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JOSHUA: a pilot randomised controlled trial of joint crisis plans for people who self harm

Submission date	Recruitment status	[_] Prospectively registered
17/09/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/05/2013	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

Protocol serial number
G0701752

Study information

Scientific Title

Acronym
JOSHUA

Study objectives
At this stage, it is premature to formulate a clear primary hypothesis. Nevertheless, the JOSHUA trial will provide an opportunity to examine the following exploratory hypotheses:

1. Use of a joint crisis plans (JCP) will lead to a significant increase in the length of time to first act of self harm during the follow-up period, compared with the control condition
2. Use of a JCP will result in a significant reduction in the number of acts of self-harm during the follow-up period, compared with the control condition
3. Regarding the most recent act of self-harm at follow-up, compared with the control condition, use of JCP will lead to a significant increase in the length of time from contemplation of self-harm to self-harm act
4. Regarding the most recent act of self-harm at follow-up, compared with the control condition, use of JCP will lead to a significant increase in help-seeking behaviour
5. Use of a JCP will result in a significant improvement in engagement with mental health services, compared with the control condition
6. Use of a JCP will lead to a significant improvement in therapeutic alliance, compared with the control condition
7. Use of a JCP will lead to a significant improvement in satisfaction with care, compared with the control condition
8. Use of a JCP will lead to a significant improvement in quality of life, compared with the control condition
9. Use of a JCP will lead to a significant reduction in total costs of care, compared with the control condition, or that the additional costs will be worthwhile in terms of improvements in outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study will be discussed at the Wandsworth Ethics Committee meeting on the 23rd September 2009.

Primary study design
Interventional

Study design
Single-centre pilot randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Borderline personality disorder

Interventions
This is a single-centre pilot randomised controlled trial of JCPs compared with a treatment as usual control condition for people with BPD. The total duration of the study will be two years.

Experimental Intervention
At each site, a clinically experienced facilitator will organise a meeting with each service user randomised to receive a JCP. The facilitator will introduce the JCP 'menu' (a list of topics to be considered for inclusion in the JCP) to each service user. He/she will then organise a meeting between the service user and the Care Co-ordinator, when the JCP contents will be finalised. The service user is encouraged to bring a carer or friend to act as an advocate. The JCP contains information for the service user, information for health professionals and details of practical help which the service user might require when in a future crisis.

The Facilitator produces a typed version of the JCP, computer-generated to allow replacement and updating (the feasibility of updating the plan will be examined during the course of the trial). Copies will be sent to all those whom the service user specifies and a copy will also be attached to each service user's electronic patient record (attached in the 'correspondence' section with an alert on the front page of the record, notifying staff of its existence).

Control intervention
After careful consideration, we have chosen to use a treatment as usual (TAU) control condition, as this provides a fair comparison with routine clinical practice and will answer the question of whether JCP use is superior to current standard care. TAU includes, as a part of the Care Programme Approach (CPA), the need for service users to receive written copies of their care plan, including a 'crisis contingency plan'. We expect that the CPA arrangements will be applied equally by routine services to intervention and control groups.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Self-harm history, assessed by a questionnaire at baseline and 6 months (trial end).

Previous research indicates that JCPs for psychotic patients give them a greater sense of control over their health management and that one of the perpetuating factors for repeat self-harm is a sense of loss of control. We therefore think that in people with BPD (whose contact with mental health services is frequently characterised by the experience of disempowerment), self-harm is a reasonable choice for a primary outcome variable in a randomised controlled trial. Self-harm is also a major clinical problem in this patient population and is of great relevance from a public health perspective, given that it is a risk factor for suicide. Therefore, if JCPs could be shown to lead to an improvement in some aspect of self-harm behaviour, or the management of self-harm, this would be of great clinical relevance However, at this stage, we have no firm empirical evidence to show whether this is the case, or indeed which aspect of this behaviour might be affected by a JCP. There is no gold standard for measure of self-harm and possible candidates include: incidence, frequency, severity, help-seeking behaviour prior to and after a self-harm event.

Key secondary outcome(s)
1. Client's experience of the treatment that he or she received at a particular service, assessed by the Treatment Experience Scale assessed at baseline and 6 months
2. Service Engagement Scale at baseline, 6 months (trial end) and trial drop-out
3. The Work and Social Adjustment Scale (WSAS) at baseline and 6 months (trial end)

4. Euroqol EQ-5D at baseline and 6 months (trial end)
5. Client Satisfaction Questionnaire at baseline and 6 months (trial end)
6. Working Alliance Inventory - short version (WAI-S) (client version) at baseline and 6 months (trial end). This is a measure of how well a client and a clinician work together.
7. WAI-S (staff version) at baseline, 6 months (trial end) and trial drop-out
8. Adult Service Use Schedule (ADSUS) to assess which services clients have accessed in the preceding 6 months, for health economics purposes, carried out at baseline and 6 months (trial end)
9. Alcohol Use Disorders Identification Test (AUDIT) at baseline
10. Hospital Anxiety and Depression scale (HADS) at baseline

Completion date
01/11/2011

Eligibility

Key inclusion criteria
1. Service users (both males and females) aged 18 years or older
2. Current contact with a local Community Mental Health Team (CMHT) (will include assessment and brief treatment, continuing care, home treatment and out-patient clinics attached to these teams)
3. A primary clinical diagnosis of emotionally unstable personality disorder (International Statistical Classification of Diseases and Related Health Problems, 10th Revision [ICD-10] code F60.3)
4. An episode of self-harm in the previous year

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Service users aged under 18 years of age
2. Those unable to give informed consent
3. Those unable to speak English. Fluency in English is necessary to complete the assessment instruments (many of which have not been validated in non-English languages) and to fully participate in the development of the Joint Crisis Plans.
4. Primary diagnosis of psychosis
5. 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

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

Date of first enrolment
01/10/2009

Date of final enrolment
01/11/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sir David Goldberg Building
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Sponsor information

Organisation
King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (UK) (ref: G0701752; grant ID: 85397)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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	01/05/2013		Yes	No
Protocol article	protocol	23/02/2010		Yes	No