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Enhancing the quality of user involved care planning in mental health services (EQUIP)

Submission date
14/05/2014

Recruitment status
No longer recruiting

Registration date
14/05/2014

Overall study status
Completed

Last Edited
14/02/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Care planning has been defined as finding out what a person's care needs are and then deciding what services can best help them. It sets out what support a person should get, why, when, and details of who is meant to provide it. Despite general agreement that involving users and carers in care planning is fundamental to improving quality of care and promoting recovery, there is evidence that this does not always occur. Users of mental health services (and their carers) say that they feel excluded and unsupported by services and want to be more involved in their care, but research tells us that this is not happening. Our research wants to improve user/carer involvement in care planning in mental health services. We have developed a training package for professionals which has been developed by and will be delivered by users/carers, researchers and health professionals. We will use this package to train health professionals in some community mental health teams and not do the training in others (chosen by chance). This is called a randomised clinical trial, and means we can then compare the sites and see if the training leads to better involvement of users and carers in their care plan. We can also see whether the benefits outweigh the costs. The training will be offered in up to ten mental health trusts. We also want to find out what organisational changes need to be made by community mental health teams and the wider NHS to improve user and carer involved care planning. We will do this by talking to and observing users, carers, health professionals and managers to find out what helps and what does not help. This is called a process evaluation. We will also test a new instrument to measure the extent of user and carer involvement in their care planning.

Who can participate?
All community mental health teams (and health professionals therein) within the participating mental health trusts will be eligible.

What does the study involve?
Community mental health teams will be randomly allocated to receive the user/carer-led training package in care planning or to continue with usual practice. We will obtain lists of service users from community mental health teams before randomly allocating the teams to the training intervention or usual practice. Around the same time (but before the training intervention has occurred), the service users will be contacted (using the lists provided), consent obtained and initial assessments undertaken. This is to ensure that there is a maximum period of

time between the initial assessment and the 6-month follow-up assessment. The initial assessment will therefore be scheduled to be undertaken as close to the training (intervention) as possible and will occur in a maximum 6-week period before the community mental health teams being trained. Service users will be followed up 6 months after the initial assessment point, aiming for follow-up assessments within 4 weeks of the 6-month deadline.

What are the possible benefits and risks of participating?
There is a potential for benefit to participants in the intervention group if the training is found to be successful. In addition, this research is important because it provides an opportunity to make a quality improvement across mental health services; such a quality improvement has the potential to be translated over both mental and physical care settings and hence benefit many thousands of patients. Taking part in the clinical study and being involved in the process evaluation are not considered as high risk for participants but there is always a risk that service users/carers may become distressed when thinking or talking about difficult personal experiences. With any questionnaire or interview, it is always possible that respondents may find some of the questions sensitive in nature. However, the majority of questionnaires to be used are validated questionnaires that have been used in previous research studies and remaining questionnaires and methods for the process evaluation have been developed and discussed with our user and carer group. If patients find any element of the data collection inappropriate, they will have the option to leave items blank in the questionnaires or not answer questions during the interviews. Information sheets will detail that participants do not have to complete any element of the study and that they are free to withdraw from the study at any time. In an attempt to minimise the risks of distress, sources of further support will be provided at the end of the questionnaires and interviews (if necessary) to ensure that participants have access to a source of support should they require it. This information will also be provided in participant information sheets.

Where is the study run from?
The study is led by the following centres in the UK:
1. Manchester Mental Health & Social Care Trust & University of Manchester
2. Nottinghamshire Healthcare Trust & University of Nottingham
The training is also being offered in up to 8 additional mental health trusts in England.

When is the study starting and how long is it expected to run for?
The study will start in June 2014 and will run until December 2016.

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

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name

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Protocol serial number
16685

Study information

Scientific Title
Enhancing the quality of user involved care planning in mental health services (EQUIP): clinical randomised controlled trial and process evaluation - cluster cohort randomised controlled trial

Acronym
EQUIP

Study objectives
Current hypothesis as of 01/06/2015:
To determine the effectiveness and cost effectiveness of a new user led training package to increase user and carer involvement in care planning for service users with severe mental illness under the care of community mental health teams and their carers.

