acquired in their
9 own recovery journey. The intervention is structured round the completion of a Personal Recovery
10 Workbook with the following structured components:
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- 16 • Setting personal recovery goals
- 17 • Help with plans to re-establish community functioning and support networks following a
18 crisis
- 19 • Using the experience of recent crisis to identify early warning signs and an action plan to
20 avoid or attenuate relapse
- 21 • Planning strategies and coping resources to maintain wellbeing once a crisis has abated
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26 Meetings take place weekly, with the aim of completing the programme of up to ten sessions within
27 three months. The peer support worker encourages the participant to consider involving friends and
28 family in the intervention, by showing them materials from the meetings, eliciting their help with
29 making crisis plans or inviting them to attend a meeting. Unless clinical staff identify any risks
30 necessitating that meetings should take place on NHS premises, they take place in the location
31 preferred by the participants, which can be their homes, an appropriate public space, or NHS
32 premises.
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38 *Peer support workers and their training*

39 Peer support workers have been recruited and employed by participating NHS Trusts for the study.
40 All are people who have themselves experienced mental health problems and used mental health
41 services, an agreed essential requirement for a mental health peer support worker^{33, 34}. We did not
42 require CRT use, as we were not aiming for a high level of matching of participant and peer support
43 worker experiences. More restrictive criteria might also have resulted in difficulty in prompt
44 recruitment of people with the required personal skills as well as experience. An introductory
45 programme of training has been arranged by the study team. This includes familiarising peer support
46 workers with the study workbook and how to support participants in using it. It also covers more
47 generic issues such as safety, confidentiality, appropriate self-disclosure, roles and boundaries,
48 engagement and listening skills and cultural sensitivity. Additional induction required by
49 participating NHS Trusts has also been attended by peer workers. An experienced peer support
50 worker from the study team additionally met each peer support team during the trial. A programme
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3 of group supervision has also been established by the peer workers, facilitated by clinicians from the
4 employing Trust. Peer support workers have been encouraged to use this additional supervision to
5 discuss general issues arising from using the Personal Recovery Workbook or from their role as a
6 peer supporter (not specific clinical concerns relating to participants, which go are addressed by
7 local NHS supervisors), and to discuss needs for any additional “top-up” training, to be provided as
8 required by the study team. Standard NHS Trust procedures are followed regarding confidentiality,
9 safety, and lone working for both peer support workers and researchers, including seeing service
10 users on NHS premises when there are safety concerns and checking researchers are safe following
11 all contacts.
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18 Control intervention

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20 In the control condition, participants are sent a Personal Recovery Workbook to complete by
21 themselves or with family and friends if they wish: this has the same content as in the Experimental
22 group.
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25 Discontinuation criteria

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

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

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

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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 Recovery³⁵ (QPR), a 22-item measure of self-rated recovery.
- b. *Self-management skills*, rated by score on the Illness Management and Recovery Scale-patient version³⁶ (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 Questionnaire³⁷ (CSQ) – an eight item measure of respondents' satisfaction with mental health services.
- d. *Symptom severity*, measured by the Brief Psychiatric Rating Scale³⁸ (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 Scale³⁹ (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 Scale⁴⁰ – a six item measure of social contact with family and friends.
- g. The EuroQol EQ-5D 3 level⁴¹ (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 Scale⁴² – a 24-item patient-report measure of general

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3 therapeutic alliance and specific recovery orientation of health service providers. This is
4 administered by following the initial interview.
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7 Further measures used to characterise the sample and to adjust in secondary analysis for variables
8 known to be associated with the primary outcome include:
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- 10 a. Socio-demographic and clinical data (including age, gender, ethnicity, accommodation and living
11 situation, employment status, educational attainment and past service use, including admissions
12 and compulsory admissions).
 - 13 b. Clinical diagnosis as recorded on electronic records using the ICD10 classification.
 - 14 c. The Social Outcomes Index⁴³ (SIX) as a measure of social circumstances: this four-item measure
15 includes questions on employment, accommodation and social contact.
 - 16 d. The Health and Lifestyles Survey social capital questionnaire⁴⁴ – a six-item measure of
17 neighbourhood social capital.
 - 18 e. Audit-C⁴⁵ – a three item self-report screening measure of alcohol use.
 - 19 f. DAST-10⁴⁶ – a ten item self-report screening measure of drug use.
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30 **Participant timeline**

