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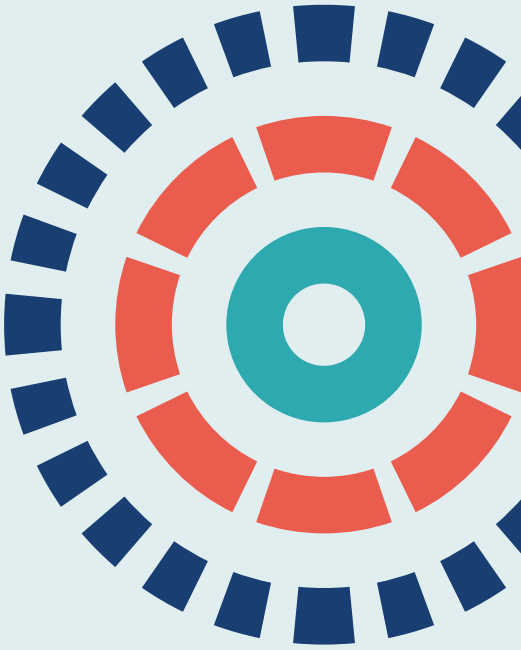

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Abstract

Training to enhance user and carer involvement in mental health-care planning: the EQUIP research programme including a cluster RCT

Karina Lovell,[1]* Penny Bee,[1] Peter Bower,[2] Helen Brooks,[1] Patrick Cahoon,[3] Patrick Callaghan,[4] Lesley-Anne Carter,[2] Lindsey Cree,[1] Linda Davies,[2] Richard Drake,[5] Claire Fraser,[1] Chris Gibbons,[1] Andrew Grundy,[4] Kathryn Hinsliff-Smith,[4] Oonagh Meade,[4] Chris Roberts,[2] Anne Rogers,[6] Kelly Rushton,[1] Caroline Sanders,[2] Gemma Shields[2] and Lauren Walker[1]

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Background: Service users and carers using mental health services want more involvement in their care and the aim of this research programme was to enhance service user and carer involvement in care planning in mental health services.

Objectives: Co-develop and co-deliver a training intervention for health professionals in community mental health teams, which aimed to enhance service user and carer involvement in care planning. Develop a patient-reported outcome measure of service user involvement in care planning, design an audit tool and assess individual preferences for key aspects of care planning involvement. Evaluate the clinical effectiveness and the cost-effectiveness of the training. Understand the barriers to and facilitators of implementing service user- and carer-involved care planning. Disseminate resources to stakeholders.

Methods: A systematic review, focus groups and interviews with service users/carers/health professionals informed the training and determined the priorities underpinning involvement in care planning. Data from focus groups and interviews were combined and analysed using framework analysis. The results of the systematic review, focus groups/interviews and a review of the training interventions were synthesised to develop the final training intervention. To develop and validate the patient-reported outcome measure, items were generated from focus groups and interviews, and a psychometric analysis was conducted. Patient-reported outcome measure items and a three-round consensus exercise were used to develop an audit tool, and a stated preference survey was undertaken to assess individual preferences for key aspects of care planning. The clinical effectiveness and cost-effectiveness of the training were evaluated using a pragmatic cluster trial with cohort and cross-sectional samples. A nested longitudinal qualitative process evaluation using multiple methods, including semistructured interviews with key informants involved locally

and nationally in mental health policy, practice and research, was undertaken. A mapping exercise was used to determine current practice, and semistructured interviews were undertaken with service users and mental health professionals from both the usual-care and the intervention arms of the trial at three time points (i.e. baseline and 6 months and 12 months post intervention).

Results: The results from focus groups ($n = 56$) and interviews ($n = 74$) highlighted a need to deliver training to increase the quality of care planning and a training intervention was developed. We recruited 402 participants to develop the final 14-item patient-reported outcome measure and a six-item audit tool. We recruited 232 participants for the stated preference survey and found that preferences were strongest for the attribute 'my preferences for care are included in the care plan'. The training was delivered to 304 care co-ordinators working in community mental health teams across 10 NHS trusts. The cluster trial and cross-sectional survey recruited 1286 service users and 90 carers, and the primary outcome was the Health Care Climate Questionnaire. Training was positively evaluated. The results showed no statistically significant difference on the primary outcome (the Health Care Climate Questionnaire) (adjusted mean difference –0.064, 95% confidence interval –0.343 to 0.215; $p = 0.654$) or secondary outcomes at the 6-month follow-up. Overall, the training intervention was associated with a net saving of –£54.00 (95% confidence interval –£193.00 to £84.00), with a net quality-adjusted life-year loss of –0.014 (95% confidence interval –0.034 to 0.005). The longitudinal process evaluation recruited 54 service users, professionals and carers, finding a failure of training to become embedded in routine care.

Limitations: Our pragmatic study was designed to improve service user and care involvement in care planning among routine community mental health services. We intervened in 18 sites with > 300 care co-ordinators. However, our volunteer sites may not be fully representative of the wider population, and we lacked data with which to compare our participants with the eligible population.