Previous hypothesis:
To determine the effectiveness and cost effectiveness of a new user led training package to

increase user and carer involvement in care planning for service users with severe mental illness under the care of community mental health teams and rehabilitation inpatient facilities and their carers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC; 08/05/2014; 14/NW/0297

Study design
Randomised; Interventional; Design type: Process of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Service Delivery; Disease: Not Applicable

Interventions
Current interventions as of 01/06/2015:
The basic design will involve a conventional cluster cohort. We will randomise community mental health teams to either the intervention (training in care planning) or to the control (no training in care planning). We will recruit service users cared for by each community team and conduct a detailed face to face assessment at baseline. We will then train the teams randomised to the intervention in care planning, and then conduct another detailed face to face assessment with the same service users six months after baseline.

The design will also include a 'cluster cross sectional' element. Six months after cluster randomisation of the facility, we will seek to collect data on ALL service users under the care of all community teams who are not part of the cluster cohort, using a simple postal questionnaire. The mixed design has a number of advantages. The 'cluster cohort' design allows us to take into account the individual participant characteristics at baseline (e.g. gender, age etc.), giving increased statistical power. However, the design may be vulnerable to drop out (i.e. service users may not return assessments at the 6-month follow-up), which may be an important factor with this client group. The 'cluster cross-sectional' design can help to avoid these problems with participants dropping out because participants only fill in one survey at one point in time (e.g. 6 months post randomisation). The adoption of a postal survey will also potentially allow us to assess the outcomes of a larger group of service users, which has the potential to make the study more statistically valid. However, we will need more participants to complete the study because this survey will only be conducted at one time point (6 months after the intervention).

Previous interventions:
The basic design will involve a conventional 'cluster cohort'. We will randomise community teams and rehabilitation inpatient facilities to either the intervention (training in care planning) or to the control (no training in care planning). We will recruit service users cared for by each community team or rehabilitation inpatient facility, and conduct a detailed face to face assessment at baseline. We will then train the community teams and rehabilitation inpatient

facilities randomised to the intervention in care planning, and then conduct another detailed face to face assessment with the same service users six months after baseline.

The design will also include a 'cluster cross sectional' element. Six months after cluster randomisation of the facility, we will seek to collect data on ALL service users under the care of all community teams and rehabilitation inpatient facilities who are not part of the 'cluster cohort', using a simple postal questionnaire. The mixed design has a number of advantages. The 'cluster cohort' design allows us to take into account the individual participant characteristics at baseline (e.g. gender, age etc.), giving increased statistical power. However, the design may be vulnerable to drop out (i.e. service users may not return assessments at the 6-month follow-up), which may be an important factor with this client group. The 'cluster cross-sectional' design can help to avoid these problems with participants dropping out because participants only fill in one survey at one point in time (e.g. 6 months post randomisation). The adoption of a postal survey will also potentially allow us to assess the outcomes of a larger group of service users, which has the potential to make the study more statistically valid. However, we will need more participants to complete the study because this survey will only be conducted at one time point (6 months after the intervention).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The Health Care Climate Questionnaire (HCCQ-10, Ludman et al., 2002); timepoint(s): baseline and follow-up 6 months later

