CORE Phase 3

Randomised Controlled Trial of a peer-provided, self-management intervention for people leaving CRT services

OPERATING PROCEDURES

1. Participant Recruitment

2. Data collection and management (including randomisation and blinding arrangements)

3. Safety monitoring and reporting

4. Peer support workers: recruitment, training and management

Version Control:

Current version: Version 3, FINAL

Previous version: Version 2, 08/12/13

Previous version: Version 1, 14/12/12

1. PARTICIPANT RECRUITMENT

Eligibility criteria

CRT service users will be eligible for inclusion in the trial if they have been on the caseload of a participating CRT for at least a week and have capacity to give written informed consent to the study. Exclusion criteria are:

a) People who in the view of the clinical team present such high risk to others, it would be unsafe for peer support workers or researchers to meet with them even in a mental health service setting.

c) People who are discharged to addresses outside the catchment area.

d) People who cannot understand the intervention when delivered in English.

CRT service users must consent to take part in the trial within one month of discharge from the CRT to remain eligible: one month after study discharge, service users become ineligible and should not be recruited.

The trial will aim to recruit at least 50% of participants with a psychosis or bipolar disorder, in order to ensure the trial population is broadly representative of CRT service users generally. Study researchers will note participants' categorisation as in the psychosis/bipolar group or not as advised by screening clinicians at each Trust. If fewer than half the sample recruited are in the psychosis/bipolar category, advice from the Trial management group will be sought.

Screening for potential participants

We will attempt to offer participation in the study to all eligible CRT service users. Study research assistants (RAs) will arrange regular times (2-3 times per week) to meet CRT staff nominated by the CRT manager to help with the study at the CRT base. Together, a study RA and CRT staff member will review a list of all current CRT service users to check their eligibility for inclusion in the study. The RA will keep a record of screened service users using the **CORE Phase 3 Screening Record (Appendix 1)**.

Following this screening process, the study RA will compile a list of eligible service users to be contacted, using the **CORE Phase 3 Potential Participants Contact Form (Appendix 2)**. This list of potential participants will be left with CRT staff at the CRT base as a list of service users for CRT staff to contact about participation in the study.

Contacting potential participants

First contact with eligible service users about participation in the study must be made by CRT staff. CRT staff will be asked to contact all eligible participants listed on the **CORE Phase 3 Potential Participants Contact Form (Appendix 2)**. Contact may be made in person, by phone or email as soon as possible once the eligibility of the service user has been established, whether or not the service user is still being supported by the CRT. Guidance for CRT staff about key information about the study to relay to service users is provided in the form **CORE Phase 3 Initial Contact with Potential Participants – Guidance for CRT staff (Appendix 3)**. CRT staff should then record whether or not potential participants agree to be contacted by a study researcher about possible participation in the study on the **CORE Phase 3 Potential Participants Contact Form (Appendix 2)** kept in the CRT base and in the service user's patient records.

The study RAs will check the **CORE Phase 3 Potential Participants Contact Form (Appendix 2)** regularly when visiting the CRT base and ask a CRT staff member helping with the study to complete a referral form, using the **CORE Phase 3 Potential Participant Referral Form (Appendix 4).**

Seeking informed consent

Once study RAs have received a referral form for a potential participant, the RA will contact the service user as soon as possible. In an initial phone conversation, the RA will:

a) Check the service user is still willing to consider participation in the study
b) Provide a brief summary of what participation in the study will involve
c) Answer any questions the service user has about the study and participation in it
d) Offer to send a study information sheet to the service user (by post or email)
e) **Either** arrange a time to meet the service user to discuss the study further and, if the service user wishes, take written consent to participate; **or** agree a time to contact the service user again to discuss participation once the information sheet has been received.

If the service user agrees to meet, at this meeting the study RA should:

a) Check if the service user has read and understood the information sheet
b) **If not:** offer the service user time to read the information sheet at the meeting and/or explain the contents of the information sheet fully to the service user; **if so:** reiterate key points from the information sheet (the extent and limits of confidentiality, the right to withdraw at any time, the randomisation process, the content of the study intervention) to check they have been understood

c) Ask if the service user has any questions and answer these fully
d) If at this point the service user is willing to participate in the study, the RA should ask them to read, then initial, sign and date the Participant Consent Form. (If the service user wants more time to think about whether to participate, the RA should agree a time to contact them again, or provide contact details for the service user to get in touch should they later decide they would like to participate.)
e) Once the participant has given written consent, the RA may conduct the baseline assessment interview at this meeting if the participant is willing (using the current, REC-approved interview schedule). If the participant prefers, the RA should arrange another time to complete the baseline assessment with the participant.
f) Once the baseline assessment interview has been completed, the RA should offer the participant a gift in cash of £20 to acknowledge their time and help with the study.
g) The RA should explain to the participant that another researcher will be in contact once the participant has been discharged from the CRTto let the participant know which trial group they have been allocated to.