31 **Table 1 about here**

32 This is summarised in Table 1. Potential participants are approached by CRT staff initially just prior to
33 or just after discharge from the team. Clinicians make an initial assessment of capacity to give
34 informed consent to enter the trial; they approach only those whom they consider to have such
35 capacity. Researchers then contact those who give permission to be approached, and further assess
36 capacity, following Royal College of Nursing guidance⁴⁷. For eligible participants who have given
37 informed consent, baseline interviews including all the above measures take place as soon as
38 possible, with a maximum of one month after CRT discharge for entry to the trial. Randomisation
39 (see below) follows baseline interviews, after which participants randomised to the control group
40 are allocated a peer support worker to begin the three month intervention. All participants are
41 contacted at 4 months following entry to the study for an initial follow-up interview. Data on the
42 primary outcome is collected from clinical records at one year, and participants are contacted 18
43 months following randomisation for a final follow-up interview with the measures above.
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55 **Sample size**

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3 A sample size of 440 is required to detect a difference in admission rates during the follow-up period
4 of 50% in the control group versus 35% in the experimental group, with 80% power and 5%
5 significance. We have based group allocation on an initial allocation rate of 1: 1.37 prior to
6 adjustment for clustering, resulting in 159 in the intervention arm and 217 in the control arm. The
7 intervention arm is then inflated for clustering (peer support worker) using an intraclass correlation
8 coefficient of 0.03, after rounding this gives 220 participants in the intervention arm and 220
9 participants in the control arm (a total of 440 participants) from six Crisis Resolution Teams, all in
10 different NHS Trusts. Thus our initial allocation rate has been selected so as to result in equal
11 numbers following inflation for clustering, making trial randomisation logistically more
12 straightforward. An intraclass correlation coefficient is confirmed as a relatively conservative
13 estimate by a meta-analysis of therapist effects in low-intensity mental health interventions⁴⁸. It is
14 expected that on average, there will be at least four peer support workers within each Crisis
15 Resolution Team, with an average cluster size of 11. Of these 440 participants, 40 were recruited
16 during the internal pilot conducted in one Trust only to establish acceptability of our trial procedures
17 and feasibility of recruitment to a randomised controlled trial of the intervention. It was agreed by
18 the Trial Steering Committee and the study funders that changes to study procedures and to the
19 intervention following this internal pilot were sufficiently minimal (increased support for Peer
20 Support Workers; addition of measures of loneliness, social network, social capital and social
21 outcome) for the internal pilot sample to be included within the main study sample.
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34 **Recruitment strategies**

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

47 **Group allocation**

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

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

44 **Data collection**

45 **Baseline interviews**

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48 Once written consent to participate in the study has been obtained, but before participants are
49 randomly allocated to intervention or control groups, a study researcher completes the study
50 baseline measures with all participants as a structured interview. This interview takes about one
51 hour to complete. It may take place at the participant's home, NHS or university premises, as the
52 participant prefers within any limits advised by CRT clinicians during the recruitment process.
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3 Following completion, participants are offered a £20 gift of cash to acknowledge their time and help
4 with the study.
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7 Researchers were given specific training in using the BPRS outcome measure, which unlike other
8 study outcome measures, is not participant self-report, but requires the researcher to rate
9 symptoms in 24 domains, based on a structured interview. Training was delivered by the Trial
10 Manager and the Principal Research Clinician on the study: it involved guidance and practice at
11 interviewing and rating subjects using role play and videos of clinical interviews. Researchers'
12 practice ratings were assessed against agreed correct ratings, and further training provided in the
13 event of unreliable scoring.
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19 Follow up interviews at 4 and 18 months