Key secondary outcome(s))
1. A measure of health service contacts (service use questionnaire); timepoint(s): baseline and 6 months follow-up
2. California Psychotherapy Alliance Scale (CALPAS - Gaston and Marmar 1994); timepoint(s): baseline and follow-up at 6 months
3. Carers and Users' Expectations of Services - carer version (CUES-C, Lelliott et al., 1999); timepoint(s): baseline and follow-up at 6 months
4. Developing Recovery Enhancing Environments Measure (DREEM - Ridway and Press 2004); timepoint(s): baseline and follow-up at 6 months
5. Glasgow Antipsychotic Side-effect Scale (GASS - Waddell and Taylor 2008); timepoint(s): baseline and follow-up at 6 months
6. Hospital Anxiety and Depression Scale (HADS, Zigmond and Snaith 1983); timepoint(s): baseline and follow-up at 6 months
7. PROM (User Carer involvement in care planning); timepoint(s): baseline and follow-up at 6 months
8. The EQ-5D-5L (Janssen et al., 2012); timepoint(s): baseline and 6 months follow-up
9. Verona service satisfaction scale (VSSS - EU-54, Ruggeri and Dall'Agnola (1993)); timepoint(s): baseline and follow-up at 6 months
10. Warwick Edinburgh Mental Wellbeing Scale (WEMWBS -Tennant et al., 2007); timepoint(s): baseline and follow-up at 6 months
11. World Health Organisation Quality of Life (WHOQOL-BREF - WHO 2004); timepoint(s): baseline and follow-up at 6 months

Completion date
31/12/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 01/06/2015:
All community mental health teams (and health professionals therein) within the 10 mental health trust locations will be eligible for inclusion.
Service users aged 18 and over with a severe mental illness (e.g., psychosis, manic depressive illness) under the care of participating community mental health teams will be eligible for inclusion for both the cluster cohort sample and cluster cross sectional sample. However, those who participate in the cluster cohort sample will not be eligible to also take part in the cluster cross sectional sample.
Service users will be asked at the point of consent to identify a carer that might be willing to be included in the study. All carers over the age of 18 will be eligible for inclusion in the cluster cohort study. All service users and carers who consent to the cluster cohort study will be eligible to take part in the process evaluation. All professionals in the relevant community mental health teams will be eligible to take part in the process evaluation.

Previous inclusion criteria:
All community teams and rehabilitation inpatient facilities (and health professionals therein) within the Manchester and Nottingham locations will be eligible for inclusion.
Service users aged 18 and over with a severe mental illness (e.g., psychosis, manic depressive illness) under the care of participating community teams and rehabilitation inpatient facilities will be eligible for inclusion for both the cluster cohort sample and cluster cross sectional sample. However, those who participate in the cluster cohort sample will not be eligible to also take part in the cluster cross sectional sample.
Service users will be asked at the point of consent to identify a carer that might be willing to be included in the study. All carers over the age of 18 will be eligible for inclusion in the cluster cohort study. All service users and carers who consent to the cluster cohort study will be eligible to take part in the process evaluation. All professionals in the relevant community teams and rehabilitation inpatient facilities will be eligible to take part in the process evaluation.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

Current exclusion criteria as of 01/06/2015:
Service users will be excluded if their participation is judged as inappropriate by clinical staff within the relevant community mental health teams . The principal exclusion criteria will be an inability to provide informed consent. We will seek to document all exclusions and report them as part of the trial CONSORT diagram.

Previous exclusion criteria:
Service users will be excluded if their participation is judged as inappropriate by clinical staff within the relevant community teams and rehabilitation inpatient facilities. The principal exclusion criteria will be an inability to provide informed consent. We will seek to document all exclusions and report them as part of the trial CONSORT diagram.

Date of first enrolment
30/07/2014

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Manchester
Manchester
United Kingdom
M13 9PL

Study participating centre
The University of Nottingham
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Manchester Mental Health & Social Care Trust (UK)

Funder(s)

Funder type
Government

Funder Name
NIHR Programme Grants for Applied Research; Grant Codes: RP-PG-1210-12007

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	11/12/2014		Yes	No
Results article	results	01/08/2015		Yes	No
Results article	results	13/08/2015		Yes	No
Results article	results	29/08/2015		Yes	No
Results article	results	30/10/2015		Yes	No
Results article	results	01/12/2015		Yes	No
Results article	results	01/02/2016		Yes	No
Results article	results	10/03/2016		Yes	No
Results article	results	08/12/2016		Yes	No
Results article	results	09/12/2016		Yes	No
Results article	results	01/08/2017		Yes	No
Results article	results	01/08/2017		Yes	No
Results article	results	01/06/2018		Yes	No
Protocol article	protocol	13/08/2015		Yes	No
Basic results		11/01/2018	14/02/2018	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes