Research programme aims and objectives

Aim

The overall aim of the programme grant is to improve user and carer involvement in care planning in mental health services.

Major objectives

· To develop, evaluate, implement and disseminate a user/carer-led training package for mental health professionals to improve the extent users and carers are involved in care planning.

· To develop and validate a patient reported outcome measure (PROM) to assess improvements in user/carer involvement

· To assess the clinical and cost effectiveness, feasibility and acceptability of this training package using a cluster randomised clinical control trial design.

· To identify the individual and organisational barriers and facilitators to implementing effective user and carer involvement in care planning.

· To use a multifaceted approach to comprehensively disseminate our findings. These

objectives are covered by four work streams incorporating seven studies.

This protocol is for work stream 2, study 5 which is the clinical randomised control trial (CRCT) and work stream 3, study 7 which is the process evaluation of the trial.

Work stream 1 (Studies 1-4)

Develop a user/carer led training programme for mental health professionals and a measure of user/carer involvement in care planning.

Work stream 2 (Study 5)

Evaluate the efficacy and cost effectiveness of user/carer involved care planning

Work stream 3 (Studies 6 -7)

Implement user/carer involved care planning by understanding the individual and organisational barriers and facilitators and examine the processes involved in the development and use of user/carer involved care planning.

Work stream 4

Disseminate user / carer involved training materials and resources for health professionals and users and carers of mental health services.

Background

Involving service users in their care and providing choice is at the centre of policy initiatives aimed at improving quality of care. This principle is enshrined and prioritised in healthcare particularly mental health care policy and guidelines. There is a wealth of evidence that users and carers want significantly more involvement in the care planning process. However there is substantial empirical evidence that the majority of users and carers are marginalised in the care planning process.

Importance of proposed research

This research is important because it provides an opportunity to make a quality improvement in mental health services which involves users and carers as co-producers of health care. Of importance is that such a quality improvement has the potential to be translated over both mental health and physical care settings and hence benefit many thousands of service users

Research team

Our team is multidisciplinary with significant content, methodological, clinical, academic, lived experience and educational expertise.

Research environment

The research will be undertaken in NHS settings (Manchester Mental Health and Social Care Trust and Nottinghamshire Healthcare NHS Trust, South West Yorkshire Partnership NHS Foundation Trust , Leicestershire Partnership NHT Trust) in collaboration with the Universities of Manchester and Nottingham.

Outputs and impact

The outputs and impact of this programme grant have the potential to be substantial. We will have developed and delivered in partnership with users and carers a training programme to improve user and carer involvement in care planning. A user/carer patient reported outcome measure (PROM) will be developed and validated. We will know the effectiveness and cost effectiveness of user and carer involved care planning. We will have developed implementation guidelines based on our findings of the organisational and individual facilitators and barriers to user and carer involved care planning. We will develop tools to disseminate findings from the projects, including a care planning audit tool, user and carer materials for users and carers to empower them to facilitate change, and training materials which can be used across mental health services. We will offer these materials to up to ten NHS mental health trusts and advise on improving user and carer involved care planning.

Research governance

The programme management group will meet every three months to discuss the progression and day to day management issues of the programme grant and will include the chief investigator (CI), all other investigators, and programme managers (PM). The CI will be responsible for the overall leadership, management and outputs of the programme. Each work stream will be led by a named work stream lead. The CI will maintain a log of the key milestones to be achieved against the timetable. Progress of these milestones and corresponding timetable will be reported at management meetings to ensure progression of the programme and to agree corrective action if necessary. The PMs will be responsible for the day to day running

and coordination of the programme and will be accountable to the CI. All research associates will be supervised by stream leads and overseen by the CI and site PIs.

Programme Steering Committee

A programme steering committee (PSC) has been established and comprises an independent chair who has expertise in programme grants and care planning and three other independent members including a user representative who has had lived experience, a carer and a clinician who has expertise and experience of working in community teams. The composition of the PSC was agreed by the National Institute for Health Research (NIHR).

A full risk assessment of the programme has been conducted by the CI and PM. A risk register has been developed and potential risks of the study identified to enable any necessary mitigating actions to take place. A RAG rated system (Red, Amber, Green) is in place (in addition to a matrix measuring each risk on likelihood of risk occurring (low/medium/high) and impact if risk did occur. The risk register is managed and monitored by the PM and CI and is a standing agenda item at each programme management meeting.

Sponsorship

Manchester Mental Health and Social Care Trust is the sponsor.

Service user and carer involvement

We have extensive user and carer involvement. Within our NIHR funded programme development grant we argued that it was difficult for both users and carers and academics to work meaningfully together as users and carers were unfamiliar with research methods and concepts. To overcome this we ran a successful six day interactive research methods course which resulted in positive feedback from users and carers. Many of the applicants were responsible for teaching their areas of expertise (e.g. Professor Anne Rogers – qualitative research; Professor Linda Davies – health economics; Professor Peter Bower - literature searching and trial design). We taught the course at a similar level to our MRes but worked in small groups with up to three facilitators. The course was devised and led by Dr Baker (Co-Investigator)

and Professor Lovell (CI). The course has been cited by the Mental Health Research Network (MHRN) as an exemplar of good practice. In addition we ran a half day workshop explaining the nature of programme grants and shared our thoughts on the proposed grant and obtained helpful feedback. A full day meeting of users and carers and the trial team was conducted to determine the measures for the evaluation phase.

We have identified a range of roles for the service users and carers who have participated in the programme development grant. We have a large advisory group (n=16) of users and carers, and two service users and one carer are formal co-applicants and have worked with the research team to co-facilitate focus groups and interviews during EQUIP studies 1 and 2. One further service user is also a member of the programme steering committee. Users and carers will be participating in the overall management of the research, in developing participant information resources, undertaking and analysing the research, contributing to the reporting of the study report and in the dissemination of research findings.

Personnel

The team is multidisciplinary with appropriate clinical, educational, methodological and service delivery expertise, supported by those with lived experience of mental illness and its management.

Chief Investigator:	Professor Karina Lovell
Work stream 2 Lead:	Professor Pete Bower
Work stream 3 Lead:	Professor Anne Rogers
Site leads:	Professor Karina Lovell (University of Manchester)
Professor Patrick Callaghan (University of Nottingham)	
Co-applicants:	John Baker, Penny Bee, Patrick Cahoon, Lindsey Cree, Linda Davies, Richard Drake, Andrew Grundy, Chris Roberts, Anne Rogers, Anita Rolfe, Caroline Sanders, Lauren Walker
Programme managers:	Kathryn Berzins and Claire Fraser
Research team:	Susan Beatty, Helen Brooks, Chris Gibbons, Matthew Hamilton, Oonagh Meade, Neil O'Leary, Nicola Olleveant, Rebecca Pedley
Trainers:	Deborah Bhatti, Debbie Butler, Donna More

This protocol is a combined document for work stream 2, study 5 which is the clinical cluster randomised controlled trial and work stream 3, study 7 which is the process evaluation of the trial. The remaining protocol will discuss each study separately under each heading for clarity.

Aims

Work stream 2 (Months 18-48)

The aim of this work package is to evaluate the efficacy and cost effectiveness of a user/carer involved training package developed earlier in the programme grant.

This aim will be achieved through the undertaking of study 5.

Study 5

a) To determine if a user/carer led training package is effective in increasing user/carer involvement in care planning and improving health outcomes for service users with severe mental illness under the care of community teams.
b) To determine if a user/carer led training package is cost-effective in improving short term health outcomes for service users with severe mental illness under the care of community teams.

Work stream 3 (Months 0-48)

The aim of this work package is to understand professionals' and users/carer perspectives about the factors that inhibit or promote user involvement and the integration of care planning into clinical settings. Furthermore, the package will investigate the impact of the training package to enhance user involvement in care planning.

The aim will be achieved through the undertaking of two studies (study 6 and 7):

Study 6

Conduct a mapping exercise in organisational structures and policies related to care planning which is reviewed and updated over the course of the project (approved by Manchester University Research Ethics Committee ref: 13304).