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

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37 Once all participants from a participating NHS Trust have been recruited into the study, a study
38 researcher contacts the appropriate administrators or informatics team within the Trust regarding
39 collection of data from patient records. The study researchers provide a list of consenting
40 participants' names, dates of birth and study identification numbers and a standardised schedule of
41 the information required for each patient, with the time period for which data is needed clearly
42 specified. Administrators are then be asked to provide the data to the research team, identifying
43 each patient by study ID number only to avoid data protection risks from transferring identifiable
44 patient data.
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50 One year after all participants from a participating NHS Trust have been recruited into the study (six
51 months and one year for the pilot trial), a study researcher again contacts the Trust's administrators
52 to collect outcomes data, using similar procedures to those described above.
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56 **Minimising loss to follow-up**
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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.

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3 The primary analyses will be complete case. All analyses will be performed according to the original
4 assigned randomisation groups. Data will be analysed using Stata. Descriptive statistics
5
6 Initial analyses will look at summary statistics for all variables, both overall and by randomised
7
8 group. Summary statistics for continuous variables will be mean, median, SD, lower quartile, upper
9
10 quartile, minimum and maximum. These variables will also be plotted to check their distribution. If
11
12 variables are skewed, then median and interquartile ranges will be reported, otherwise mean and
13
14 standard deviation will be reported. Summary statistics for categorical variables will be frequency
15
16 and percentage within each category. No statistical significance tests for baseline characteristics by
17
18 randomised group will be performed, but balance will be assessed visually.

18 Primary Outcomes

19
20 Data on readmission during the study period will be analysed using logistic regression with random
21
22 intercepts, with clustering by peer support worker being modelled using random effects. Those in
23
24 the control group will be considered to be clusters of size one for analysis purposes. Condition
25
26 (psychosis versus no psychosis) and centre will be entered into the model as fixed effects. This
27
28 analysis will be reported in terms of an odds ratio and 95% confidence interval.

29 Secondary Outcomes

30
31 For the analysis of the scales, linear regression with random intercepts will be utilised (with peer
32
33 support worker as the random effect), controlling for the baseline value of the outcome, condition
34
35 (psychosis versus no psychosis) and centre. These will be reported in terms of mean difference in
36
37 outcome between the two randomised groups with associated 95% confidence intervals.

38
39 To assess the total days spent in acute care, we will perform Poisson regression analysis with
40
41 random intercepts, with the peer support worker being entered as a random effect. Centre will be
42
43 entered into the model as a fixed effect. This analysis will be reported as coefficient and 95%
44
45 confidence interval.

46
47 Time to first readmission during the study period will be analysed using Cox regression frailty model.
48
49 However, if the frailty model fails to converge, then Cox regression with robust standard errors will
50
51 be used. The condition (psychosis versus no psychosis) and centre will be added as fixed effects.

52 Supportive analyses

53
54 Conducted on the primary outcome, adjusting for any marked differences in randomised groups in
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56 terms of demographic characteristics, service use in the year preceding entry to the study and scores
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58 on outcome measures; amount of improvement for both groups between baseline and follow-up;
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3 analyses of outcomes adjusting for non-compliant participants in the treatment group using a
4 dichotomous variable compliant is defined as three or more meetings attended; analyses adjusting
5 for whether peer support schemes were already established in the catchment area or newly
6 introduced for the study. Those in the treatment as usual group will be assigned to the same
7 category as those who are non-compliant in the intervention group.
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11 Participants attending fewer than three meetings with a peer support worker will be defined as non-
12 compliant. Non-compliance will be examined using Complier Average Causal Effect (CACE) analysis.
13 We will look at baseline predictors of attending fewer than three meetings using random effects
14 logistic regression (those in the intervention group only).
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20 21 Process analysis

22 The following descriptive information will be provided about the content of the intervention and the
23 degree of match between the peer support workers and the participants. The following variables
24 will be reported:
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28 *Use of the Personal Recovery Plan*

