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CORE: Crisis Team Optimisation and Relapse Prevention - Phase 3

Submission date	Recruitment status
10/10/2012	No longer recruiting
Registration date	**Overall study status**
11/10/2012	Completed
Last Edited	**Condition category**
19/06/2023	Mental and Behavioural Disorders

✓ Prospectively registered
✓ Protocol added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
Background and study aims
Crisis resolution teams (CRTs) are specialised teams that provide rapid assessment and treatments to people having a mental health crisis. CRTs were introduced in the UK in 2001 in order to improve experiences for people suffering a mental health crisis (sudden breakdown) and to limit the amount of people who were admitted to hospital. Although there have been positive effects of implementing CRTs such as reducing inpatient admissions and lowing healthcare costs, many service users reported issues in the long term, such as continuity of care between services during and following a period of CRT care. The aim of this study is to find out whether working through a self-management workbook with support when leaving CRTs could help to promote recovery and reduce the risk of further episodes (relapse).

Who can participate?
Adults who have been on the caseload of a participating CRT for at least a week.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are offered up to 10 meetings with a peer support worker over a course of four months, who helps them to work through a self-management workbook. The workbook is made up of structured sections, helping the participant to set personal recovery goals, re-establishing their social support network, advice to help prevent the crisis happening again, and planning strategies and coping resources for when the crisis is resolved. Those in the second group are also given the self-management workbook to complete but are given no additional guidance about how to use it. At the start of the study and then after 4 months, participants are interviewed in order to assess how well they are coping. One year after the start of the study, the participants medical records are also reviewed in order to find out about how much they have used mental health services and if they have been admitted to hospital. An additional follow up interview will be completed with participants 18 months after study entry.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
February 2014 to April 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Brynmor Lloyd-Evans
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Study website
http://www.ucl.ac.uk/core-study

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number
15999

Study information

Scientific Title
Optimising team functioning, preventing relapse and enhancing recovery in Crisis Resolution Teams (CRTs): the CORE Programme (Crisis team Optimisation and RElapse prevention) Phase 3:

Randomised controlled trial of a peer provided, self-management intervention for people leaving CRT services

Acronym
CORE Phase 3

Study hypothesis
Current hypothesis as of 05/02/2014:
1. Provision of a peer-provided, self-management programme for people leaving Crisis Resolution Teams will reduce readmission to acute care over one year follow-up.
2. Provision of a peer supported, self-management programme for people leaving Crisis Resolution Teams will improve satisfaction with services, self-rated recovery, illness management, social inclusion , symptoms and loneliness, social support and neighbourhood social capital at follow-up post-treament and at 18-month follow-up, and reduce inpatient bed use over one year follow-up.

Previous hypothesis:
1. Provision of a peer-provided, self-management programme for people leaving Crisis Resolution Teams will reduce readmission to acute care over one year follow-up.
2. Provision of a peer supported, self-management programme for people leaving Crisis Resolution Teams will improve satisfaction with services, self-rated recovery, illness management, employment, symptoms and perceived continuity of care at follow-up post-treament, and reduce inpatient bed use over one year follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 19/07/2012, ref: 12/LO/0988

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Condition
Mental health

Interventions
Current interventions as of 05/02/2014:
Peer-provided self management
Participants in the treatment group will be offered up to 10 meetings with a peer support worker, who will support them in developing a personal recovery plan using a manualised workbook. Participants in the control group will be given the self-management workbook but no additional guidance or peer support to help use it.
Followed up by a research interview after 4 and 18 months and via patient records over 12 months

Previous interventions:
Peer-provided self management
Participants in the treatment group will be offered up to 10 meetings with a peer support worker, who will support them in developing a personal recovery plan using a manualised workbook.
Followed up after 6 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Re-admission to acute care measured at one year from study entry

Secondary outcome measures
Current secondary outcome measures as of 05/02/2014:
1. Days in acute care over 1-year follow-up
2. Time to readmission (1-year follow-up)
3. Mental health service use (1-year follow-up)
4. Illness management measured at 4-month follow-up interview - IMR questionnaire
5. Psychiatric symptoms measured at 4-month follow-up interview - BPRS questionnaire
6. Satisfaction with services measured at 4-month follow-up interview - CSQ questionnaire
7. Self-rated recovery measured at 4-month follow-up - QPR questionnaire
8. Social inclusion at 4-month follow-up SIX questionnaire
9. Loneliness at 4-month follow-up UCLA Loneliness Scale questionnaire
10. Social network at 4-month follow-up Lubben SNS questionnaire
11. Neighbourhood social capital at 4-month follow-up - Health and Lifestyles survey Neighbourhood social capital questionnaire

Added 07/12/2016: Outcomes 4-11 will also be assessed at 18 month follow-up.

Previous secondary outcome measures:
1. Employment status measured at 4 month follow up interview
2. Illness Management measured at 4 month follow-up interview - IMR questionnaire
3. Inpatient bed days, measured one year following study entry
4. Perceived continuity of care, measured by Continu-um questionnaire at 4 month follow-up

5. Psychiatric symptoms measured at 4 month follow up interview - BPRS questionnaire
6. Satisfaction with services measured at 4 month follow-up interview - CSQ questionnaire
7. Self-rated recovery measured at 4 month follow up - QPR questionniare

Overall study start date
01/04/2011

Overall study end date
30/04/2017

Eligibility

Participant inclusion criteria
Current inclusion criteria as of 05/02/2014:
1. Adults (aged 18+) who have been on the caseload of a participating Crisis Resolution Team for at least a week
2. Male and female
3. A threshold has been set that at least half the participants recruited must be identified during screening at services as having schizophrenia or other psychosis or bipolar disorder

Previous inclusion criteria:
1. Adults (aged 18+) who have been on the caseload of a participating Crisis Resolution Team for at least a week
2. Male and female

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 440

Participant exclusion criteria
Current exclusion criteria as of 05/02/2014:
1. People who lack capacity to consent to take part in the study
2. People who in the view of the clincal team at their Crisis Resolution Team present such a high risk of harm to others, it would be unsafe for researchers or peer support workers to meet with them even in a mental health service setting
3. People who are discharged to addresses outside the catchment area
4. People who cannot understand the intervention when delivered in English

Previous exclusion criteria:
1. People who lack capacity to consent to take part in the study
2. People who in the view of the clinical team at their Crisis Resolution Team present such a high risk of harm to others, it would be unsafe for researchers or peer support workers to meet with them even in a mental health service setting
3. People who are already on the caseloads of a highly intensive community service, such as an Assertive Outreach Team
4. People who are discharged to addresses outside the catchment area
5. People who cannot understand the intervention when delivered in English

Recruitment start date
06/02/2014

Recruitment end date
03/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
W1 7EJ

Sponsor information

Organisation
Camden and Islington NHS Foundation Trust (UK)

Sponsor details
Research and Development Department
Bloomsbury Building
St Pancras Hospital
4 St Pancras Way
London
England
United Kingdom
NW1 0PE

Sponsor type

Hospital/treatment centre

Website
http://www.candi.nhs.uk/

ROR
https://ror.org/03ekq2173

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/10/2017		Yes	No
Other publications	intervention development	09/11/2017		Yes	No
Results article	results	04/08/2018		Yes	No
Results article	results	01/04/2019	16/04/2019	Yes	No
Other publications	Cost-effectiveness	02/06/2023	19/06/2023	Yes	No