Conclusions: We co-developed and co-delivered a training intervention and developed a unidimensional measure of service user and carer involvement in care planning and an audit tool. Despite a high level of satisfaction with the training, no significant effect was found; therefore, the intervention was ineffective. There was a failure of training to become embedded and normalised because of a lack of organisational readiness to accept change. Working with NHS trusts in our 'Willing Adopters' programme with enhanced organisational buy-in yielded some promising results.

Future work: Research should focus on developing and evaluating new organisational initiatives in addition to training health-care professionals to address contextual barriers to service and carer involvement in care planning, and explore co-designing and delivering new ways of enhancing service users' and carers' capabilities to engage in care planning.

Trial registration: Current Controlled Trials ISRCTN16488358.

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List of abbreviations

AMA	Ask Me Anything
BAME	black, Asian and minority ethnic
CALPAS	California Psychotherapy Alliance Scale
CI	confidence interval
CMHT	community mental health team
CPA	Care Programme Approach
CQC	Care Quality Commission
CRN	Clinical Research Network
CSO	clinical studies officer
CUES	Carers' and Users' Expectations of Services
CUES-C	Carers' and Users' Expectations of Services – carer version
DREEM	Developing Recovery Enhancing Environment Measure
EQ-5D	EuroQol-5 Dimensions
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
EQUIP	Enhancing the Quality of User and Carer Involvement in Care Planning
GASS	Glasgow Antipsychotic Side Effect Scale
HADS	Hospital Anxiety and Depression Scale
HCCQ-10	Health Care Climate Questionnaire
ICC	intracluster correlation coefficient
MAGIC	Making Good Decisions in Collaboration
MRC	Medical Research Council
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NPT	normalisation process theory
PPI	patient and public involvement
PROM	patient-reported outcome measure
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SD	standard deviation
SUCAG	service user and carer advisory group
TARS	Training Acceptability Rating Scale
TIDieR	Template for Intervention Description and Replication
WEMWBS	Warwick–Edinburgh Mental Wellbeing Scale
WHOQOL	World Health Organization Quality of Life

Plain English summary

Service users and carers using mental health services want to be more involved in decisions about their care. Guidance recommends user and carer involvement for the best care, but this does not always happen. Our research aimed to train mental health professionals to enhance service user and carer involvement in care planning.

We listened to the views of service users, carers and health professionals, and used this information to design training for staff in community mental health teams. We co-delivered the training with service users and carers.

We tested how well the training worked by measuring how involved service users felt in their care before and after staff were trained, and compared this with people cared for by staff who had not been trained. Although professionals were positive about the training, it did not change how involved people felt in their care or any health outcomes and was not good value for money; therefore, the intervention was not effective. This was because health professionals were not able to apply what they had learned in training to their everyday practice. Our dissemination work following the trial where some NHS trusts began to implement organisational change showed some promising results.

We worked with service users and carers to design a tool for NHS trusts to measure levels of involvement in care planning. We also created animations and leaflets to communicate information about care planning and being involved in care decisions, and publicised these widely through social media sites such as Facebook (Facebook, Inc., Menlo Park, CA, USA; www.facebook.com) and Twitter (Twitter, Inc., San Francisco, CA, USA; www.twitter.com). In addition, we produced a video with our service user and carer advisory group to share the key messages of our research.

Scientific summary

Background

Evidence is accumulating to confirm that increased service user and carer involvement can lead to positive outcomes for both health-care systems and their users. Care planning is one area of contemporary practice that is conducive to service user involvement. Although principles of service user and carer involvement are embedded in policy ideologies, research has found that they have been suboptimally translated in practice. Service users and carers consistently report feeling unsupported by care planning processes and continue to request greater involvement in their care.

Identified barriers to service user and carer involvement in mental health services include poor information exchange, ritualised practices that limit opportunities for involvement, inhibitions or misconceptions regarding patient confidentiality and/or professional resistance to sharing decision-making power. Our systematic review found conceptual differences in the interpretation and meaning of involvement between service users and professionals. Although professionals tended to focus on objective evidence of service user involvement, such as ensuring that care plans were shared with and signed by service users, service users and carers tended to prioritise the qualitative experience of their involvement, specifically the consistency and quality of their care planning relationships.

If meaningful service user and carer involvement in care planning is to be achieved, there is a pressing need to agree and foster a system-wide, user-centred model of collaboration and involvement. Our research programme aimed to address the gap between policy and practice by addressing this need.

Aims and objectives

The aim of the programme grant was to improve service user and carer involvement in care planning in mental health services. We created a programme of work to address this by designing, evaluating, implementing and disseminating a training intervention for mental health professionals, which was co-designed and co-delivered with service users and carers.

Our programme had four separate but inter-related workstreams.

Workstream 1

- Co-develop and co-deliver a training intervention for health professionals in community mental health teams to enhance service user- and carer-involved care planning.
- Develop a patient-reported outcome measure of service user involvement in care planning, develop an audit tool and assess individual preferences for key aspects of care planning involvement.

Workstream 2

- Evaluate the clinical effectiveness and cost-effectiveness of the training intervention to enhance service user- and carer-involved care planning in secondary care mental health services.