- 29
30 a) From participant data at follow up: the proportion of participants in the treatment and control
31 groups discussing or reading each of four sections of the recovery plan. A composite score of 0-4 will
32 be reported for overall extent of awareness of the recovery plan, combining participants' reports of
33 whether they had looked at each section of the workbook.
34
35 b) From participant data at follow-up: the proportion of participants in the treatment and control
36 groups making a written plan for each of four sections of the recovery plan. A composite score of 0-
37 4 will be reported for overall extent of development of a written recovery plan by combining
38 participants' reports of whether they had looked at each section of the workbook.
39
40 c) From a random sample of contact records provided by Peer Support Workers: we will report the
41 proportion of meetings at which: the recovery plan was discussed or a written plan developed, and
42 the frequency with which other informal or professional carers were involved.
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51 *Peer Support Workers' style*

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53 The mean RPRS total and index scores (recovery promoting strategies, and core relationship) and
54 range of mean scores among Peer Support Workers will be reported.
55
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57 Degree of match between Peer Support Workers and participant
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3 The proportion of participants who were matched with their Peer Support Workers will be reported
4 regarding:

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7 *Degree of match between peer support worker and participant*

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

- 11
12 a) Diagnosis
13 b) Experience of hospital admission (ever admitted yes/ no)
14 c) Gender
15 d) Ethnicity
16
17 e) Age
18
19

20 In the event of positive study outcomes, an exploratory regression analysis will be conducted to
21 model the relationship of these process factors to study outcomes.
22

23
24 **Missing data**

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26 It is not expected that there will be much missing data for the primary outcomes, as these data will
27 come from the trust's informatics department. However, there may be missing data for other
28 outcomes. All items within a scale may be missing, or individual items within a given scale may be
29 missing. Some scales have recognised ways to impute missing items up to a given number of items,
30 which will be used as appropriate. The extent and patterns of missingness will be evaluated to
31 determine whether it is associated with any of the outcomes. If variables are associated with
32 missingness, these will be controlled for in complete case analysis to maintain the missing at random
33 assumption.
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41 **Analysis plan for the Economic Evaluation**

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43 **Aim**

44 The aim of the economic evaluation is to calculate the probability that peer-provided self-
45 management is cost-effective compared to control over 1 year for a range of values of willingness to
46 pay for a quality adjusted life year (QALY) gained. The cost perspective is in alignment with the
47 National Institute for Health and Care Excellence (NICE) Technology Assessment Guidance which
48 provides guidance on the implementation of new health care technologies in the English National
49 Health Service (NHS)
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55 **Outcomes**

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57 • Mental health service use (community and acute services) during one year follow up period.
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- 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 Unit⁷. 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 colleagues⁴⁹. We will calculate the mean area under the curve for

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3 each group from baseline to 4 months, controlling for any baseline differences using regression
4 analysis⁵⁰. Confidence intervals will be constructed using non-parametric bootstrapping. To calculate
5 QALYs over 1 year, we will assume both groups have a linear return to their patient specific baseline
6 EQ-5D at 1 year, unless they have had an acute readmission. Patients with an acute readmission
7 between 4 months and 1 year will have a QALY decrement attributed calculated using regression
8 analysis and 4 month patient data.
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13 Baseline, 4 month and 18 month EQ-5D-3L responses will be used to calculate QALYs over 18
14 months. This will also be calculated as area under the curve adjusting for baseline (Hunter et al
15 2015).
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17

18 19 *Confidence intervals*

20 95% confidence intervals for mean costs and QALYs will be calculated using non-parametric
21 bootstrap with replacement.
22
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24 25 *Incremental cost-effectiveness ratio (ICER)*

26 The mean costs and QALYs calculated above will be used to calculate the mean incremental cost per
27 QALY gained of peer-provided self-management compared to control at 1 year using 1 year
28 modelled QALYs and 1 year costs. An 18 month ICER will be calculated using 18 month QALY data
29 and 18 month modelled cost data.
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33 34 *Cost-effectiveness plane (CEP) and cost-effectiveness acceptability curve (CEAC)*