If at any point during this process the service user decides they do not want to take part in the study, the RA should accept this without seeking further explanation. The RA should then notify the nominated CRT staff helping with the study that the service user has declined and ask them to record this in the service user's patient records.

When arranging to meet potential participants, RAs should adhere to any guidance about risk and limitations on meetings provided by CRT staff in the referral form. If visiting a participant at home, the RA should arrange to check in with a colleague following the interview. Camden and Islington NHS Foundation Trust lone worker policy should be followed in the event of any failure to check in.

Recording participation in the study

The RA should contact the Trial Manager as soon as possible once a participant has provided written consent and confirm with the Trial manager the participant's unique study ID number. A record linking participant's names and ID number should be made immediately using the **CORE Phase 3 Participant ID Masterfile (Appendix 5)**. This should be stored, with the original participant consent form and contact details securely and separately from all study data.

Once a participant has consented to take part in the study, the RA should also inform the manager and consultant psychiatrist from the CRT team from which they were recruited and the participant's GP, using the standard letters approved by the Research Ethics Committee, accompanied by a copy of the participant's consent form. The RA should ask the CRT manager to ensure copies of the letter and consent form are stored in the participant's electronic patient record. The RA should record that they have sent copies of the consent form to the CRT and to the GP using the **CORE Phase 3 Participant ID Masterfile (Appendix 5)**.

The study RAs should also keep an anonymised electronic record of the numbers of participants screened, eligible and recruited to the study, with reasons for non-eligibility and non-recruitment, using the **CORE Phase 3 Recruitment Record (Appendix 6)**.

2. Data collection and management (including randomisation and blinding arrangements)

Researcher permissions and training

Before taking consent and collecting data from study participants, study research assistants (RAs) must have the following in place:

- Letter of access or equivalent from the participating NHS Trust
- Up to date certificate of Good Clinical Practice (GCP) training
- Instruction in study data collection procedures and use of measures from the Trial Manager or delegate

Copies of RAs letters of access and evidence of GCP training will be stored in the Trial Master File. Approval from the CI and Trial manager to collect data will be confirmed in the Delegation Log in the Trial Master File.

Data collection timepoints

Data will be collected directly from study participants at two timepoints:

i. Baseline data will be collected **either** in the same meeting, once a participant has provided written consent; **or** in another meeting arranged as soon as possible after this date.
ii. Follow-up data will be collected at four months following date of study entry or as soon as possible following this date that a meeting with a study participant can be arranged. Follow-up interviews should not be carried out earlier than four months following study entry.

Baseline data from patient records will be collected once all participants at a site have been recruited. Follow-up data from patient records will similarly be collected once the follow-up data collection date has been reached for all participants.

Peer support workers at all sites will be asked to bring completed Contact Logs for all meetings with trial participants to weekly supervision. The study data officer will contact supervisors at all sites weekly to arrange for these records to be transferred to the study team, where they will be stored securely at UCL or UWE.

Randomisation Procedures

Randomisation will be carried out using procedures developed by “Sealed Envelope” an independent data management company commissioned by the Priment Clinical Trials Unit to support data management for the CORE Phase 3 trial. Only the Study Chief Investigator,

Trial Manager, senior Research Clinician and Data Officer will have access to the Trial randomisation database.

Once a participant has provided written consent to participate in the study, the study RA should contact the Trial Manager or study Data Officer as soon as possible to establish the participant's unique study ID. The RA will provide the Trial Manager with details of the participant's name and date of birth and which service they were recruited from. The Trial Manager will use this information to enter the participant in the study randomisation database provided by "Sealed Envelope".

Once the Trial Manager has been informed by "Sealed Envelope" of the participant's allocation status, the TM will wait for confirmation from the study Research Assistants that the participant has been discharged from the CRT and then the TM or Data Officer will:

i. Inform the Peer Support Workers' supervisor, and/or other contact point at the participating clinical service, of all participants allocated to receive peer support
ii. Inform all participants of which group they have been allocated to and send a copy of the study Recovery Plan and guide to participants in the control group, who will not receive peer support

The Trial Manager may delegate these tasks to a study data officer or equivalent, but will not involve the study RAs in these tasks, in an attempt to maintain their blindness to participants' allocation status.