Workstream 3

- Understand the contextual, individual and organisational barriers and facilitators, and examine the processes involved in the development and use of service user- and carer-involved care planning.

Workstream 4

- Disseminate our training intervention materials and patient-mediated resources produced during the programme to all relevant stakeholders using multiple methods.

Methods and results

Workstream 1

Development of training intervention

Nine focus groups (four with service users and carers, four with health professionals and one mixed group) involving 17 service users, 16 carers and 23 health professionals were undertaken to inform the content, length and delivery mode of the service user- and carer-led training package. Seventy-four individual qualitative interviews with service users ($n = 25$), carers ($n = 21$) and health professionals ($n = 28$) were conducted to determine the priorities and core concepts underpinning service user and carer engagement and involvement in care planning. Data from the focus groups and interviews were combined and analysed using framework analysis, and then synthesised alongside evidence gathered from a scoping review of systematic reviews of successful training implementation to develop the training intervention. We trained service users and carers to co-deliver the training intervention to health professionals working in community mental health teams.

Development of the patient-reported outcome measure and audit tool

We conducted a systematic review reporting the use, development and validation of user- and carer-reported outcome measures, which confirmed the need for a new patient-reported outcome measure to be developed. Potential items for the patient-reported outcome measure were generated from data collected in the focus groups and interviews described above and examined for validity by members of the service user and carer advisory group through cognitive interviewing. Testing of the resultant 61-item patient-reported outcome measure was completed with 402 service users and carers, followed by a second round of completion by a random sample of 59 participants to measure test–retest validity. Detailed psychometric and statistical analysis was conducted using classical test, Mokken and Rasch analyses, and a final 14-item patient-reported outcome measure was produced, providing a unidimensional measure of service user and carer involvement in the mental health-care-planning process.

We developed an audit tool to inform clinicians, services, auditors and researchers who want to quantify levels of user and carer involvement in care planning. For the audit tool, we completed a three-round consensus exercise with our service user and carer advisory group ($n = 16$) and reduced the 61 candidate patient-reported outcome measure items to form a shorter six-item audit tool. Psychometric analysis assessed the performance of the audit tool using a combination of classical test, Mokken and Rasch analyses. Test–retest reliability was calculated using *t*-tests of interval level scores between baseline assessments and the 2- and 4-week follow-ups.

Stated preference study

We completed a stated preference survey to assess the strength of user and carer preferences and weights for key items included in the audit tool. We used a binary discrete choice experiment with five attributes (whether or not preferences for care are included in the care plan, whether or not the care plan helps me manage risk, completeness of the information in the care plan, whether or not important decisions are explained to me and whether or not all important aspects of my life are catered for) and an additional attribute describing the time per person spent on care-planning-related activities. We recruited 232 service users and carers, of which 89% completed all choice questions. Most responses were from service users ($n = 166$, 72%), of whom 34 (20%) also identified themselves as carers. Mixed logit regression results demonstrated that preferences were strongest for the attribute ‘my preferences for care are included in the care plan’. The least preferred attribute was whether or not the information included in the care plan was complete.

Workstream 2

A pragmatic cluster trial with community mental health teams in England was designed to evaluate the clinical effectiveness and cost-effectiveness of the training intervention developed in workstream 1. The trial used cohort and cross-sectional samples to minimise threats to validity.

The cluster cohort was recruited at baseline and followed over the 6 months of the trial, and the cluster cross-section was recruited at the end of the trial. Consenting service users cared for by each community mental health team were recruited, and carers were recruited from consenting service users. Each community mental health team was randomised to either the intervention (training in care planning) or control (usual-care planning). The community mental health teams randomised to the intervention received the training package.

The primary outcome was service user self-reported 'autonomy support' measured using the Health Care Climate Questionnaire.

Secondary outcomes included patient self-reported involvement in decisions [Enhancing the Quality of User and Carer Involvement in Care Planning (EQUIP) patient-reported outcome measure], satisfaction with services (Verona Service Satisfaction Scale); side effects of antipsychotic medication (Glasgow Antipsychotic Side Effect Scale); well-being (Warwick–Edinburgh Mental Wellbeing Scale); recovery and hope (Developing Recovery Enhancing Environment Measure); anxiety and depression (Hospital Anxiety and Depression Scale); alliance and engagement (California Psychotherapy Alliance Scale); quality of life (World Health Organization Quality of Life questionnaire); carer satisfaction (Carer and User Expectations of Services); quality-adjusted life-years (EuroQol-5 Dimensions, five-level version); and use of health-care services. Measures were completed at baseline (pre training) and at 6 months post training (cohort), and at 6 months post training only (cross-sectional). Satisfaction with the training by health professionals was measured using the Training Acceptability Rating Scale.