Study 7:

The aims of this study are to examine: (i) how user/carer involved care planning training and its principles impacts on and is incorporated into existing routine clinical practices; (ii) how care planning affects the way in which professionals relate to, communicate with and negotiate therapeutic options with users; (iii) how the new care planning training and arrangements impact on existing methods of coping, self-care and the development of service user expertise and how it shapes and transforms relationships between service users and professionals; (iv) the impact on networks, a sense of control, security and identity compared to previous care planning practices;

i) service users' perceptions of their preparation and support in relation to engaging with the form and content of the new system of care planning and its benefits and use .

The objectives are to examine:

i) How training for user involved care planning and its principles impacts on and is incorporated into existing routine clinical practices;

ii) How care planning affects the way in which professionals relate to, communicate with and negotiate therapeutic options with users;

iii) How the new care planning training and arrangements impact on existing methods of coping, self-care and the development of service user expertise and how it shapes and transforms relationships between service users and professionals;

iv) The impact of training on service users' perceptions of networks, a sense of control, security and identity compared to previous care planning practices;

v) Service users' perceptions of their preparation and support in relation to engaging with the form and content of the new system of care planning.

Background

Study 5

The full programme grant application describes the background to the need for the programme as emanating from the observation of the increased importance being attributed to involving service users in their care, whilst at the same time the majority of service users and carers still feeling marginalised in the care planning process. There is evidence that service users and carers want significantly more involvement in the care planning process, but this is not always achieved.[92] There are inconsistencies in practice, and embedded within this

there is poor communication.[1] Compounding these problems, there are also problems with the quality of the relationships with and between professionals at all levels.[93,94]

This research is important because it seeks to develop a standardised training package to achieve better care planning, and to test the efficacy and cost effectiveness of this package. It will provide an opportunity to improve the quality of mental health care across community and rehabilitation inpatient mental health services.

Study 7

A process evaluation of the training programme delivered as part of the trial is deemed appropriate because successful implementation of the user/carer led care planning implicates a range of factors including the integrity of the intervention and the acceptability of the intervention to both clinicians and service users. [73] This current study is designed to explore how far the user/carer led care planning has been taken up by and implemented in the daily work of the health professionals who attended the training and what the consequences of this uptake has been. It will complement and supplement the evidence provided by the main randomised trial (as recommended by the MRC framework for evaluation of complex intervention).[74]

Where results from the trial are positive, the process evaluation will consider the conditions, mechanisms and processes that gave rise to this success to help translation into other areas. Conversely, if findings are negative or inconclusive, the process evaluation can examine the sources or barriers to implementation and consider why these negative results are observed.

Method

Study 5

Study Design

The study will adopt a cluster randomised trial design. The training package will be delivered to clinical staff working in community teams. A cluster design is required to avoid contamination.

We will adopt a mixed design, including both a 'cluster cohort' design, and a 'cluster cross sectional' design (see Figure 1 for an outline of the design, and Figure 2 for the CONSORT flow diagram).

In the 'cluster cohort' design, we will recruit service users cared for by each community team and conduct a detailed face-to-face assessment at baseline. Each community team will then be randomised to either intervention (training in care planning) or control (usual care planning). We will then train the intervention community teams in care planning, and conduct another detailed face to face assessment with the same service users 6 months after the baseline assessment.

The design will also include a 'cluster cross sectional' element. Six months after randomisation, we will distribute a questionnaire to all service users who are not part of the 'cluster cohort' but who are under the care of all community teams using a simple postal questionnaire.

The advantages of the design are outlined in Box 1.

Box 1 Advantages of the mixed design

The 'cluster cohort' design allows more accurate adjustment for baseline characteristics at an individual level, giving increased statistical power.

However, for the cluster cohort, service users need to participate in two relatively long face to face assessments, which may be burdensome to service users or difficult to organise if people move often. This means the cluster cohort may be vulnerable to recruitment issues (where only a small number of eligible service users take part) and attrition (i.e. where service users do not attend for follow-up), both reducing external validity.

The 'cluster cross-sectional' design can help ameliorate these problems. Service users only have to agree to assessment once, and the assessment is designed to be less burdensome as it includes fewer measures. This means that a higher proportion of patients may agree to take part and be retained in the study, potentially increasing the sample size and the external validity of the results. However, it will tend to have less power due to the reduced ability for baseline adjustment. We will sample a proportion of eligible service users for the 'cluster cross-sectional' design to reduce cost and administrative burden.

Adoption of the combined design provides protection against problems in either of the individual approaches.

A potential threat to the validity of a cluster randomised trial is recruitment bias, where professionals allocated to different trial arms recruit differently depending on their allocation, leading to selection bias and baseline incomparability. [95] Whilst it is preferable to recruit patients prior to allocation, the logistics of the trial means that clusters will need advance notice of their training date, which will require us to inform them of their allocation. However, initial patient selection in the EQUIP trial is not by professional referral, but will use existing registers of patients. This will be undertaken by the Mental Health Research Network (MHRN), Clinical Studies Officer (CSO). This will limit the ability of professionals to influence recruitment, as their only impact will be to exclude patients. We will stress the importance of including all eligible patients, provide guidance on exclusion criteria and report details of all exclusions by trial arm in the study report.

Once service users have been recruited, the clusters will be allocated randomly to either intervention or control. To reduce selection bias, allocation will be determined through an external telephone randomisation service at the Clinical Trials Unit of the Manchester Academic Health Science Centre. Clusters will be submitted to the randomisation service in pairs. Each pair will be from the same site (Manchester/Nottingham/SW Yorkshire/Leicestershire) and similarly matched in other characteristics where possible. One member of the pair will be allocated to intervention by random selection, the other allocated to control. To reduce detection bias, we will seek to blind researchers undertaking assessments of the quality of care planning to the group to which clusters have been allocated. We will report the success or otherwise of our attempts at blinding.

Service user/carer consent

Participants in randomised trials usually provide written informed consent for a range of research procedures, including participation in the trial, randomisation and data collection.

However, conventional informed consent procedures are not always appropriate in the context of a cluster, randomised trial.[96] In the EQUIP trial, community mental health services and their constituent community teams are making the decision to take part in the EQUIP trial and agree to randomised allocation. This is described as a 'cluster cluster' design, and is distinguished from an 'individual cluster' design.[97] In the latter, randomisation is at the level of the cluster, but specific services are delivered to individuals, and service users can

consent to receive or not receive that intervention. Our recent CADET trial was an example of an individual cluster design.[98] In 'cluster' designs such as EQUIP, service users cannot opt out of a cluster in the same way, as the community teams will have been trained in the new methods. Our recent WISE study was an example of this design.[99]

Not all cluster randomised trials seek individual patient consent.[100] In the EQUIP trial, seeking formal consent for participation and randomisation may be inappropriate, as these processes are not under control of the service users. Therefore, we seek to adopt the following consent procedures.

Service managers and staff will act as 'ethical guardians' for their service users. If the service, and the community teams consent to take part in the trial, then individual service users will not be asked for specific consent to be randomised as part of the EQUIP trial. Service users cannot therefore 'opt out' of their cluster allocation. The Mental Health Research Network (MHRN), Clinical Studies Officers (CSOs) will be responsible for accessing patient details and determining who is eligible to take part in the study and be contacted. They will be responsible for sending out information about the study to the identified service users, along with an invitation to participate. The research team will not have access to service user details until they have returned the consent to contact form.

Service users in the 'cluster cohort' will undertake a detailed face to face assessment at two points in time (baseline and 6 months). For these, we will adopt a formal written consent procedure. We will explain to service users that their community teams are involved in a study to test the effectiveness of a new training package on service user/carer involvement in care planning compared to the usual care planning experience. Participants will be told that we will do this by delivering the training to some mental health teams and not to other teams to see if receiving the training has an impact on the extent of service user/carer involvement in care planning.

Carers in the 'cluster cohort' will undertake a postal survey at baseline and at six months. Carers will be asked to participate via nomination by a service user. Response to the questionnaires will be treated as consent. Carers will also be asked to complete a baseline questionnaire and a consent to contact form in six months to allow the follow up questionnaire to be completed which is returnable to the research team in the prepaid envelope provided.

Service users in the 'cross sectional sample' will undertake a short postal survey at six months only. For these, we will treat this part of the study as a survey. Service users will receive a postal invitation to the survey, seeking their views on the quality of the care planning process that they have received. Response to the survey will be treated as consent, as is usual in survey work. Respondents will receive a £5 voucher for completing the survey. A follow up letter may be sent to encourage responses.

We have utilised these procedures in a previous, similar study conducted as part of another NIHR programme grant (RP-PG-0407-10136, ethical approval Salford and Trafford, 09/H1004/6 Amendment 3).

The study will be registered on a public database prior to recruitment of patients and will receive an appropriate ISRCTN.

Figure 1 EQUIP cluster randomised trial design

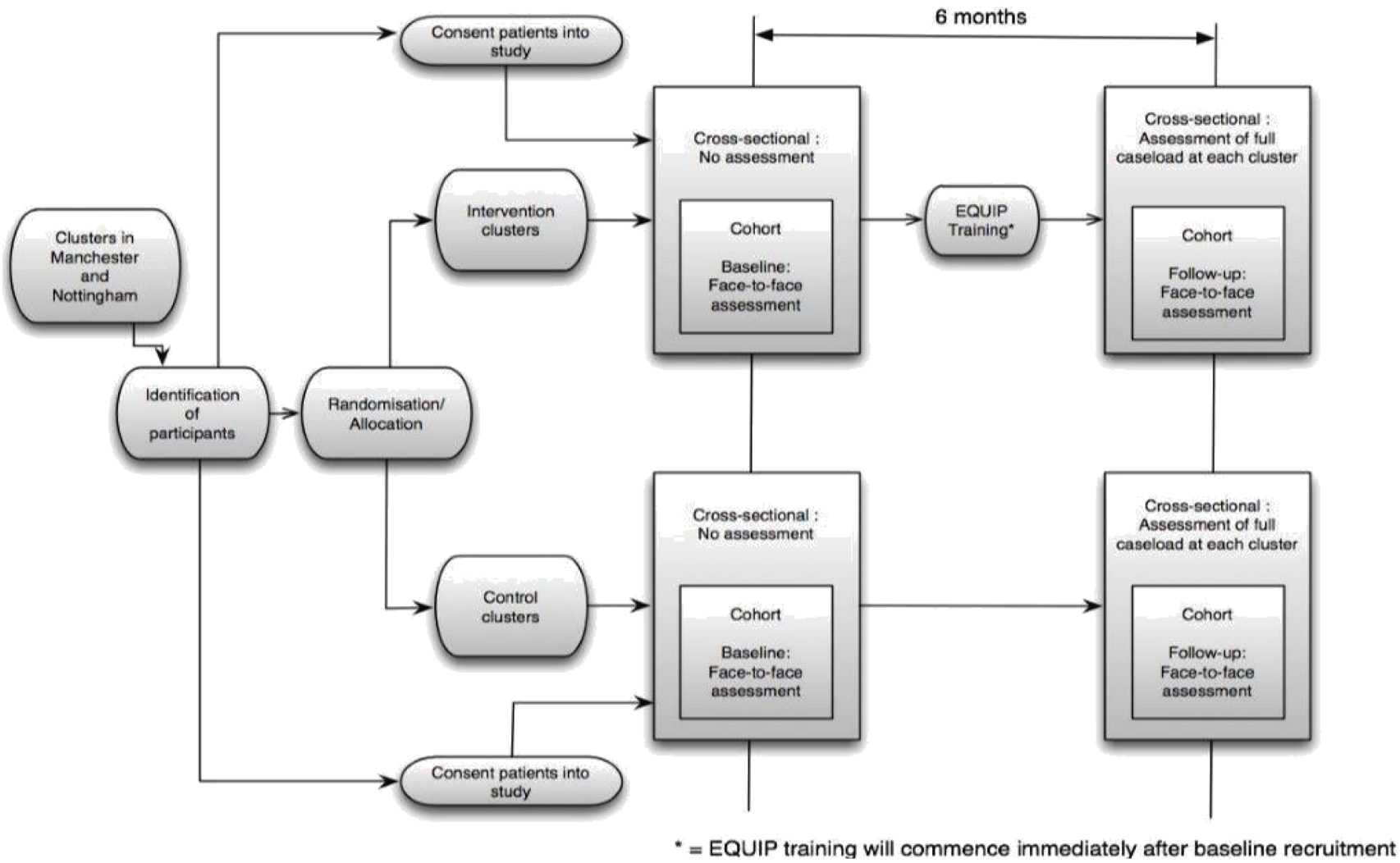
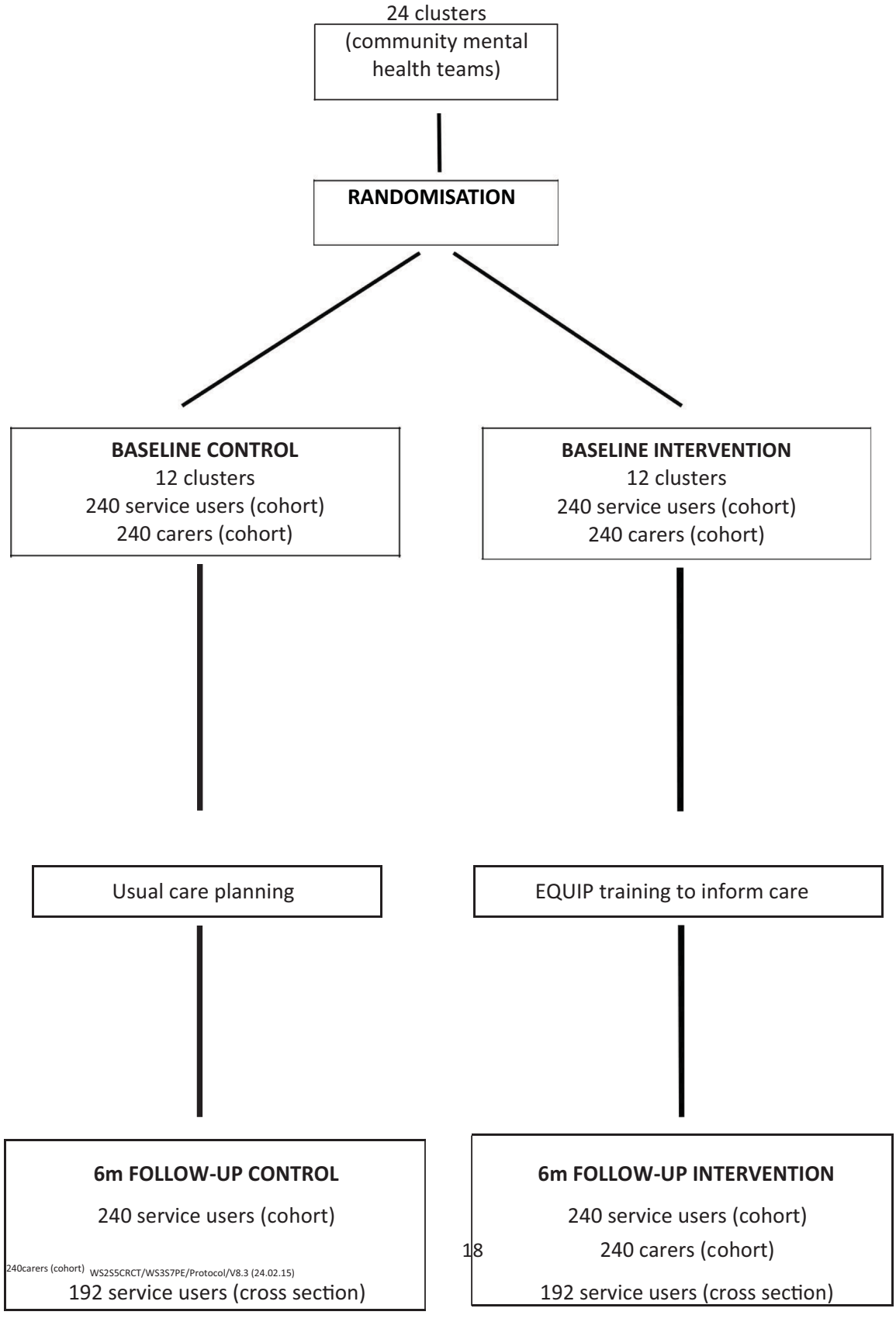


Figure 2 EQUIP CONSORT Flow Diagram



Study 7:

Study Design

The study will involve a qualitative process evaluation exploring embedding and implementation nested within the trial (work stream 2, study 5) using multiple qualitative methods comprising:

- Semi-structured in-depth interviews with professionals, service users, carers at multiple time-points;
- Observation of how service users and staff approach, adopt and use the new user/carer involved care planning;
- Diary records of user and carer experiences, practices and uses of care planning;
- Social network approach to explore the role of social networks in care planning and the impact of user/carer involved care planning on these networks and network dynamics and access to new resources.