NB: Participants and involved clinical services will not be informed of the participants' allocation status until the participant has been discharged from CRT care. The study intervention will therefore always begin once a period of CRT care has ended.

The study data officer will contact the peer support workers' supervisors weekly to confirm which PSW trial participants have been allocated to. This will be recorded in the trial database and also serve as a check to ensure all participants in the treatment arm are allocated a PSW promptly.

Blinding Procedures

We will attempt to maintain the blindness of the study research assistants (RAs) who will conduct follow up interviews with participants. RAs will not have access to the study randomisation database and will not be informed by the Trial Manager or others which group participants have been allocated to. The following tasks will be carried out by the trial data officer or trial manager, who are not blind and will not collect follow-up data for the study:

- Randomising participants
- Informing participants and PSWs' supervisors of participants' allocation status
- Collecting safety monitoring data from PSWs' supervisors and CRTs
- Checking with supervisors which PSW each participant has been allocated to
- Collecting PSWs' contact logs from PSW supervisors
- Liaising with PIs and the study clinical reviewer re assessing study-relatedness and signing off SAE forms
- Contacting trial participants to ask if they would consider re-allocation to a different PSW in the event of early study drop out.
- Contacting trial participants in the treatment arm to complete the Recovery Promoting Relationships Scale (after completion of other follow-up data)

Wherever possible within study resources, a different RA will complete the follow up interview for each participant from the RA who completed the baseline interview and led on screening and arranging contact of participants at the site. When arranging and at the start of follow-up interviews, RAs will ask participants not to disclose whether or not they have received peer support. Should an RA become unblinded while arranging a follow-up interview, arrangements will be made wherever possible within study resources for a different RA to go and collect the follow-up data. The study follow-up interview does not require participants to divulge their allocation status at any point. Once the study follow-up interview is complete, the study researcher will inform the Trial Manager or Data Officer, who will contact participants from the intervention group to complete (unblind) the process measure (the Recovery Promoting Relationships Scale).

The study database will include a box to check if the RA became unblinded during follow-up data collection.

Data storage

RAs will record participants' answers to questionnaires in baseline and follow-up interviews on paper copies of the questionnaire schedule during the interview. These paper copies should be labelled with the participant's ID number following the interviews and stored securely in clearly labelled, locked filing cabinets in a locked office. All data collected from or about an individual participant should be kept together in an individual casefile for that participant, identified only by their study ID number.

All paper documents with study data collected from or about participants from researchers based at University College London will be stored at UCL. Paper documents from interviews conducted by the study RA based in Bristol will be stored securely at offices at the University of the West of England. The Principal Investigator at the Bristol site will be responsible for ensuring data at UWE is stored securely in accordance with Good Clinical Practice and study requirements; The Trial Manager will hold this responsibility at UCL.

NB: All documents of any sort containing data collected from study participants should be labelled using participants' ID number only and kept separately from: participant consent forms and contact details and the study ID Masterfile.

Data entry

Data collected from participants and about participants from patient records will be entered directly onto the study database managed by "Sealed Envelope". The Trial Manager will provide authorisation for study RAs to access the study database (which is separate from the study randomisation database and does not reveal participants' allocation status). The "Sealed Envelope" study database has built-in functions to require authorisation from the Trial manager to amend study data once it has been entered and to keep a record of all changes made.

3. Safety monitoring and reporting

Definition of Serious Adverse Events

Anticipated potential Serious Adverse Events (SAEs) which will be screened during the CORE Phase 3 RCT include:

- Admission to psychiatric hospital or other mental health acute care service
- Attempted suicide
- Death by any cause
- Assault by the participant on a peer support worker
- Assault by a peer support worker on a participant or others during the course of their work

- Any other life-threatening, disabling or incapacitating event for a study participant brought to the attention of the study team by participating clinical services.

Study-related SAEs

Readmissions to hospital or other acute care are likely among the participant group, who are recruited from acute care services: readmission need not necessarily be related to the trial. Whether or not an SAE is related to the study will be judged in each case by the person reporting the SAE and the local PI, and referred for clinical review if related or possibly related to the trial.

Monitoring of Serious Adverse Events

The CORE Trial Management Team (TMT) will monitor SAEs in the following ways:

1. Peer support workers will be prompted to report any SAE immediately to the involved clinical team on the session feedback form they complete after each meeting with a participant.

2. The manager or identified study link workers in the involved clinical team will retain a list of study participants in their site. The manager or link worker will be asked to pass on information about any SAEs involving study participants immediately to the Principal Investigator, the Trial Manager or the Chief Investigator.

3. The Data Officer will contact the PSWs' supervisors at each site weekly to check participant allocation and collection of PSW contact logs. At this point, the data officer will also check whether the supervisor is aware of any SAEs involving study participants.

4. Routine patient records will be screened regularly to check for any unreported SAEs among study participants. The frequency and process for checks will be agreed with participating NHS Trusts, but would typically involve screening patient records every 1-2 months being undertaken by; a) study researchers with approved access to patient records; b) Trust informatics departments; or c) staff from participating clinical services. Information required from patient records will be a) number of any new admissions to acute care or deaths among study participants; and b) whether any link to participation in the study can be identified from available reports of the circumstances of these events.

The **CORE Phase 3 Serious Adverse Events Monitoring Form (Appendix 7)** provides a template for collecting required data for periodic screening of patient records for SAEs.

Reporting of Serious Adverse Events

When informed of an SAE involving a study participant by the clinical service or through records screening, the Trial Manager, PI or CI or study researcher will complete **The Priment Serious Adverse Event Form (non-CTIMP) (Appendix 8)** immediately. This will involve getting a view from the most appropriate clinician within the participating NHS Trust (typically a clinician currently supporting the participant, or otherwise connected with the study) about whether the event could be considered study-related. The study representative completing the form will forward it to the local PI and the Trial Manager without delay.

Any SAE which is life-threatening, or potentially related to the trial therapy will be forwarded by the Trial Manager to the Trial Clinical Reviewer immediately by the Trial Manager. Other SAEs will be deferred for review by the Clinical Reviewer at the next Trial Management Group Meeting, or within two months if no TMG meeting is scheduled.

Sonia Johnson will act as the Clinical Reviewer for the Trial (David Osborn in her absence). As the Clinical Reviewer is a member of the study team, she will seek independent advice from the Steering Group Chair (George Szmukler) about potential trial-related SAEs.

Any SAE identified by the Trial Clinical Reviewer as trial-related and with major implications for the conduct of the trial of the safety of participants will be reported to the REC within 15 days of the Chief investigator becoming aware of the event. Other SAEs will be reported to the REC as part of the Annual Safety Report (ASR).

Any SAE resulting in the death of a participant or homicide by a participant will be reported immediately to the Chair of the study Data Monitoring and Ethics Committee (DMEC), who will decide whether or not a DMEC meeting should be convened immediately. Other study-related SAEs may be reported immediately to the Chair of the DMEC if advised by the Trial Clinical Reviewer and Steering Group Chair; otherwise they will be included in routine reports to the DMEC.

Planned safety reporting

An annual safety report will be sent to the REC each year on the anniversary of the start of study data collection. This will provide figures for total numbers of SAEs and a brief report of any areas of safety concerns.

Data regarding all SAEs will be reported the Chair of the study Data Monitoring and Ethics Committee (DMEC) in advance of DMEC meetings, which will take place at least annually. This report will include:

a) Current participant recruitment rates and numbers of participants dropping out of the intervention and/or lost to follow up

b) Current numbers of serious adverse events in both trial arms

c) Numbers of serious adverse events in each trial arm thought to be study-related and anonymised details of study-related adverse events.

The Chair of the DMEC will then decide whether inspection of study data is warranted. Minutes of DMEC meetings and any reports of scrutiny of study data written by the DMEC will be forwarded to the Chair of the Study Steering Committee Meeting in advance of the next Steering Committee Meeting, to allow discussion if needed between the Chairs of the DMEC and the steering committee about necessary advice/action regarding study safety concerns.

4. Peer support workers: recruitment, training and management

General

CORE Phase 3 peer support workers (PSWs) will be employed and managed by local NHS Trusts. Local NHS policies and procedures will apply to PSWs and, if necessary, override the guidance below.

These guidelines provide an overview of how the CORE Phase 3 trial intervention is planned and should be adhered to by Peer Support Workers and involved clinical services as far as possible to ensure the study intervention is delivered as consistently as possible.

Recruitment of PSWs

Ideally, peer support workers should be recruited through competitive interviewing process, with representatives from the involved Crisis Resolution Team, the study team and a service user representative/peer support worker involved in the selection process.

A job description and person specification for the peer support worker role have been approved by Camden and Islington NHS Foundation Trust (the lead NHS Trust), matching the role as a Band 3 post under Agenda for Change. This job description can be made available to other Trusts participating in the study as required.

Payment of PSWs

Peer support workers will be paid from a dedicated budget for the study treatment costs, from money provided by the participating Trust to cover excess treatment costs (ETC) associated with the study. ETC have been sought from Trusts on the basis of:

- 2.5 hours' work paid for each 1 hour meeting between a PSW and a service user, allowing time for preparation and writing up the meeting
- PSWs are to be paid for meetings where the service user does not turn up or cancels at short notice (i.e.less than 48 hours notice (unless the PSW is willing and able to rearrange to another convenient time)
- 2 hours' work to be paid for each attendance at 1 hour group supervision, allowing time for preparation and reflection

Training of PSWs

Five days of training will be provided by the study team for all PSWs before they start supporting any service users as part of the study. The study senior research clinician and service users with experience of peer support will be involved in delivering this training. The training will involve:

- 5 days of training in delivering the study intervention. This will include: orientation and guidance in using the recovery plan and guide; PSWs developing their own personal recovery plan; training in sharing your story and appropriate self-disclosure; working with diversity and difference.
- A local induction meeting at each site with the PSWs' supervisor and a contact from the study team. . This will include familiarisation with local arrangements for: safety procedures and check-ins, contacting service users, record keeping, supervision.

Involvement of staff from the participating CRT is crucial for the local context training day and desirable for all days.

Nine days of training were budgeted for in the Excess Treatment Costs for the study. This allows up to four more days for additional training or induction required by the participating NHS Trust and/or any top up training required once PSWs have started work, as agreed by the participating service manager, NHS clinical supervisor and study team.

Supervision of PSWs

Weekly group supervision for PSWs should be provided by the NHS Trust employing the PSWs. The supervision team should ideally include:

- A senior clinician with experience of using self-management materials
- An experienced service user representative or peer support worker not working as one of the study PSWs
- A member of staff from the involved Crisis Resolution Team (if not already covered by the above)

Participating NHS Trusts should also clarify when and from whom PSWs can receive individual supervision if required; and whom they can contact should they need to discuss their role or concerns about clients more immediately than the next supervision group.

The senior research clinician and Public Involvement Coordinator from the study team (or other appropriate members of the study team) will also provide a regular weekly one-hour

time for PSWs to participate in a conference call. This would provide an additional source of support or advice with issues relating to use of the self-management booklet or reflecting on the PSW role with an experienced peer colleague. These sessions would explicitly not be used to discuss concerns or information about specific trial participants.

If PSWs from any site do not use this phone support regularly, at least every two months the study Public Involvement Coordinator will contact the supervisor at the site and offer to come and meet the PSWs at a regular supervision session or at another convenient time. Through these means, we will ensure that PSWs do have access to peer supervision throughout the course of the trial.

Allocation of service users to PSWs

There is an expectation that PSWs will be prepared to work with up to 5 service users over a six month period in the pilot trial and up to 15 service users over a 15 month period for the main trial. However, PSWs are free to agree or decline to work with additional service users when this work is offered, in order to keep their time commitments and stress levels manageable.

Allocation of service users participating in the CORE Phase 3 trial to PSWs will be managed by the PSWs' supervisors within each Trust. Trial participants will be asked if they have any preference for a worker of their own gender by the study Data Officer: this preference will be followed wherever possible. We do not plan any attempts to match service users to specific PSWs, based on type of illness, personal characteristics or interests. However, any guidance from CRT staff regarding risk or clinical appropriateness should be followed (e.g. if a male or female PSW is required).

Once a PSW has been allocated to work with a service user, the expectation is that they will continue to work with the service user throughout the period of support. Service users will not be offered a change of peer support worker except in exceptional circumstances where the peer support worker is unable to complete the programme of support due to ill health or other reason. If a participant declines to meet the PSW again after fewer than three sessions, the PSWs' supervisor or the study data officer will contact the participant to ask if they would be willing to continue the study intervention with a different PSW. If so, the participant will be allocated a different PSW if possible, to ensure receipt of the study intervention.

Meetings should be arranged between the PSW and the service user at mutually convenient times. Any specific requirements from the service user (e.g. to fit meetings around work or

caring commitments) should be ascertained in advance by the involved CRT and considered when choosing which PSW to allocate the service user to. Meetings may be arranged at evenings or weekends, if permitted by the CRT. Meetings may take place in the service user's home, an appropriate public space or NHS premises as the service user prefers – within any limitations due to risk which have been specified by the CRT.

Duration of the intervention

Peer support workers should offer a maximum of ten meetings, each of about an hour, to service users they are supporting. The service user may opt to receive less than ten sessions of support if they wish. Meetings which the service user misses or cancels at short notice (i.e. less than 48 hours) should be included in the ten sessions. Meetings should be roughly once a week, with the aim that that the period of support is completed within three months of the first meeting. "Double sessions", more frequent, or more spaced out meetings can be accommodated for specific pieces of work or to suit the PSW's and the service user's availability and preference. Meetings between the PSW and the service user should be concluded within four months at an absolute maximum.

Within guidelines of the involved NHS Trust, PSWs may contact service users between sessions (e.g. to provide support after an important event or provide a reminder or encouragement at an agreed time). However, the expectation is that these contacts would be brief and few (i.e. not more than once or twice maximum between sessions, whether by phone or email, with contact between sessions less than 30 minutes in total). Service users will also require a means to contact or leave a message for their PSW, e.g. to rearrange a session. PSWs should not offer to or be expected to be contactable by the service user they are supporting at all times however.

Content of the intervention

The content and style of the support provided by the peer support workers must be flexible to meet the needs of the individual service user being supported. However, for all service users, the peer-provided, self-management support in CORE Phase 3 should include the following:

- Encouragement and help for the service user to read the recovery and complete a written personal recovery plan. (The recovery plan and guide need not be used in a linear fashion. Other methods of covering the content of the plan may be developed for those with literacy difficulties or very reluctant to make a written plan using the

recovery booklet.) The recovery plan should usually be shown/given to the service user in the first session.

- A willingness by the PSW to share their own story and recovery journey where appropriate to generate hope and model coping strategies to aid recovery.
- Encouragement to consider other supporters (family or friends, mental health or other support staff) who could be involved in developing or being aware of the service user's recovery plan. (Meetings between the PSW with the service user and their family or support staff to discuss the recovery plan are encouraged where the service user agrees to this. PSWs should check with service users whether they would like anyone else to be present at the initial meeting.)
- Encouragement and help for the service user to identify and link into other ongoing sources of support (e.g. service user groups, other support services, local recreational groups or education services).
- PSWs can support service users with other specific goals or problems, but should: a) where possible help the service user identify ongoing sources of support which could offer help, rather than provide the help themselves; and b) be mindful of the limits of the PSW role and encourage the service user to seek expert advice where appropriate.
- Peer support workers can use social activities with the service user (e.g. going for coffee, for a walk) as means to help build rapport or reduce anxiety, but these should not become the main focus of the support, which should specifically focus on helping people with recovery goals.
- Peer Support Workers will be provided with important information regarding risks associated with the service user they are supporting, in order to ensure their safety. PSWs will not otherwise be provided by the CRT with information regarding the service user's circumstances and clinical history in advance of meeting the service user.

Reports

In addition to record keeping required by the Crisis Resolution Team, PSWs are expected to keep a brief record of the content of each session with service users for the study team, using the **Peer Support Worker Contact Log (Appendix 10)** approved by the Research Ethics Committee.

Details of local site arrangements for recruiting and managing the peer support workers, additional to this general guidance,will be clarified for all sites and recorded using the schedule provided – **Appendix 9**.

CORE Phase 3 Screening Record (Appendix 1)

No.	Service user name	CRT start date	With CRT for 7 days (Y/N)	English language ok (Y/N)	Living in area (Y/N)	Capacity to consent (Y/N)	Risk level ok (Y/N)	Eligible (Y/N)	Transfer to CRT contact form (Y/N)

CORE Phase 3 Potential Participants Contact Form (Appendix 2)

CRT staff: Please could you contact the service users listed below to ask them if they are willing to be contacted by a researcher to discuss taking part in the CORE study. Please use this form to record all service users you contact.

The study researchers can provide you with a summary of key information about the study to tell service users.

When a service user agrees to talk to a researcher about the study, please contact one of the research team who will ask you for some referral information.

Thank you very much for your help with the study.

Service name:

Service user's name	Phone number	Contacted by: (CRT staff name)	Date of contact	Agreed to talk to a researcher (Y/N)	Outcome: (Declined, recruited, could not contact)

CORE Phase 3 Initial Contact with Potential Participants – Guidance for CRT staff (Appendix 3)

Inclusion Criteria:

- Have been on the CRT caseload for at least a week, or who have so far had a shorter period of treatment, but are expected to remain on the caseload for at least a week.
- Have the capacity to give written informed consent to the study.

Exclusion Criteria:

- People who in the view of the clinical team present such a high risk to others that it is inappropriate for peer support workers or researchers to meet with them even in mental health service premises.
- People who are discharged to addresses outside the catchment area and are not likely to return to the area imminently.
- People who cannot understand the intervention when delivered in English.

Summary of Key Information for Potential Participants:

What will participating in the study involve?

A researcher will meet everyone who agrees to take part in the study to collect some information about you, your health and your views on mental health services in an interview lasting about an hour. You would be offered £20 for your time and help with this interview.

You would then be allocated at random to one of two groups. People in group A would be offered help from a peer support worker to make your own recovery plan. Peer support workers are people who have previously used mental health services and who has received training to support others who have recently used a Crisis Resolution Team. The aim of the support is to help with recovery from a mental health crisis and manage good health in the future.

Altogether, you would be offered eight to ten weekly meetings with the peer support worker, each lasting up to an hour at a time and place that is mutually agreed upon. You would guide what will be discussed in each meeting but the peer support worker will offer to help you develop and write down your own recovery plan, which may cover:

- Setting personal goals for recovery
- Developing ways to keep well and sources of support
- Warning signs that a crisis might be starting and planning what to do

People in group B will be sent a copy of the recovery plan but will not be offered any meetings with a peer support worker.

About four months after you agreed to take part in the study, a researcher will contact you again and ask to complete another interview with you asking about your health and views on services now. The study is completely voluntary and you could choose to withdraw at any time and without giving a reason.

What if the service user is interested in taking part or wants more information?

With the service user's agreement, the CRT staff can pass on the person's details to a researcher who will contact them to provide more information and register the person if they decide to take part.

Referral Process (if the service wants to find out more information, or wants to participate in the study)

1) Please ask for the service user's verbal consent to pass on contact details to a CORE researcher.

2) Please record in the Potential Participants' Contact Form (kept in the CRT where you work) whether the service user agreed to be contacted by a researcher

3) Please also make a note of their agreement in the service user's Patient Record.

4) Please contact a CORE study researcher who will take some referral details from you about the service user

Contact details (for the research team)

[Insert local researcher details here]

CORE Phase 3 Potential Participant Referral Form (Appendix 4)

Service User Details			
Referral Date			
Service User Name			
NHS Number			
Home Address			
Telephone		**Mobile**	
Preferred method of Contact:		**Can a message be left?**	
Are there risk-related limits on meetings	*(e.g. location of meetings, gender of researcher or PSW)*	**Are there any additional support requirements?**	*(e.g. literacy, mobility)*
GP Name		**GP address**	
Does this service user have psychosis or bipolar disorder? ☐ No ☐ Yes, the service user has *either* psychosis *or* a bipolar disorder			

Referrer Contact Details	
Referring Clinician's Name	
CRT service	
Referrer's Contact Details	

UCL staff details and Contact Notes	
Name of staff taking referral	
Contact Notes	

CORE Participant ID Masterfile (Appendix 5)

CRT Service:

Recruitment total at this service	Participant name	Study ID	Date of study entry	Copy of consent form + letter sent to CRT *(RA name + date)*	Copy of consent form + letter sent to GP *(RA name + date)*	Participant + CRT told re allocation status *(RA name + date)*	Follow-up interview due date	Send study report? (Y/N)	Withdrawals: N = no further participation W = withdrawal – do not use previously collected data *(RA name + date)*

Recruitment total at this service	Participant name	Study ID	Date of study entry	Copy of consent form + letter sent to CRT *(RA name + date)*	Copy of consent form + letter sent to GP *(RA name + date)*	Participant + CRT told re allocation status *(RA name + date)*	Follow-up interview due date	Send study report? (Y/N)	Withdrawals: N = no further participation W = withdrawal – do not use previously collected data *(RA name + date)*

CORE Phase 3 Recruitment Record (Appendix 6)

Please refer to the CORE Phase 3 Screening Record and Potential Participant Contact Form to complete this record

Service user's initials	**Date of entry to CRT**	**Eligible for study** (Y/N)	**Reasons for ineligibility** 1. Capacity to consent 2. Risk 4. Living outside area 5. Understanding of English NA: Not applicable: person eligible	**Recruited to study** (Y/N)	**Reasons why not recruited** 0. Ineligible 1. Not contacted by CRT staff 2. Not contacted by study researcher 3. Contacted but not consented within one month of CRT discharge 4. Declined before contact with researcher 5. Declined following contact with researcher NA: Person was recruited to the study

Appendix 7: SAE Monitoring Form

CORE Phase 3 Serious Adverse Events Monitoring Form

Please use this form to record safety data from patient records for participants in the CORE Phase 3 trial.

Data collection period

Date from:

Date to:

Participant Name	NHS number (if available: d.o.b. if not)	Date of new hospital admission	Date of other new admission to acute care	Date of Death

*For all SAEs recorded on this form, study researchers will then review admission records and progress notes to determine whether there is any indication the event was study-related. A study researcher will complete an SAE reporting form (Operating procedures – Appendix 8) for all SAEs recorded on this form (whether or not study-related).

Priment SAE Reporting Form (Appendix 8)

Appendix 2: Example Serious Adverse Event Form (Non CTIMP Study)

REPORT OF SERIOUS ADVERSE EVENT (SAE)
(For all studies except clinical trials of investigational medicinal products)

The Chief Investigator should report any SAE that is both related to the research procedures and is unexpected. Send the report to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event. For further guidance *see:* http://www.nres.npsa.nhs.uk/applicants/review/after/safety.htm.

1. Details of Chief Investigator

Name:	
Address:	
Telephone:	
Email:	
Fax:	

2. Details of study

Full title of study:	
Name of main REC:	
Main REC reference number:	
Research sponsor:	
Sponsor's reference for this report: (if applicable)	

3. Type of event

Please categorise this event, ticking all appropriate options:

Death ☐	Life threatening ☐	Hospitalisation or prolongation of existing hospitalization ☐
Persistent or significant disability or incapacity ☐	Congenital anomaly or birth defect ☐	Other ☐

4. Circumstances of event

Date of SAE:	
Location:	
Describe the circumstances of the event: *(Attach copy of detailed report if necessary)*	
What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

5. Declaration

Signature of Chief Investigator:	
Print name:	
Date of submission:	

6. Acknowledgement of receipt by main REC (please insert name):

The [ ] Research Ethics Committee acknowledges receipt of the above.

Signed:	
Name:	
Position on REC:	
Date:	

Signed original to be sent back to Chief Investigator (or other person submitting report)
Copy to be kept for information by main REC.

APPENDIX 9 – CORE PSWs – Local site arrangements

NHS Trust	
Peer Support Workers (names and contact details)	
Dates of CORE study PSW training	
Other mandatory Trust training	
PSW supervisors (names and contact details)	
PSWs' line manager (if different from above)	
CRT in which recruitment is taking place (address and phone number)	
Location of PSWs' supervision (if different from CRT)	
Day/time of PSW weekly group supervision	
PSW check-in/lone worker procedures (inc. arrangements for provision of work phones)	
PSW Trust record-keeping requirements	
PSW employment arrangements (Trust or external agency)	
PSW payment arrangements (arrangements for timesheets/ payment authorisations etc)	
Dedicated UCL staff researchers for CRT (names, email, contact numbers, blind/not blind status)	

CORE Phase 3: Peer Support Worker Contact Log (Appendix 10)

PSW's Name:

NHS Trust:

Service user study ID:

Please complete a Contact Log record for each meeting you have with a study participant. Please bring completed contact logs to your weekly supervision meeting. Your supervisor will forward them to the study team. This record for the study team is additional to any records you are expected to provide for the NHS Trust for which you are working. Please do not include any personal information which could identify the person you are supporting in this log for the study team.

Meeting #		
Date:		
Did the service user attend? (Y/N)		
Did anyone else attend this meeting? **a) Family/carers (Y/N)?** **b) Mental health or other support staff (Y/N)**	**a)** **b)**	
Did you bring any information to, or discuss information at this meeting? **a) About other local services (Y/N)?** **b) About diagnosis or medication (Y/N)?** **c) About ways of coping with difficulties/symptoms (Y/N)?**	**a)** **b)** **c)**	
Did you use the workbook at all in this session? (Y/N)		
If yes, which sections did you use? *(Please tick any which apply.)*	**Talk about contents**	**Write plans or review written plans**
Moving on after a crisis		
Keeping well		
Managing ups and downs		
Goals and dreams		
Please describe briefly the content of the session and any comments on how it went:		
To your knowledge, has any serious adverse event involving the service user occurred since your last meeting? (Y/N)**		

**Serious adverse events include: admission to psychiatric hospital or a crisis house, readmission to the Crisis Resolution Team, death, attempted suicide, the service user assaulting others or threatening a peer support worker. If you are aware of a serious adverse event, please inform your supervisor or the CRT team immediately and seek their advice. Please ask your supervisor or the CRT staff to contact the study team asap.