We randomised 36 (intervention, $n = 18$; usual care, $n = 18$) community mental health teams in 10 NHS trusts in England and co-delivered our training intervention to 350 mental health professionals, of whom 304 were care co-ordinators. We recruited 604 service users with serious mental illness and 90 carers under the care of community mental health teams into the cluster trial, with 82% retention at the 6-month follow-up. A further 682 participants were recruited to the cross-sectional study. Training was deemed highly acceptable by health professionals. The results showed no statistically significant difference in the primary outcome (Health Care Climate Questionnaire) (adjusted mean difference –0.064, 95% confidence interval –0.343 to 0.215; $p = 0.654$) or other outcomes between intervention and usual care at the 6-month follow-up.

Overall, the training intervention was associated with a net saving of –£54.00 (95% confidence interval –£193.00 to £84.00), with a net quality-adjusted life-year loss of –0.014 (95% confidence interval –0.034 to 0.005). The 95% confidence intervals of the net differences cross zero, indicating that there was no evidence that the costs or health benefit differed between the training intervention and control. There was a net saving per quality-adjusted life-year lost of £3600. Whether or not the savings offset the quality-adjusted life-year loss depends on the decision-makers' willingness to pay to gain 1 quality-adjusted life-year. If decision-makers are willing to pay £5000–15,000 to gain 1 quality-adjusted life-year, then the probability that the training intervention was cost-effective was between 0.16 and 0.41. This ranged between 0.09 and 0.65 in the sensitivity analyses using the quality-adjusted life-year. The training was positively evaluated, with the inclusion of service users and carers delivering the training as the most valued aspect.

Workstream 3

We conducted a preimplementation qualitative study prior to the development of the training package. This aimed to understand the organisational structures, influences, context and policies relating to care planning within mental health services in order to feed into the intervention design and to increase the likelihood of it being implemented in normal practice. This complemented the analysis in workstream 1 and involved a mapping exercise of contemporary care planning policies as well as 13 semistructured interviews with key

informants involved locally and nationally in policy, practice and research. Interviews were analysed using normalisation process theory, which complemented the data collected during workstream 1.

We conducted a nested longitudinal qualitative process evaluation using multiple methods to complement and supplement the evidence provided by the cluster trial in workstream 2. A series of interviews were undertaken with service users ($n = 29$), professionals ($n = 21$) and carers ($n = 4$) from both the usual-care and the intervention arms of the cluster trial at three time points (baseline and 6 and 12 months post intervention). Data were analysed thematically to obtain an in-depth understanding of staff experiences of receiving and utilising the EQUIP intervention and to examine changes to practice over time.

The results demonstrated that, despite buy-in from those delivering care planning in mental health services, there was a failure of training to become embedded and normalised in local provision. This was attributable to a lack of organisational readiness to accept change, combined with an underestimation and lack of investment in the amount of relational work required to successfully enact the intervention.

Workstream 4

We disseminated our training intervention materials and patient-mediated resources produced during the programme using multiple methods.

'Willing Adopters'

Mental health trusts involved in the programme were invited to become 'Willing Adopters' following the completion of workstream 2. Trusts negotiated a range of options for engagement, including delivery of the training to other community mental health teams or teams in the trust, a 'train the trainers' course for health professionals, service users and carers to deliver the training package within their trust, patient-mediated materials developed through the programme, and the audit tool for trusts to measure service user and carer involvement in care planning before and after training. The 'Willing Adopters' programme was delivered in seven NHS mental health trusts, with each trust opting for a variation on which components they wished to adopt. The EQUIP 'Willing Adopters' training was delivered to 192 attendees (staff members, $n = 177$; service users and carers, $n = 15$) in addition to the roll-out by some of the NHS trusts. Acceptability of training demonstrated high levels of overall satisfaction. Trusts that implemented the EQUIP 'Willing Adopters' programme have shown some promising results with changes in Care Quality Commission ratings.

Dissemination

We developed multiple methods to disseminate our findings, including two animations detailing findings from workstream 1 based on the '10 Cs of care planning', which included our National Institute for Health Research award-winning animation about carers' perspectives of care planning. To maximise impact and increase the reach of the animations, a targeted approach to promotion via social media was employed alongside individual events, such as a Reddit (San Francisco, CA, USA) 'Ask Me Anything' session, which achieved a reach of almost 9 million.

We also developed 'EQUIP cards': pocket-sized fold-out cards designed for service users and carers, which contained useful information and prompts to support involvement in care planning decisions. We have distributed over 50,000 EQUIP cards and posters to service users, carers and mental health staff involved in care planning via mail-outs to NHS trusts and third-sector organisations, and directly to service users alongside appointment letters for care planning meetings. A video was developed by the service user and carer advisory group with Patient Voices (Programme Pilgrim Projects Ltd, Landbeach, UK) to disseminate findings from the entire programme.

Conclusions

We co-developed and co-delivered (with service users and carers) a highly acceptable training intervention for health professionals working in community mental health teams with people with serious mental illness.

We developed a 14-item patient-reported outcome measure, 'Enhancing the Quality of User and Carer Involvement in Care Planning' scale, which displays excellent psychometric properties and is capable of unidimensional linear measurement. We developed a validated six-item audit tool to inform clinicians, services, auditors and researchers who want to quantify levels of user and carer involvement in care planning. Our stated preference study found that service users and carers are willing to spend time improving the way in which they are involved in their care planning. These findings could be used to help services target improvements in care planning to the aspects most important to service users.

Despite high levels of satisfaction with the training, our pragmatic cluster trial with cohort and cross-sectional samples found no significant effect between community mental health teams receiving the training and those not receiving the training. There was no evidence that the costs or health benefit differed between the training intervention and the control. There was a failure of training to become embedded and normalised in local provision. This was caused by a lack of organisational readiness to accept change, combined with an underestimation and lack of investment in the amount of relational work required to successfully enact the intervention. Our in-depth qualitative work and process evaluation showed consistent deficits in care planning involvement. We used a systematic approach to disseminate our results and have rolled out the training, patient-mediated materials and resources to NHS trusts. We have filled a training gap to encourage shared understanding and language between services users and carers.

Our inability to show an effect of the training may in part be explained by data from our qualitative process evaluation, which suggested that, despite ideological buy-in from trained staff, our training failed to become embedded and normalised in local provision. Supervision sessions were offered to staff post training but demonstrated very low uptake. This widespread failure to engage in supervision may in part reflect the fact that professionals' work priorities, workload and availability were not conducive to incorporating new knowledge and skills from training into their existing role. Qualitative data collected at the 6- and 12-month follow-ups suggested that there was an absence of organisational readiness to accept change and an underestimation of and deficient investment in the amount of relational work required to make it successful. This combination of stretched staff and services, in the absence of organisational requirement and support to incorporate training into usual practice, most probably had an impact on the probability of eliciting measurable changes in service user and carer involvement. Our 'Willing Adopters' programme with enhanced organisational buy-in and support has demonstrated promising results with Care Quality Commission changes.

Recommendations for research

- There remains an urgent need to develop ways of improving service user and carer involvement in their care plans. More complex, comprehensive and enduring interventions may be required, such as the use of incentives, linkage to routine outcome monitoring and better integration into routine clinical systems. However, such comprehensive models raise significant challenges for their implementation (and their assessment in a rigorous, controlled fashion).
- Research should focus on developing and evaluating new organisational initiatives to address contextual barriers to service and carer involvement in care planning. These initiatives should include the introduction of both 'bottom-up' and 'top-down' structural changes, such as accountability systems, as well as system-level strategies that encourage or facilitate shared access to care plans.

Trial registration

This trial is registered as ISRCTN16488358.

Funding

Funding for this study was provided by the Programme Grants for Applied Research programme of the National Institute for Health Research.

SYNOPSIS

The problem we set out to address

For the last two decades, mental health policy and ethos have placed increasing emphasis on involving services users, and their carers, in their own care. This vision is in part driven by a strong moral argument that health-care delivery should be shaped and informed by the very people whom it aims to affect. Service users and carers, by virtue of their lived experience, can bring a wealth of experiential knowledge and expertise to mental health-care management.

Research evidence is accumulating to confirm that increased service user and carer involvement can lead to positive outcomes for both health-care systems and their users.[1–5] Service user involvement has been shown to enhance service quality and care engagement, reduce rates of enforced treatment and readmission and lessen social isolation and stigma.[6–8]

Care planning is one area of contemporary practice that is conducive to service user involvement.[5–12] Mental health-care planning has been defined as 'the process through which services in relation to an individual's care are "assessed, planned, co-ordinated and reviewed"'[13] (contains public sector information licensed under the Open Government Licence v3.0). The National Institute for Health and Care Excellence (NICE) states that people using mental health services should develop a care plan with mental health and social care professionals, and be given a copy of this care plan with an agreed date for review.[14] The Five Year Forward View for Mental Health[15] upholds collaborative care planning as a priority goal for mental health services, and an essential Care Quality Commission (CQC) standard.[16]

Although principles of service user and carer involvement are embedded in policy ideologies, evidence suggests that they have been suboptimally translated in practice. Service users and carers consistently report feeling unsupported by care planning processes and continue to request greater involvement in their care.[7,16,17] Dissatisfaction is evident across a variety of service settings and with a range of professional roles.[18,19] A recent CQC review of care involvement has highlighted 'longstanding concerns' with care planning involvement, concluding that routine practice can diverge quite substantially from policy recommendations for 'person-centred care'[20] (contains public sector information licensed under the Open Government Licence v3.0).

Identified barriers to service user and carer involvement in mental health services include poor information exchange,[5] ritualised practices that limit opportunities for involvement,[5,17] inhibitions or misconceptions regarding patient confidentiality and/or professional resistance to sharing decision-making power. Importantly, our recent systematic review[5] found conceptual differences in the interpretation and meaning of involvement between service users and professionals. Although professionals tended to focus on objective evidence of service user involvement, such as ensuring that care plans were shared with and signed by service users, service users and carers tended to prioritise the qualitative experience of their involvement, specifically the consistency and quality of their care planning relationships.

If meaningful service user and carer involvement in care planning is to be achieved, then there is a pressing need to agree and foster a system-wide, user-centred model of collaboration and involvement.[21,22] Our research programme aimed to address the gap between policy and practice by addressing this need.

Aims of the programme

The Enhancing the Quality of User and Carer Involvement in Care Planning (EQUIP) programme was led by the University of Manchester and Manchester Mental Health and Social Care NHS Trust (now Greater Manchester Mental Health NHS Foundation Trust) in collaboration with the University of Nottingham and Nottinghamshire Healthcare NHS Trust. Prior to the programme grant award, we were awarded a Programme Development Grant (RP-DG-1209-10020) to undertake preparatory work, including a literature review, delivering a research methods course for service users and carers to increase service user and carer capacity to engage with the proposed research (see *Appendix 1*). In our programme of work, we aimed to develop, evaluate, implement and disseminate a co-produced and co-delivered training intervention for mental health professionals to improve service user and carer involvement in care planning.

This work was divided into four separate but inter-related workstreams (*Figure 1*).

Workstream 1

- Develop a co-produced training intervention to improve service user and carer involvement in care planning for mental health professionals.
- Develop and validate a patient-reported outcome measure (PROM) of service user involvement in care planning, develop an audit tool and assess individual preferences for key aspects of care planning involvement.

Workstream 2

- Evaluate the clinical effectiveness and cost-effectiveness of a co-delivered training package to enhance service user and carer involvement in care planning in secondary care mental health services.

Workstream 3

- Understand the contextual, individual and organisational barriers and facilitators, and examine the processes involved in the development and use of service user- and carer-involved care planning.

Workstream 4

- Disseminate our findings, training intervention materials and patient-mediated resources produced during the programme to all relevant stakeholders using multiple methods.

Programme management

The programme was sponsored by Manchester Mental Health and Social Care Trust, and the EQUIP multidisciplinary team was based across two sites (University of Manchester and University of Nottingham) and collectively formed the Programme Management Group, which met quarterly to monitor programme progression. The chief investigator was responsible for the overall leadership, management and output from the programme, and there was a designated lead for each workstream. Each site had a principal investigator, who led monthly team meetings with all programme site staff. A full risk assessment of the programme was conducted by the chief investigator and the trial manager, and a risk register was developed. The risk register was managed and monitored by the trial manager and the chief investigator, and was a standing agenda item at each Programme Management Group meeting. A Programme Steering Committee was established, comprising an independent chairperson with expertise in programme grants and care planning, and three other independent members including a service user and a clinician with experience of working in community teams. The Programme Steering Committee met biannually throughout the duration of the programme.

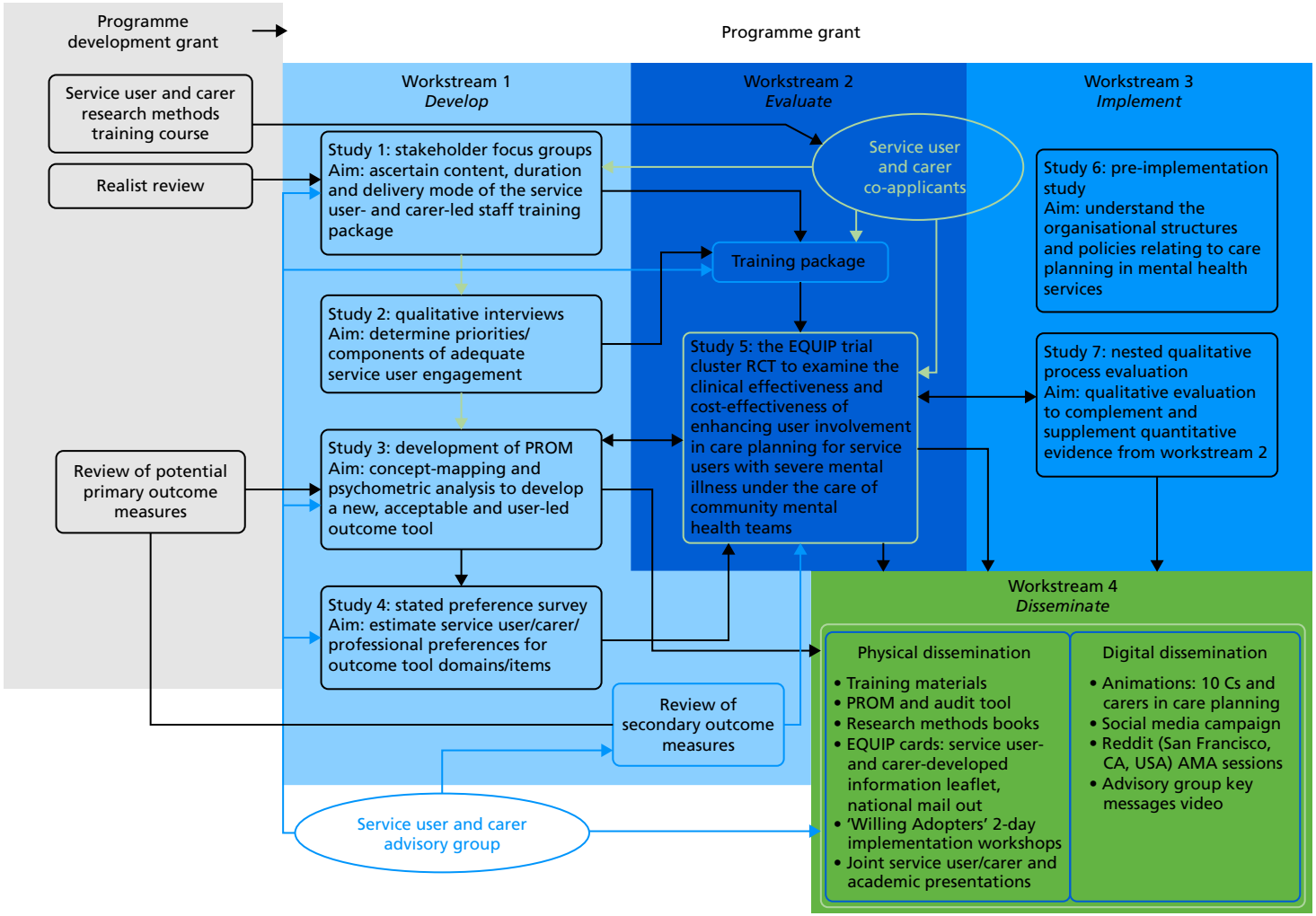

FIGURE 1 The EQUIP programme. Blue arrows denote service user and carer advisory group involvement. Dark blue boxes denote direct service user and carer advisory group input/output. Green arrows and boxes indicate significant input from service user and carer co-applicants/researchers. AMA, Ask Me Anything; RCT, randomised controlled trial.

Ethics

The programme received a favourable ethics opinion from the National Research Ethics Service on 8 August 2014 (National Research Ethics Service Committee North West Lancaster, Research Ethics Committee reference 14/NW/0297; Integrated Research Application System project ID 125899).

Patient and public involvement

In our programme development grant (RP-DG-1209-10020), we developed and delivered a 6-day interactive training course on research methods for service users and carers to facilitate active engagement in the research programme. From this cohort, two service users and a carer became co-applicants on the programme grant, and others formed the service user and carer advisory group (SUCAG). Two service users were appointed (0.5 whole-time equivalent) for the duration of the programme and the carer (through personal choice) was appointed on a casual basis.

The service user and carer co-applicants have been integral to the research design, data collection, analysis and dissemination in workstreams 1 and 3, co-developing and delivering the training in workstream 2 and disseminating in workstream 4. The co-applicants have been supported to lead on writing papers and presenting at conferences, and to facilitate this process each service user and carer co-applicant was paired with a writing mentor. Three of the EQUIP papers[16,17,23] have been led by co-applicants and all have developed considerable research skills; Andrew Grundy has completed the first year of a PhD (Doctor of Philosophy) qualification.

The service user co-applicants have also been fundamental in the provision of the research methods training, which we continued to deliver throughout the programme. A research methods book based on the training with significant contribution from service users and carers has been developed.

A SUCAG was convened at the start of the programme grant and held 11 meetings between March 2013 and April 2017. Members of the SUCAG were recruited from the first two cohorts of the service user and carer research methods training course, and those with similar experience from the Nottingham area. An independent chairperson of the group was recruited via expression of interest from the pool of trained service users and carers.

Members of the SUCAG (14 in total) have had a primary role in advising the study team throughout the grant. Activities have included confirming outcome measures for the trial across a range of domains that were identified by service users and carers as part of the programme development work; informing development of the PROM through identification of key questions of ‘quality in care planning’; co-developing a definition of care planning; contributing to the methodological development of workstream 3, particularly in relation to the use of diaries and observations of care planning meetings; contributing to the development of the trial outcome measure packs (advice on presentation and ordering of measures to reduce participant fatigue); contributing case studies for intervention training; and reviewing all the participant trial documentation, for example by providing reviews of the participant information sheets and covering letters prior to submission for ethics review.

The SUCAG meetings have also provided a regular opportunity for the research team to provide feedback on the programme progress and to explain the funder reporting requirements, for example the 24-month checkpoint reporting process.

Members of the SUCAG were invited to apply to become trainers to co-deliver the training intervention for health professionals in workstream 2. The rationale for running a ‘train the trainers’ course was that few had any experience in training and expressed fears and concerns about training mental health

professionals. Nine people applied and all were offered places on a 'train the trainers' course (with the view that six would co-deliver the training and three would be held in reserve in case of sickness/absence).

Throughout the programme grant, we have used the EQUIP website (http://research.bmh.manchester.ac.uk/equip), Twitter (https://twitter.com/Care_Plan) (Twitter, Inc., San Francisco, CA, USA; www.twitter.com) and regular study newsletters to engage with interested parties and to keep them up to date with the programme. We have also sought to use online and innovative media platforms to actively engage with service users, carers and health professionals via our patient-mediated materials (e.g. the service user 10Cs[16] animation of care planning and accompanying EQUIP cards, http://research.bmh.manchester.ac.uk/equip/10Cs, and the award-winning carers animation, http://research.bmh.manchester.ac.uk/equip/mentalhealthcareplanning). With the SUCAG, we have developed a video dissemination of patient and public involvement (PPI) in the study to ensure that it is accessible to a wider public audience beyond our research participants and colleagues in health and academia.

The strength of PPI throughout the programme grant has been underpinned by having a nominated lead for PPI in place to co-ordinate PPI activities across the four workstreams, to liaise with the SUCAG and to provide support to co-applicants with lived experience of mental health difficulties. We were awarded the Mental Health Research Network award for outstanding carer involvement in March 2014. In 2018, we were awarded the National Institute for Health Research (NIHR) Clinical Research Network (CRN) McPin MQ Service User & Carer Involvement in Mental Health Research Award. Notably, all of our SUCAG members have taken up advisory group roles in other studies.

We have all benefited and feel privileged to have worked with service users and carers. There is little doubt that the quality of the programme has been much enhanced by our co-development, delivery, production and dissemination activities.

Workstream 1: development

The aims of workstream 1 were to develop a:

- training intervention to enhance service user and carer involvement in care planning in secondary care mental health services
- PROM that better meets user and carer requirements for quantifying the extent of their care planning involvement in UK mental health services.

Key findings from a systematic review conducted as part of the programme development grant (RP-DG-1209-10020; see *Appendix 1*) created a foundation on which to build up evidence through the workstream using focus groups (study 1) and interviews (study 2) with service users, carers and mental health professionals. Following data collection, findings were synthesised by the whole research team during a 'synthesis day' and key material was generated with which to develop training material for a course for health professionals. The data collected were also used to inform the content for a PROM and the audit tool (study 3) and a stated preference survey (study 4) to measure service user and carer involvement in care planning.

Outputs

The findings of the systematic review are published in Bee *et al.*[24] (see *Appendix 2*).

Study 1

The aim of study 1 was to develop the content, delivery mode and length of a user- and carer-led training intervention for health professionals, and to improve user and carer involvement in care planning.

Methods

Focus groups were conducted with a range of stakeholders (service users, carers and mental health professionals). Focus group interview schedules were informed by the systematic review[5] and developed by the research team, with input from academics, clinicians and service users and carers from the research programme and the SUCAG. Schedules covered current perspectives on user involvement in care planning, the process and outcomes of care planning, prior experiences of service user and carer involvement and potential training requirements. Focus groups lasted approximately 60–90 minutes and were undertaken at a range of locations to support participation: at university campuses, trust sites and community locations (e.g. at carers' centres and participants' homes). Participants received high-street gift vouchers worth £25 for taking part.

Participants were recruited purposively from Manchester Mental Health and Social Care Trust using a range of methods (trust intranet advertisements, press releases, posters in trust premises and information distributed through carer and service user networks and forums). An initial target to conduct six focus groups was exceeded, with a total of nine focus groups taking place, involving 61 participants across the groups. Four focus groups were conducted with service users and carers ($n = 34$), four were with health professionals ($n = 18$) and there was one mixed group with users, carers and professionals ($n = 9$).

Focus groups were recorded, transcribed and anonymised, then analysed using a qualitative framework approach,[25] an acknowledged method of analysing primary qualitative data pertaining to health-care practices with policy relevance.[26] Data from the focus groups were synthesised with further data from individual interviews (study 2) and key findings are reported in study 2.

Study 2

The aim of study 2 was to determine the priorities and core concepts underpinning service user and carer engagement and involvement in care planning in mental health services.

Methods

Individual qualitative interviews were conducted with service users, carers and mental health professionals.

Data from individual interviews were collected with the intention to combine with study 1 data to prevent missing any issues that participants might be reluctant to raise in a focus group situation.[27] Participants were recruited as per study 1, with further recruitment from Nottinghamshire Healthcare NHS Trust via poster displays, trust newsletters and the intranet, university press releases, oral presentations at service user and carer groups and via service user and carer news bulletins and websites. Interviews lasted approximately 60–90 minutes and were undertaken at a range of locations to support participation: at university campuses, trust sites and community locations (e.g. at carers' centres and participants' homes). Participants received high-street gift vouchers worth £25 for taking part. A total of 74 interviews across Manchester ($n = 43$) and Nottingham ($n = 31$) were completed (22 service users, 21 carers, 3 user/carers and 28 professionals). A number of interview participants also took part in the focus groups in study 1 ($n = 22$).

Interviews were recorded, transcribed and anonymised, and analysed in combination with data from study 1 using framework analysis. Framework analysis is commonly used within qualitative health research and allows for both inductive and deductive coding to be incorporated into the analysis process, which means that codes emerging from the data can be combined with important codes that were identified prior to the study. The analysis team comprised service user and carer co-applicants working alongside experienced qualitative researchers for independent coding purposes. The team read their transcripts on multiple occasions to familiarise themselves with the data before starting to code the transcripts. The data and analysis were managed using a Microsoft Excel® (Microsoft Corporation, Redmond, WA, USA) database comprising participant characteristics, along with a Microsoft Word (Microsoft Corporation, