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# CRIMSON Study: Randomised controlled trial (RCT) of Joint Crisis Plans to reduce compulsory treatment of people with psychosis

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 15/02/2008 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 13/03/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 28/11/2017 | Mental and Behavioural Disorders | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
G0601660

# Study information

### Scientific Title
CRIMSON Study: Randomised controlled trial (RCT) of Joint Crisis Plans to reduce compulsory treatment of people with psychosis

### Acronym
CRIMSON

### Study objectives
The hypotheses to be tested are whether, compared with treatment as usual, Joint Crisis Plans improve: the proportion of service users treated under a section of the Mental Health Act, total costs, perceived coercion, service user engagement with mental health services, therapeutic alliance, and use of the Mental Health Act for the Black service users.

More details can be found at: http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0601660&CaseId=9012

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
This study has been reviewed and approved by King's College Hospital Research Ethics Committee (ref: 07/h0808/174)

### Study design
Individual-level single-blind randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

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

### Health condition(s) or problem(s) studied
Psychosis

### Interventions
Service users under the care of community services in each of the participating inner-city sites (Birmingham, London and Manchester/Lancashire) will be identified by CPA and IT record systems and Care Co-ordinator case lists. Participants will be randomised to control or intervention. Those randomised to the intervention group will develop a Joint Crisis Plan. Those randomised to the control group, will continue to receive treatment as usual.

The Joint Crisis Plan (JCP) intervention aims to empower the holder and to facilitate early detection and treatment of relapse. It is developed by a mental health service user in collaboration with staff with the assistance of an independent facilitator. Held by the service user, it contains his or her treatment preferences for any future psychiatric emergency, when he or she may be too unwell to express clear views. The JCP format has developed over the last decade after widespread consultation with national service user groups, interviews with organisations and individuals using JCPs, and after detailed developmental work with service users in South London.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
Proportion of service users admitted or otherwise subsequently detained under an order of the Mental Health Act during the follow-up period (18 months)

### Secondary outcome measures
1. Cost
2. Perceived coercion, assessed at baseline and at follow-up (18 months post baseline) using the Treatment Experience Survey (questionnaire) delivered at interview
3. Engagement with mental health services, assessed at baseline and follow-up (18 months post baseline) using the Engagement and Acceptance Scale (questionnaire) delivered at interview
4. Therapeutic relationship for service users and staff, assessed at baseline and follow-up (18 months post baseline) using the Working Alliance Inventory (questionnaire) delivered at interview

### Overall study start date
01/04/2008

### Completion date
30/11/2011

## Eligibility

### Key inclusion criteria
Eligible service users will have the following:
1. Contact with a local Community Mental Health Team (CMHT) (will include assertive outreach teams, early intervention teams, and community forensic teams, but not home treatment teams.)
2. Have been admitted to a psychiatric in-patient service at least once in the previous two years
3. Have a diagnosis of psychotic illness, including bipolar affective disorder (using Operational

Criteria Checklist OPCRIT 47)
4. Be on the local NHS Trust Enhanced Care Programme Approach (CPA) Register

We shall include service users who do not speak English. For non-English speakers, both written translation and interpreters are needed. and we shall employ interpreters in French, Portuguese and some West African languages as required, and will be examined at the pilot stage.

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
540 (180 per site)

### Key exclusion criteria
1. Those unable to give informed consent
2. Current in-patients will not be recruited to avoid any perceived potential coercion to participate, nor any patient subject to a compulsory community treatment order

Note: No other exclusions will be made, to maximise the external validity of the trial.

### Date of first enrolment
01/04/2008

### Date of final enrolment
30/11/2011

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Head of Health Service and Population Research Department**
London
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## Sponsor information

### Organisation
King's College London (UK)

### Sponsor details
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### Sponsor type
University/education

### Website
http://www.kcl.ac.uk

### ROR
https://ror.org/0220mzb33

## Funder(s)

### Funder type
Research council

### Funder Name
Medical Research Council (UK)

### Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 05/11/2010 | | Yes | No |
| Results article | results | 11/05/2013 | | Yes | No |
| Results article | economic results | 25/11/2013 | | Yes | No |
| Results article | results | 24/11/2017 | | Yes | No |