35 The results of the non-parametric bootstrap will be presented on a CEP. A CEAC will also be
36 constructed using the bootstrap data from a range of values of willingness to pay for a QALY gained.
37 The probability that the peer-provided self-management is cost-effective compared to control at a
38 willingness to pay for a QALY gained of £20,000 will be reported.
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43 44 *Supportive Analyses*

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

- 46 • Cost-effectiveness complete case analysis at 4 months.
- 47 • Housing, employment and GP contacts are recorded at baseline and 4 months only. No other
48 health care contacts or societal costs were collected so as to minimise patient burden when
49 completing questionnaires. Two analyses will be conducted, one including employment and one
50 excluding employment, using the 4 month data only for the 3 variables, each costed using PSSRU
51 and assuming mean national values for wages.
- 52 • Testing the impact of a range of assumptions about QALYs over the 4-12 month period.
- 53 • Different values for the QALY decrement as a result of an inpatient admission.
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- 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 chairs the DMC; a non-clinical social scientist and a statistician. The DMC is independent of the sponsor; it has no competing interests. Minutes and recommendations from DMC meetings 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

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3 The trial sponsor regularly audits a sample of their sponsored trials, including inspection of processes
4 and procedures for storing data.
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7 **Ethics and dissemination**

8 9 Ethical approval

10 Ethical approval has been obtained from the London Camden and Islington Research Ethics
11 Committee (REC ref: 12/LO/0988), who have approved all amendments to protocol. The main
12 substantial amendment since the study was originally approved has been the addition of a follow-up
13 interview at 18 months (also approved by the Research Ethics Committee). The current version of
14 the protocol is Version 5, which includes the additional 18-month follow up interview that was
15 added to the original study design. The version of the protocol in use during participant recruitment
16 was Version 3, 17/11/2013. The consent form used during participant recruitment was V2, 17/11/13.
17 An updated consent form used to reconfirm consent for 18-month follow up interviews was V4,
18 04/11/15. Both consent forms are included as supplementary files.
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28 Consent

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

51 All data recorded on paper forms will be stored securely at University College London or the
52 University of the West of England (for data collected by a study researcher based there) in
53 accordance with university data protection procedures. Data collection forms will identify
54 participants only by their study ID. Participant consent forms, contact details and a single master
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3 copy linking participants' names and IDs will be held separately from other data. All data will be held
4 in locked filing cabinets in locked offices within university buildings.
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7 An independent data management service (Sealed Envelope) commissioned by the Priment Clinical
8 Trials Unit will oversee the development and management of a secure database for all quantitative
9 study data. Participants will be identified only by a study identification number in the database. Data
10 will be entered by study researchers using secure log-ins. Once recruitment and data collection are
11 complete, the data management service will advise on arrangements for the study team to access
12 the data for analysis.
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18 Once data collection is complete, all paper forms will be transferred to University College London.
19 Data will be held securely by the study team for up to one year after the end of the study, then
20 archived securely in accordance with University College London data protection procedures.
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23 Dissemination

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

31 **Ethical approval**

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35 The trial received a favourable opinion from the London Camden and Islington Research Ethics
36 Committee (REC ref: 12/LO/0988F). Consent forms are in supplemental files 1 and 2.
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39 The following sites have approved the trial: Camden and Islington NHS Foundation Trust; Surrey and
40 Borders Partnership NHS Foundation Trust; North East London NHS Foundation Trust; South London
41 and Maudsley NHS Foundation Trust; West London Mental Health NHS Trust; Avon and Wiltshire
42 Mental Health Partnership NHS Trust
43
44
45

46 **Competing interests**

47
48 The authors have no relevant declarations of interest.
49
50

51 **Author's contributions**

52
53
54 The trial design was developed by SJ, BLE, DH, DO, SP, OM, RG, FN, TW, CH and NM. LM and GA
55 developed the statistical analysis plans and RH the economic analysis plan. AM has led on the
56 development of the intervention. SJ is the Chief Investigator, based at University College London and
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3 BLE the project manager. DO provided oversight as a triallist in the PRIMENT Clinical Trials Unit. All
4 authors have contributed and approved this manuscript.
5
6

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13 Scale and advice regarding its use.
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23 Applied Health Research and Care (CLAHRC) North Thames at Bart's Health NHS Trust. The views
24 expressed in this paper are those of the authors and not necessarily those of the NHS, the NIHR or
25 the Department of Health.
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31 Data sharing: We will make data available via the corresponding author with as few restrictions as
32 possible once the main study outputs are published.
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For peer review only

	-1	0	T1	T2	T3
	Enrolment Screening	Allocation Baseline & Randomisation	Follow- up 4 month s	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.

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.

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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

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 the 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.

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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		

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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)

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

Yes

No

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

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Name of participant

Date

Signature

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Name of researcher

Date

Signature

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	<u>1-2</u> N/A
Protocol version	3	Date and version identifier	1
Funding	4	Sources and types of financial, material, and other support	<u>24</u> 22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, <u>23-24</u>
	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	<u>24</u> 22

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6		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)	<u>21-23</u> 20-22
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12	Introduction			
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14	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
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16		6b	Explanation for choice of comparators	4
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18	Objectives	7	Specific objectives or hypotheses	4-5
19				
20	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
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24	Methods: Participants, interventions, and outcomes			
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26	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
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29	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)	<u>6, 8</u> 5-6
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32	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	<u>6-9, 29</u> 6-7
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35		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)	<u>9</u> 8
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38		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	<u>9</u> 8-9
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	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, 30-31 <u>9-10</u>
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, 30-31 <u>10-11</u>
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	<u>12-14</u>
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	<u>12-14</u>

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	<u>12-13</u>
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	<u>12-13</u>
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	<u>12-13</u>
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	<u>13-14</u>

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6 | 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a [1342](#)
7 participant's allocated intervention during the trial
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9 **Methods: Data collection, management, and analysis**

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11 | Data collection 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any [13-1412-13](#)
12 methods related processes to promote data quality (eg, duplicate measurements, training of assessors)
13 and a description of study instruments (eg, questionnaires, laboratory tests) along with their
14 reliability and validity, if known. Reference to where data collection forms can be found, if not in
15 the protocol. - [The structured interview schedule and scoring guidance provided to researchers](#)
16 [for using the BPRS are available from the corresponding author on request.](#)
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19 | 18b Plans to promote participant retention and complete follow-up, including list of any outcome data [14-1513-14](#)
20 to be collected for participants who discontinue or deviate from intervention protocols
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22 | Data management 19 Plans for data entry, coding, security, and storage, including any related processes to promote [1514](#)
23 data quality (eg, double data entry; range checks for data values). Reference to where details of
24 data management procedures can be found, if not in the protocol
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26 | Statistical methods 20a Statistical methods for analysing primary and secondary outcomes. Reference to where other [15-1614-19](#)
27 details of the statistical analysis plan can be found, if not in the protocol
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29 | 20b Methods for any additional analyses (eg, subgroup and adjusted analyses) [16-2115-16](#)
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31 | 20c Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis),
32 and any statistical methods to handle missing data (eg, multiple imputation) [17-18](#)
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35 **Methods: Monitoring**
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5		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	<u>2120</u>
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11			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
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14		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	<u>2120</u>
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16					
17		Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	<u>2220</u>
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21		Ethics and dissemination			
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23		Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	<u>2220</u>
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26		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)	<u>2220</u>
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30		Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	<u>2220</u>
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33			26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
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36		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	<u>22-2324</u>
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Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	2324
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	2324
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	2324
	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	<u>Included as supplementary files</u>
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](http://creativecommons.org/licenses/by-nc-nd/3.0/)" license