In-depth and network interviews

Service users: Service users (15-20) (and where possible carers 5-10) in the intervention cluster will be interviewed prior to the introduction of the care planning training and at two subsequent time-points in order to capture processes and change (6 and 12 months).[101] This is important because our previous work indicates that the introduction and incorporation of new practices can be initially disruptive followed by a period of re-adjustment.[102,103] The interviews will explore the experience of care planning and everyday management of mental health problems for service users, the nature of interaction with staff and the degree to which care planning is viewed/ experienced as empowering or constraining in relation to previous systems of care planning. We will also interview up to 10 service users in the control arm of the study at the time points detailed above to compare the findings with the intervention arm.

Service users will also be asked to complete a social network diagram relating to the members who are perceived to input into care planning and this will be redone at subsequent follow up interviews to investigate changes in networks. The network

approach to be undertaken will follow personal network 'concentric circles' method.[104] Participants will be presented with a diagram containing three concentric circles. They will be asked to place those people or places they consider most important in relation to care planning in the central circle, those considered important but not as important as those in the central circle in the middle circle and those who they consider important but not as important as those in the central two circles in the outer circle. Network members can include any sources of support including family, friends, health professionals, pets, community groups, internet support groups etc. We will draw on a method we have used previously whereby after individuals plot their networks, questions will be asked about the role of these individual network members in relation to care planning. The broad focus will explore which relationships are most important to care planning, the relationships that develop as part of care planning involvement over time, resource access and the wider role of social networks and relationships in relation to care planning.

Service users will be told that the interviewer does not know which arms of the study their care team was in and not to mention individual practitioner or team names when completing the network diagram to reduce the likelihood of unblinding the researcher as to group allocation.

Professionals: Staff in the intervention cluster (15-20) will be interviewed prior to the introduction of the care planning training and at two subsequent time-points in order to capture processes and change. Interviews with professionals will focus on their views, expectations and experiences of care planning training within the broader contextual issues regarding the organisation and delivery of care for people with severe mental illness. They will be asked to reflect on professional experience of barriers and enablers for high quality care. They will be prompted to draw on examples from clinical practice in order to illustrate views and experiences. Similar work has been undertaken in other illness areas.[105] We will also interview up to 10 staff members in the control arm of the study at the time points detailed above.

Observation

The inclusion of an ethnographic approach is relevant for studying complex care trajectories and for key consultations.[106] Structured observational methods will be used to focus on professional and service user/carer interactions

with professionals in care planning meetings. Observation will include attention to how the system fits into the everyday routines of management and care practices for service users and professionals. We will also spend at least one day shadowing each of the community teams or inpatient facilities in the study in order to observe how information is introduced interpreted and responded to, and to observe the impact of the training on clinical encounters.

Diaries

This method is designed to capture salient moments in the use of new practices (e.g. difficulties or when aspects of the care plan were particularly useful). A number of studies have highlighted the utility of diaries for recording change in experience and management of long term conditions including mental health and voice diaries have been successfully used. Service user participants will be offered a choice of format (written or audio), and the frequency of diary entries will be flexible to ensure people are not over-burdened.

Study setting and sample size

Study 5

Recruitment and randomisation of community teams and rehabilitation inpatient facilities

Twenty four community teams will be recruited, from several different geographical areas (Manchester, Nottingham, South West Yorkshire and Leicestershire). All community teams in each geographical area will be eligible for inclusion. Community teams will be randomly allocated to receive the user/carer-led training package in care planning or to continue with usual practice.

Recruitment and training will be undertaken in sequence, to maximise efficiency in delivery of training to community teams, but also to ensure there is sufficient time to permit the relevant baseline assessments to be undertaken with service users, cared for by each community team.

We will obtain lists of service users from community teams and then the teams (clusters) will be randomised. Around the same time as randomisation (but before

the training intervention has occurred), the service users will be contacted by postal invite with one follow up phone call (using the lists provided), consent obtained and baseline assessments undertaken. This is to ensure that there is a maximum period of time between the baseline assessment and the six month follow up assessment. The baseline assessment will therefore be scheduled to be undertaken as close to the training (intervention) as possible and will occur in a maximum six week period prior to the community teams being trained. Service users will be followed up six months from the baseline assessment point, aiming for follow-up assessments within two weeks of the six month deadline.

Recruitment of professionals in community teams

Trust managers have agreed that we can recruit all community teams. To recruit professionals we will use our applicants to champion the study (Drake, Rolfe, Lovell and Callaghan). Teams will be introduced to the trial via a letter of support from the Chief Executive, and/or via meetings with senior managers attended by the CI and PM. Meetings will also be held with area team managers (and if requested, staff) across both sites to facilitate engagement with and understanding of the trial.

Recruitment of service users/carers

To recruit service users in the 'cluster cohort', the direct care team within the community team (cluster) will produce a list of all patients who meet eligibility to participate in the trial, including any reasons for exclusions. This will be referred to as a list of their 'caseload'. These patient lists will be used by the MHRN CSO (or admin support within the Trust) to send out an introductory letter, participant information sheet and consent to contact form to each patient, inviting them to take part in the study. Patients will be required to 'opt in' by returning the consent to contact form in a pre-paid envelope to the research team. CSOs will contact non responders by telephone on one occasion to allow patients to opt in over the telephone. Some Trusts prefer that the initial distribution of introductory letter and participant information sheet and consent to contact form be carried out by a clinician during a routine meeting with the service user. Where this is the preferred approach, the clinician will introduce the study to the service user and give them the information pack. The clinician will discuss participation with the service user and if the service users wishes to be contacted by a university researcher to receive more information and discuss participation in the trial, the clinician will complete the

consent to contact form with the service user and pass it to the research team. This will be done by secure fax or over the telephone.

The research team will then follow up the consent to contact forms, to answer any further questions, and when a participant is recruited, the researcher will continue with a face to face informed consent process. Following signed consent, all baseline measures will be completed. In some sites CSO may be available to support with data collection. Where this is the case they will be trained by the research team with regard to collecting data and follow their own NHS Trust Lone Worker procedures.

Service users will be asked at the informed consent meeting to nominate a carer to be included in the study and if they choose to do so, will be provided with a questionnaire pack (including introductory letter, information sheet, questionnaire, pre-paid envelope and consent to contact at follow up form).

To recruit service users in the 'cluster cross sectional' study, we will conduct a postal survey of all service users under the care of each community teams six months after randomisation, excluding those already recruited to the 'cluster cohort'.

Sample size

The primary outcome is the HCCQ-10 (Health Care Climate Questionnaire) identified by our user consultation group as their preferred outcome measure. However, data on the use of this scale in service users with severe mental illness is limited, and so we have used a standardised effect to consider sample size and power. A trial with 12 clusters per arm and a mean of 20 service users per cluster is feasible within four sites (Manchester, Nottingham, South West Yorkshire and Leicestershire) combined for the cluster cohort component. This will result in a sample size of 480. A trial of this size will have power greater than 80% to detect a standardised effect size of 0.4 assuming an ICC of 0.05 and an 80% follow-up rate. Power will be increased by inclusion of baseline covariates. Additional data gathered in the cluster cross-sectional component should increase power for the corresponding analysis. We will aim to recruit the same sample size for the cross sectional survey with the same number of clusters and mean number of service users per cluster. We will assume a

loss to follow up rate of 20% for the cohort study so the sample size for the cross sectional study will be n=384 in order to be comparable to the cohort sample.

Mental Health professionals:

All mental health professionals (nurses, doctors, social care workers) and allied health professionals working in the identified community teams will be asked to participate. Maximising participation is important to ensure that all service users under the care of the community teams have the potential to benefit from the proposed training intervention. All consenting professionals allocated to the intervention group will receive user/carer-led training in care planning.

Service Users and Carers - cluster cohort study

All service users cared for by the participating community teams and meeting study inclusion criteria will be asked to participate in the 'cluster cohort' study. We aim to recruit 20 service users per cluster, with a minimum of 10 and maximum of 30.

All service users consenting to the study will be asked if there is a family member, friend or carer involved in their care. Identified carers of each service user will also be asked to participate. It is not clear how many service users in the study will have identified carers, but we will try to recruit all eligible carers (maximum of two carers per service user). The analysis of the trial is primarily focussed on the service users, and the carer data will be analysed separately.

Service Users - cluster cross-sectional study

All service users cared for by the participating community teams and meeting study inclusion criteria, who did not consent to the 'cluster cohort' study will receive a postal invitation to the survey. Three hundred and eighty four completed responses are required to give the same followed-up sample as the cluster cohort study (assuming 20% loss to follow-up rate). We will not include carers in the cluster cross sectional study.

Study 7

Semi-Structured In-Depth Interviews

Service users: A purposeful maximum variation strategy (Patton, 2001) will be deployed in order to select users from the caseload of staff teams to ensure a mix which accord to socio-demographic variables including age, socioeconomic status, diagnosis and gender. We will adopt a case study approach to follow approximately 15-20 service users and 5-10 carers over time. In addition, we will interview a number of service users (up to 10) who are not exposed to staff training in the control cluster in order to compare those in the experimental cluster.

Service users who consent to take part in the randomised control trial will be provided with an invitation letter, information sheet and consent to contact form relating to the process evaluation. If service users wish to take part they will complete the consent to contact form and return to the research team who will answer any questions and organise a time and date to take informed consent and undertake the baseline interviews.

Professionals: We will sample between 15-20 members of staff from community teams and in the intervention arm of the study involved in care planning for interview. We will distribute invitation letters, information sheets and consent to contact forms to all staff members within relevant community teams with support from the MHRN CSOs. If participants wish to take part they will complete and return the consent to contact form in the pre-paid envelope provided to the research team who will then telephone the participant to organise a time and date to take informed consent and undertake the baseline interviews. We will also interview 10 staff members from the control arm of the study.

Observation

Service users and professionals: Service users who consent to the semi-structured interviews within the process evaluation will be informed about the observation sessions and invited to participate. If they agree to participant, we will approach their care team to obtain consent from the other participants. It is envisaged that 10 observation sessions of care planning meetings will be undertaken. All relevant parties (service users and professionals) will need to consent in order for an observation session to be carried out. In addition, researchers will spend a day shadowing each of the community teams recruited into the study if they consent.

Diaries

Service users: A purposive sample of service users who consent to take part in the semi-structured interviews within the process evaluation will be invited to complete a diary. Participants will be offered both a written and audio version of the diary and the timing of diary recordings will be flexible to ensure participants do not become overburdened.

Inclusion criteria

Study 5

All community teams within Manchester and Nottingham, South West Yorkshire and Leicestershire 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 will be eligible for inclusion. We will seek consent from service users to access health records to collect data on diagnosis, service use and treatment history.

Service users will be excluded if their participation is judged as inappropriate by the community teams, for example, if a patient is not deemed to have capacity to provide fully informed consent. We will seek to document all exclusions and report them as part of the trial CONSORT diagram.

Any carer of the service user will be eligible for inclusion in the 'cluster cohort' study if they agree to take part. Consent will be implied by response via the return of the baseline questionnaires.

Study 7

All participants consented to the cluster cohort sample of the randomised control trial will be eligible to take part in the process evaluation.

Intervention Design

Study 5

Intervention – User/carer-led Training package to inform care planning

All consenting mental health professionals (nurses, doctors and allied health professionals), will receive the training intervention developed through work stream one designed to improve user involvement in care planning. The training intervention consists of two days training, e learning package and follow-up supervision. The development and content of the training intervention is detailed in a separate protocol (Training Protocol). We will document attendance at training by all professionals.

Training fidelity will be assessed by taking audio-recordings of training sessions if all participants consent. We will record as many sessions as teams consent to (from March 2015 onwards) and then, depending on the final number, sample them for analysis. We will develop a coding frame to measure adherence and competence. Adherence will be measured using our training manual and competence using other validated measures. Two independent coders to code these recordings and allow us to analyse the findings.

Comparator - Usual care

This will consist of 'usual practice' in care planning, without access to the specialist training described above. We will have considerable detail about what 'usual practice' consists of and how it varies from unit to unit from work stream three.

Study 7

N/A

Outcome Assessment

Study 5

Primary outcomes

The Health Care Climate Questionnaire (HCCQ-10)[46] is the primary outcome measure for the service users in the trial.

The HCCQ-10 was developed to assess patient experience of health care and the degree to which their care offers autonomous support. The scale has 10 items, which are scored on a 7-point scale ranging from 'strongly disagree' to 'strongly agree'. An overall score is calculated as the mean of the items (expressed out of 100), where a higher score indicates greater support for autonomy.

A new measure of user involvement in care planning (PROM) will be used as the primary outcome for the carers in the study (discussed in more detail in the next section).

Secondary outcomes

A new measure of user involvement in care planning (PROM) was developed in consultation with our user and carer advisory group during work stream one. The need for this measure was determined during the programme development grant as existing measures of user involvement were not deemed adequate by the advisory group. The newly developed PROM will be included as a secondary outcome to measure user and carer involvement in care planning. The new measure has excellent psychometric and scaling properties, by application to the Rasch model.[39]
The scale is suitable for both service users and carers. Items are scored on a 5-point Likert scale from 'Completely disagree' to 'Completely agree'. Higher scores will reflect greater service user and carer involvement with care planning. Data from this study will provide further evidence of the acceptability, validity and sensitivity to change of this measure for this population.

Secondary outcome measures were determined using experts and a consensus discussion exercise with the user/carer advisory group. Key domains to measure were recommended by the advisory group based on proposals from the NIHR Mental Health Research Network (2010). The seven domains identified were quality of life; alliance/engagement; satisfaction; wellbeing; mental health symptoms; recovery and hope; and medication side effects. Six of these domains have one questionnaire selected for completion, whilst the domain 'satisfaction' has separate questionnaires for both service users and carers.

Satisfaction (service users)

Verona service satisfaction scale (VSSS – EU-54)[47], is a
specific setting, validated, multi-dimensional, self-administered scale for measuring patients' satisfaction with mental health services. There are seven dimensions; overall satisfaction, professional skill and behaviour, access, efficacy, types of intervention and relatives involvement. Subjects are asked to express their overall feeling about their experience of the mental health service they have been attending in the last year. Satisfaction ratings are on a 5 point Likert scale, with higher scores representing greater satisfaction. Global and subscale scores can be obtained. Reliability testing has shown that the VASS-EU has good internal consistency and stability.[47]

Satisfaction (carers)

Carers and Users' Expectations of Services – carer version (CUES-C)[54] will be used to measure carers' views of services. This is a self-rating scale consisting of 13 items each with two parts (A and B), totalling 26 questions. All questions are answered using a three point scale. There are three parts to the questionnaire; part A measures the impact of caring, part B measures the quality of support provided by carers and part C is a free text response for advice and help. Scores for each part range from 0 to 26, with higher scores representing more dissatisfaction and the need for more support. The scale has been found to be suitable to use to assess carers experiences.[54]

Medication side effects

Glasgow Antipsychotic Side-effect Scale (GASS)[48] is a self-rating scale to detect the side effects of antipsychotic medication. The scale consists of 22 questions and scores range from 0 to 66. Higher scores reflect more frequent experience of side effects, with total scores providing three categories of severity (absent/mild side effects, moderate side effects and severe side effects).

Well-being

Warwick Edinburgh Mental Wellbeing Scale (WEMWBS)[49] is a short, psychometrically robust scale, which is easy to complete. It has 14 items scored on a 5-point Likert scale ranging from 'none of the time' to 'all of the time' based on experience over the past two weeks. Scores range from 14-70 and a higher score indicates a higher level of mental wellbeing.

Recovery and hope

Developing Recovery Enhancing Environments Measure (DREEM)[50] is a self-report measure used to assess mental health recovery of people who receive mental health services. It is a166-item questionnaire which is organised into 24 subscales (such as 'stage of recovery' and 'elements of recovery'), including a final section consisting of open ended questions. The scale is scored on a five-point Likert scale ranging from 'strongly agree' to 'strongly disagree', with low scores representing more positive experience. Dinniss et al (2007) found that DREEM was an effective and useful device for listening to the user voice.[107]

Mental health symptoms

Hospital Anxiety and Depression Scale (HADS)[51] is a 14 item scale using a four-point Likert scale. Items are added to give two scores, one for anxiety and one for depression, with higher scores representing more severe symptoms. Scores range from 0 to 21 for both anxiety and depression. This is a well-used and validated measure.[108]

Alliance/engagement

California Psychotherapy Alliance Scale (CALPAS)[52] is a 12-item, self-report questionnaire which provides a total score. It has four subscales: 'the patients capacity to work purposefully in therapy', 'the affective bond with the therapist', 'therapist's empathic understanding' and 'involvement and the agreement between the patient and therapist on the goals and tasks of treatment'. Each item is rated on a six-point Likert scale, with scores ranging from 12 to 84, with higher scores representing better alliance. It has good reliability and validity.[52]

Quality of life

World Health Organisation Quality of Life (WHOQOL-BREF) is a 26-item questionnaire consisting of four domains (physical, psychological, social relationships and environment). Each question uses a five point Likert scale, ranging from a score of one to five, with higher scores representing more positive ratings. Total scores are commuted within each domain. It has been shown to demonstrate good reliability and validity.[53]

Economic outcomes

Health Status

The EQ-5D-5L measure[109] will be used to asses health related quality of life for the economic analysis. The EQ-5D-5L, has two parts; part one, a five item questionnaire consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Each dimension has three levels, ranging from no problems to severe problems. The five dimensions can be combined to describe the respondents' health state. Part two is a VAS which records the respondents self-rated health on a vertical VAS scale, where the end points are labelled, 'best imaginable health state' and worst imaginable health state'.

This information is used as a quantitative measure of health outcome as judged by the individual respondents.

Service Use Questionnaire

A measure of health service contacts (service use questionnaire) is required to allow identification of service users in the intervention arm who have had contact with a trained worker. Although this will be used to assess receipt of the intervention and the causal pathway rather than cost per se, the measure will be derived from the economic analyses.

Allocation of outcome measures

Cohort Sample

Service Users:

- Demographic data will be collected at baseline.

1. Primary Outcome – The HCCQ will be administered to the cluster cohort sample at baseline and at the six month follow-up.

o Secondary Outcome – the following seven measures will be administered at baseline and six months: VSSS-54, GASS, WEMWBS, DREEM, HADS, CALPAS-12, WHOQOL-BREF, along with the PROM.

o Economic Outcome – the EQ-5D-5L and the Service Use questionnaire will be administered at baseline and at the six month follow-up.

This information will be collected via a face to face method. As the 'cluster cohort' assessment is more burdensome, service users will receive a £10 voucher for their time after completion of the interview at six months.

Carers:

o Demographic data will be collected at baseline.

o Secondary Outcome – The PROM will be administered to the cluster cohort sample at baseline and at the six month follow-up. The CUES-C and the WHOQOL-BREF will also be administered at baseline and at the six month follow up

o Economic Outcome – The EQ-5D-5L will be administered at baseline and at the six month follow up.

This information will be collected via a postal method. Carers will receive a £5 voucher following receipt of the questionnaires at the six month time point.

Cross-section Sample

Service Users:

- Demographic data will be collected at the six month time point.
- Primary Outcome – The HCCQ will be administered at the six month time point only.
- Secondary Outcome – PROM
- Economic Outcome – The EQ-5D-5L and the service use questionnaire will be administered at the six month time point only.

This information will be collected via a postal method. All respondents will receive a £5 high street voucher if they provide their name and postal address. Names and addresses will be requested on a separate from the questionnaire.

There will be no collection of carer information in the cross-sectional part of the study.

Table 1 shows the list of measures to be used, with which respondents, and at what time point

Table 1 Summary of Outcome Measures

Outcome measures		BASELINE		6 MONTH FOLLOW UP		
		Service Users (cohort)	Carers (cohort)	Service Users (cohort)	Carers (cohort)	Service Users (cross-section)
Primary Outcome	Autonomy support	HCCQ-10		HCCQ-10		HCCQ-10
	User and carer involvement		EQUIP PROM		EQUIP PROM	
Secondary Outcome	User and carer involvement	EQUIP PROM		EQUIP PROM		
	Satisfaction	VSSS-54	CUES-C	VSSS-54	CUES-C	
	Medication side effects	GASS		GASS		
	Well-being	WEMWBS		WEMWBS		
	Recovery and hope	DREEM		DREEM		
	Mental health symptoms	HADS		HADS		
	Alliance/engagement	CALPAS-12		CALPAS-12		
	Quality of life	WHOQOL-BREF	WHOQOL-BREF	WHOQOL-BREF	WHOQOL-BREF	
Economic outcome	Health status	EQ-5D-5L	EQ-5D-5L	EQ-5D-5L	EQ-5D-5L	EQ-5D-5L

Study 7

N/A

Analysis

Study 5

Statistical analysis

A draft statistical analysis plan for primary and secondary outcomes, including sub-group analyses will be presented to the Programme Steering Committee prior to the commencement of the data analysis. Analysis of outcomes will follow intention-to-treat principles: outcome data will be sought and included in the analysis for all service users irrespective of receipt of the intervention or completion of care planning during the time scale of the EQUIP trial.

Standard data checking procedures will be used as part of the data cleaning procedure prior to locking the database and linkage to group allocation. We will then model the pattern of missing data in terms of baseline characteristics of service users and treatment allocation to check for differential non-response. Depending on the patterns of missing data we may at this point choose to use multiple-imputation with deletion. This may also be used to inform possible sensitivity analyses for missing data assumptions.

For the cluster cohort study the intervention effects for the primary outcome (HCCQ) and secondary outcome measures will be estimated using a linear mixed model with a random intercept for community teams. The baseline value of the outcome will be used as a covariate together with other covariates pre-specified in the statistical analysis plan. The same statistical modelling procedure will be used for estimation of the intervention effect in the cluster cross-sectional study using a restricted set of covariates. Full detail of covariates for each model will be confirmed in the statistical analysis plan. For the primary outcome we will estimate and present the treatment effect for the cohort and cross-sectional designs separately. We will then test for heterogeneity of the treatment effect and present this pooled estimate as a secondary outcome.

Economic analysis

A cost effectiveness acceptability analysis will be conducted, from the perspectives of health and social care providers and service users, the key stakeholders in treatment decisions. The time horizon for the primary economic analysis will be at scheduled follow up (six months). Data on service use and health status (EQ-5D-5L) for the economic analysis will be collected for all participants at baseline and follow-up.

Data about the use of primary and community care based services will be collected by questionnaire completed by interview with the service users at the baseline and six month follow up assessments (cohort group). This is to ensure completeness of data collection and help to ensure that any questions or uncertainties about what should be reported can be addressed by the researcher completing the assessment. Data will also be collected from the cross-sectional group at the six month time point via the postal survey.

The service use questionnaire will ask for information about whether hospital inpatient and outpatients services have been used and if so, the name of the hospital, and this will be checked via records held by the case manager electronic record systems (with patient consent).

An economic patient questionnaire (service use questionnaire) to collect the service use information from service users will be adapted from those used in previous mental health evaluations. Service users will be asked for information about the number of care planning meetings they have attended. Data will also be collected from health records (with consent) about the resources (staff and facilities) used in the care planning process. The data from the service use questionnaire will be combined with the data in the health records to allow a detailed description of the service use and costs associated with care planning.

The time and expenses of service users, carers and staff involved in providing and receiving the training intervention will be documented along with details of facilities used. These data will be used to estimate the total cost of the training package. For the primary analysis, the cost of the training package will be allocated to trial participants by dividing the total cost by the number of participants randomised to the intervention group. This assumes that the investment in the training intervention lasts for six months (and has no impact after that time) and will only benefit the staff

trained and the participants in the trial. This may over-estimate the costs of the training package if the training has a longer effect on the staff trained and/or the staff trained apply their training to more participants than they see in the trial. The training may also have a wider effect than just on the staff trained and change care planning/service provision for wider group of staff. The effect (on the cost effectiveness of the intervention) of changing assumptions about the duration of effect and number of service users/carers affected will be explored in sensitivity analyses.

The main measure of health benefit will be the quality adjusted life year (QALY), in line with the perspective adopted and NICE guidelines (NICE 2013). QALYs will be estimated from survival and health status measured by the EQ-5D-5L.[109-111] The EQ-5D-5L is a validated generic health status measure, used in national health surveys in the United Kingdom and in clinical trials in mental health, covering five domains (mobility, self-care, usual activity, pain/distress, and anxiety/depression). The EQ-5D-5L has been used extensively in mental health evaluations and demonstrated to identify small but consistent differences between groups. It correlates well with clinical outcome measures and has the potential to capture the impact of an intervention on physical as well as mental health.[112,113] The EQ-5D-5L is designed as a self-report measure and will be completed by trial participants at baseline and follow up.

The five level version will be used (no problems, slight problems, some problems, severe problems or unable to do activity). Utility values, that reflect preferences for different health states, will be derived from the published utility tariffs developed for the 5 level instrument. QALYs will be estimated as:

$$QALY = \Sigma[(U_i + U_{i+1}) /2] \times (t_{i+1} - t_i)$$

where U = utility value and t = number of days between assessments.

Within trial primary analysis

The primary measure for the economic analysis will be the incremental cost effectiveness ratio (ICER). Accordingly, no statistical tests of differences in mean costs or outcomes will be conducted. The ICER will be estimated as the:

$$\frac{Cost_{intervention} - Cost_{usual\ care}}{Utility_{intervention} - Utility_{usual\ care}}$$

The estimates of incremental costs and outcomes from the regression will be bootstrapped to simulate 10,000 pairs of net cost and net outcomes of the intervention group for a cost effectiveness acceptability analysis, as recommended by NICE for health technology appraisals (National Institute for Clinical Excellence, 2013). These simulated data will be used to estimate the probability that service user/carer led training and care planning is cost effective in comparison to routine provision.

In the UK there is no agreed universal value for the potential benefit measures used in cost effectiveness analysis. Determining an amount decision makers are willing to extend to in order to gain a single unit of benefit is a common approach in health economics. Utility value simulation encompassed values ranging between £1 to £30,000, representing costs decision makers are prepared to meet, based on NICE recommendations.[114]

Data for cost effectiveness acceptability simulation will be determined by first reappraising 10,000 net outcome scores from the bootstrap simulation by a single WTPT, repeated for each WTPT. Net benefit statistic (NB) for each pair of simulated costs and outcomes for each WTPT can then be calculated:

$$NB = (O * WTPT) - C, \text{ where } O = \text{net outcome score and } C = \text{net cost.}$$

Cost-effectiveness acceptability curves illustrate the amount of bootstrapped simulations where the net benefit of an intervention is greater than zero for each WTPT.[115–118]

Assuming a 'cluster cohort' design is used factors known to influence costs and QALYs (e.g. ethnicity, socio economic status, previous service use) will be collected at baseline to statistically control for their impact. A linear mixed model with a random effect for cluster will be used in all trial based analyses to control for these.
Descriptive analysis and data manipulation will be conducted using SPSS, and the main statistical analyses and estimation of net benefit statistics and cost-effectiveness acceptability analysis will be conducted using STATA.

Within trial sensitivity analyses

Sensitivity analyses will explore whether the conclusions of the primary analysis will change in the following cases

Alternative assumptions about the duration and breadth of the effect of training are used to estimate the cost per participant of the intervention

The primary measures of outcome for the clinical evaluation are used as the measure of health benefit to estimate the ICER

The costs and QALYs are extrapolated to 12 months.

Case 1 will assume that the cost per day of health and social care estimated for the 3 month follow up is constant over the following 9 months and that the health status and utility value estimated at the 3 month follow up is constant over the following 9 months

Case 2 will assume that the cost per day of health and social care estimated for the 3 month follow up declines over the following 9 months and that the health status and utility value estimated at the 3 month follow up is constant over the following 9 months

Case 3 will assume that the cost per day of health and social care estimated for the 3 month follow up declines over the following 9 months and that the health status and utility value estimated at the 3 month follow up also declines over the following 9 months

Case 4 will assume that the cost per day of health and social care estimated for the 3 month follow up increases over the following 9 months and that the health status and utility value estimated at the 3 month follow up is constant over the following 9 months

Case 5 will assume that the cost per day of health and social care estimated for the 3 month follow up increases over the following 9 months and that the health status and utility value estimated at the 3 month follow up also increases over the following 9 months

Case 6 will assume that the cost per day of health and social care estimated for the 3 month follow up increases over the following 9 months and that the health status and utility value estimated at the 3 month follow up declines over the following 9 months

Economic model

An economic model will be developed to explore the impact of the intervention over alternative time periods, in different settings and populations. The model structure will be developed from a focussed review of the economics literature about care planning and training and refined/validated by discussion with EQUIP research team. Data to populate the model will be derived from the focussed review of the economics literature, review of national databases and datasets (e.g. Hospital Episode Statistics) and the trial. The primary and sensitivity will use incremental cost effectiveness and cost effectiveness acceptability approach outlined for the within trial evaluation. Probabilistic sensitivity analysis will be used to assess the level of uncertainty due to the data. Deterministic sensitivity analysis will be used to explore the impact of structural uncertainty.

Study 7

We will examine the processes involved in the development and adoption of user/carer involved care planning drawing on Normalisation Process Theory.[119] NPT (which comprises of four components: coherence (sense making work), cognitive participation (relational work) , collective action (operational work), reflexive monitoring (appraisal work) has been developed from empirical studies of the implementation of complex interventions in health care contexts and in relation to mental health contexts in particular. We will focus on: (a) implementation of user/carer involved care planning - the way this is developed and translated into practices (of mental health professionals, users, carers and others); (b) embedding - the manner in which care planning becomes, (or does not become), routinely incorporated in everyday work of service users and professionals; (c) integration - how care planning is sustained as part of the everyday lives of individuals at work and at home d) networking - how it generates access to new networks and resources.

Analysis of interview and observational data will be conducted with reference to principles of the constant comparative method[120] whereby analysis will be carried out concurrently with data collection so that emerging issues can be explored iteratively. Anonymised verbatim transcripts of audio recordings will be imported into the software package Atlas.ti for data management. Analysis will draw upon the techniques of grounded theory approaches[121] including initial coding of text segments, followed by re-coding and memo writing to generate conceptual themes driven by the Normalisation Process Theory (NPT). The transcripts will be read by at least two researchers. Themes (based on the four constructs of

NPT) will be compared within and across cases, paying particular attention to negative cases and possible reasons for differences. In addition to the thematic analysis, an exploration of narratives will be valuable for the longitudinal study of the impact of care planning on individual cases. Both thematic and narrative approaches have been prominent in previous qualitative studies focused on the day-to-day living with mental health conditions, and will serve as complementary analytic techniques.[122] Analysis of diary records and observational data will be complementary to the above and where appropriate will be used to illustrate relevant issues emerging from the interviews or observation records and may be used to help elicit interview data.

User engagement

Study 5 and 7

Service users and carers have been involved with key aspects of the trial and process evaluation development, including helping to develop and deliver the user/carer led training in care planning, deciding on the secondary outcome measures to be used and development of the PROM.

Governance and Ethical issues

The key ethical concerns for the programme include confidentiality, participant anonymity and informed consent to participate in research. The study includes both mental health service users and carers as participants and as such there are specific ethical issues to be considered. Research governance principles and ethical committee approvals bind all applicants and their institutions. We will ensure we adopt the highest standards of research conduct including involvement of service user representation in both the management and delivery of the research.

This studies will be conducted in compliance with the study protocol, GCP and both University and NHS regulatory and monitoring requirements. The work stream teams will meet every three months and the CI will be responsible for the overall leadership, management and outputs of the programme. The PI from each site will maintain a log of the key milestones to be achieved against the timetable. The work stream leads will be responsible for the day to day running and co-ordination of the studies and will be accountable to the PI. All research associates will be supervised by the work stream leads.

Possible risks and anticipated benefits for research participants and society

The overall aim of the programme grant is to improve user and carer involvement in care planning in mental health services. Despite the fact that the majority of mental health policy documents, literature on best practice and literature produced by user and carer groups advocate that involving users and carers in care planning is fundamental to improving the quality of care and promoting recovery, there is substantial evidence that this does not always occur. This research is important because it provides an opportunity to make a quality improvement across community mental health services, such a quality improvement has the potential to be translated over both mental health and physical care settings and hence benefit many thousands of service users.

A full risk assessment of the EQUIP study will be undertaken prior to its commencement.

Study 5

Completing the measures is not perceived as being high risk but there is always a risk that service users/carers may become distressed when thinking about difficult personal experiences. This risk has been assessed in the overall risk assessment for the work stream and as a result sources of further support will be included at the end of the questionnaires 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

Data collection may require the researcher to visit participants at their work places or their homes. The School of Nursing, Midwifery and Social Work's Lone Worker Policy will be employed, as well as project specific risk assessment.
These involve research staff leaving details of their visits with a supervisor who they contact before and after the visit and using 'PeopleSafe' technology. When NHS CSOs carry out data collection they will follow their NHS Trust lone worker policies.

There is a risk to researchers that they might become distressed when collecting sensitive data within questionnaires. This has been assessed as a low risk but interviewers will have access to their supervisors for support on a regular basis and as required. NHS CSOs will have access to

their supervisors within the NHS for support as well as regular contact with the EQUIP Programme Managers and Clinical Leads.

Informing potential participants of possible risks and anticipated benefits

All potential participants will be provided with an information sheet written to current NRES guidelines and favourably reviewed by the relevant ethics committee, prior to the study commencing. Service users and carers have been involved in developing the participant information sheets to ensure they are accessible. The information sheet will be provided to potential participants at the point of them expressing an interest in participating. It will provide potential participants with information about the study, including the potential benefits and risks of taking part, confidentiality and the right to withdraw as described above. Researcher contact details will be provided so participants can contact them with any queries prior to the participant deciding to take part. Researchers will further discuss risks and benefits immediately prior to the data collection taking place.

Obtaining informed consent

The exact consent methods to be used in the trial have been discussed in detail in the methods section. Prior to commencement of the study, the purpose and process of the study will be explained to the service users (cohort) and any questions raised will be addressed, before they sign the consent form. Service users (cross-section) and carers (cohort) will have the opportunity to have the purpose and process of the study explained to them and any questions addressed. Consent will be implied by return of the completed questionnaire and the consent to contact at follow up form (for carers).

Participants may change their mind and withdraw from the study at any point and this will not affect the care they receive.

Documentation and data management

All data will be stored securely in line with local data management arrangements. All questionnaires and other paper records will be stored in secure storage facilities at the University of Manchester and the University of Nottingham. Personal identifiable paper records will be stored separate from anonymised paper records. All electronic records will be pseudo-anonymised using a reference number for each participant and stored on a password protected server at the University of Manchester. Consent forms and other paper records will be stored as essential documents in a locked cabinet on University premises until the end of the project, at which point they will be archived until five years after the last publication arising from the study, or ten years after the programme grant completion, whichever is the greatest. All participant contact information will be destroyed securely and immediately at the end of the trial.

Study 7

Semi-Structured In-Depth Interviews

Service users and professionals

Many people enjoy being interviewed although there is also always a risk that people may become distressed when describing difficult personal experiences which may be the case during the interviews with service user and carers / family member participants. This risk has been assessed in the overall risk assessment for the work stream and as a result the research has an interview distress policy and debriefing sheet to ensure that participants are supported both during and after group participation, if this should become necessary. The interviewers and their supervisors are sensitive to these issues and are experienced at supporting people experiencing distress.

Visiting people at home carries an additional risk and the School of Nursing, Midwifery and Social Work's Lone Worker Policy will be employed, as well as project specific risk assessments. These involve interviewers leaving details of their interview with a supervisor who they contact before and after the interview and using the 'PeopleSafe' system (http://peoplesafe.co.uk/). In the event of NHS CSOs carrying out data collection they will follow their individual NHS Trust Lone Worker policies.

There is a risk to interviewers that they might become distressed by listening to interviewee experiences. This has been assessed as a low risk but interviewers will have access to their supervisors for support on a regular basis and as required.

There is a potential risk that health professionals or service users may disclose examples of bad practice or risk of harm. We will follow ethical and legal practice and all information provided by participants will be handled in confidence. However, any suggestions of serious harm to self or others that is disclosed during the interviews cannot be treated as confidential. Where information given in a research context suggests that there is a threat of serious harm to the participant or others, researchers will disclose this to the relevant authorities, but also inform the participants and their guardians/responsible others of their intentions and reasons for doing so. Contemporaneous notes will be kept in case a complaint arises. Professor Karina Lovell has been nominated as the first point of call for researchers working on the project who will advise researchers as to the relevant authorities that need to be contacted and support the researcher and participant as necessary. We have identified two clinical leads in both study sites who will further facilitate this process should this become necessary

Observation

Service users and professionals

It is not anticipated that that there are risks associated with the observation of care planning meetings as these meetings would have occurred anyway without observation. However, if participants do become upset or uncomfortable during the observation the distress protocol will be followed. Furthermore and as above there may be disclosure of bad practice or risk of harm which would be addressed in the same way as above.

There is also a risk that one party will not agree to being observed. In order for the observation to take place, consent must be obtained for all the people taking part in the care planning meetings. If one party does not consent, participants will be offered the opportunity to take part in an interview after a care planning meeting to share their views.

Diaries

Service users

There is a risk that diaries will not be completed adequately or at all. In order to combat this, researchers recruiting participants to the study will explain the value of completing the diary sheets to the study and participants will be offered the choice of either a written or audio version of the diary. In addition, a flexible approach to diary completion will be undertaken and participants will be asked to complete diaries at their discretion and will not be subject to a strict structure to encourage completion. In addition, we have other methods to capture this data if it is not recorded in the diary (e.g. social network methods and semi-structured interviews).

Informing potential participants of possible risks and anticipated benefits

All potential participants will be provided with an information sheet written to current NRES guidelines and favourably reviewed by the relevant ethics committee, prior to the study commencing. Service users and carers have been involved in developing the information sheet to ensure it is accessible. The information sheet will be provided to potential participants at the point of them expressing an interest in participating. It will provide potential participants with information about the study, including the potential benefits and risks of taking part as described above. Researchers contact details will be provided so participants can contact them with any queries prior to the participant deciding to take part. Interviewers will further discuss risks and benefits immediately prior to the interview taking place.

Obtaining informed consent

Semi-Structured in-depth interviews/observations/diaries: There will be several days between the potential interviewee receiving the information about the study (via invitation letter distributed at point of consent for trial or sent by the Trust with MHRN support) and the interview/observation/diary completing taking place. At the beginning of the visit the purpose and process of the study will be explained again, before potential participants are asked to sign a consent form. Participants may change their mind and withdraw from the interview at any point and they will be informed of this. Consent forms will be stored as essential documents in a locked cabinet on University premises until the end of the project, at which point they will be archived until five years after the last publication arising from the study, or ten years after the project's completion, whichever is the greatest.

Documentation and data management

All data will be stored securely in line with local data management arrangements. All interviews will be digitally recorded using encrypted digital recorders, with the interviewee's consent, and transcribed verbatim by a transcription company who have a confidentiality agreement with the University. If participants prefer for the interview to not be digitally recorded then the researcher undertaking the interview will take detailed notes. The audio files will be uploaded onto a University password protected server and then deleted from the digital recorder. All paper records will be stored in secure storage facilities at the University of Manchester. Personal identifiable paper records will be stored separate from anonymised paper records. All electronic records will be pseudo-anonymised using a reference number for each participant and stored on a password protected server at the University of Manchester. Interview transcripts will be pseudo-anonymised and stored on a University password protected server. At the end of the study transcripts will be archived until five years after the last publication arising from the study, or ten years after the project's completion, whichever is the greatest. All participant contact information will be destroyed securely and immediately at the end of the trial.

Approved amendments made to the original above protocol submitted to ethics

		Protocol Version
1	Method of randomisation changed from using sealednvelope.com to using the Clinical Trials Unit at Manchester Academic Health Science Centre.	8.1
2	Clinical studies officers to follow up non-responders to the initial mail out with a phone call to obtain consent to contact.	8.1
3	Participants in the cross-sectional survey to receive £5 gift vouchers	8.2
4	Addition of a follow-up letter to people sent the cross-sectional survey who failed to respond.	8.2
5	Audiotaping of training sessions	8.3
6	Alteration to how service users were provided with initial information about the trial - approached by clinician before being sent information in the post.	8.4