

A randomised controlled trial of Joint Crisis Plans for people with psychotic illnesses

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| Submission date 19/05/2003 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 19/05/2003 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 07/09/2009 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

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

N/A

Study information

Scientific Title

Study objectives

1. To measure the cost effectiveness of Joint Crisis Plans for people with psychotic illnesses with respect to hospital admission
2. To establish the feasibility of a more definitive RCT of Joint Crisis Plans

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committees of the South London and Maudsley NHS Trust, Lewisham University Hospital, South West London and Saint George's NHS Trust, and Thames Gateway NHS Trust. Ethical Approval Number: 188/97

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Psychosis and bipolar affective disorder

Interventions

Active intervention: Joint Crisis Plan production

Introductory meeting

Having informed the participant and their keyworker of the allocation, the research worker arranged a meeting between himself, the participant and if possible the keyworker. The aims of this meeting were, first, that the research worker would explain the overall procedure for

producing the JCP, and, second, that the keyworker should introduce the JCP menu to the participant, help him or her to identify early warning signs of relapse and formulate possible advance statements to be included.

Joint Crisis Planning meeting

To finalise the JCP contents the research worker then organised and facilitated at a meeting between the participant, team consultant or other qualified team psychiatrist and keyworker, where the JCP contents were finalised. The participant was encouraged to bring a carer or other to act as an advocate. The research worker's role as facilitator was to act as a neutral third party external to the team. By taking this role, he was in the best possible position to achieve the following aims:

1. To ensure that different options for the menu are explored
 2. To help all parties reach consensus wherever possible, such that the participant is happy to carry the JCP and all those it designates to act in future are willing to carry out the designated action
 3. If consensus cannot be reached one of two options are chosen by the patient; either the differences are made clear but the JCP retains this title as other contents have been agreed jointly, or, the document is renamed a crisis card because of the lack of joint agreement
- During the meeting, the contents of the plan were written down by the research worker in the form of the first person and using the exact words agreed on.

Checking the JCP content

After the planning meeting the research worker produced the typed version of the JCP as an A4 sheet. He then either met with the participant to check the content, or sent him or her the JCP and consulted him or her about the content over the telephone. If the participant wanted changes to be made, the research worker consulted relevant CMHT members if he deemed that the change required the team's agreement first.

Distribution

Once any further changes had been made, copies were sent by the research worker to all those whom the participant had designated on the menu. The participant was also sent a clear plastic wallet for the JCP.

Control intervention

The Joint Crisis Plan represents a new form of information held on paper by a patient. It was decided that in order to receive the best available care under usual conditions, the control group should receive whatever information was currently available on paper. At the time this consisted of two types:

1. A copy of the Care Plan done as part of the Care Programme Approach (CPA)
2. Leaflets on local services, different types of mental illness and other aspects of care

As all participants should have been given a copy of their care plan if covered by the CPA, and as none of the participating teams routinely gave out the second type of information, it was decided to make the latter the control intervention. Prior to beginning recruitment, the investigator and research worker visited each CMHT base and hospital to which patients from the participating sectors were admitted to collect whatever information was available.

Participants in the control group were given whatever was available relating to their CMHT and Trust, plus any other relevant information we had found at their site or elsewhere. The types of information distributed were as follows:

Hospital admission (what to expect, what to bring, rules)

Mental health resource centres (services available, opening hours)

Medication

Mental Health Act information booklet for patients ('Out of the Maze')

Social Security information on welfare benefits

Advocacy services

Social Services and voluntary sector information on local services (drop in centres, vocational training etc.

Information on mental illnesses

Trust policies, e.g. on confidentiality, patients' access to their own notes and making a complaint where available.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Hospital admission

1. Admitted or not
2. Compulsory admission
 - 2.1. Compulsory admission without police involvement
 - 2.2. Compulsory admission with police involvement
3. Number of days spent in hospital
4. Discharged or not

Secondary outcome measures

Not provided at time of registration

Overall study start date

04/01/2000

Completion date

31/03/2004

Eligibility

Key inclusion criteria

1. Patients had first to be currently under the care of one of the recruited community mental health teams.
2. On the day on which the clinical casenotes were consulted to retrieve diagnostic and sociodemographic information, the patient had to have been admitted to a psychiatric inpatient service at least once in the previous two years.
3. They had to have a diagnosis of psychotic illness or bipolar affective disorder without psychotic symptoms, operationalised from the clinical casenotes using the Operational Criteria Checklist, OPCRIT5, which uses a computer algorithm to assign diagnoses according to International Statistical Classification of Diseases and Related Health Problems, Tenth edition (ICD-10), Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM-IV) and a number of other diagnostic criteria. Patients were not recruited while staying on a psychiatric ward but if otherwise eligible they were contacted once they had been discharged or sent on extended leave.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

152

Key exclusion criteria

Inability to understand the JCP's function through mental incapacity or insufficient command of English to understand the consent procedure.

Date of first enrolment

04/01/2000

Date of final enrolment

31/03/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

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Sponsor information

Organisation

King's College London (UK)

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Sponsor type
University/education

ROR
<https://ror.org/0220mzb33>

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) training fellowship in health services research

Funder Name
South London and Maudsley NHS Trust (SlaM) (UK)

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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 17/07/2004 | | Yes | No |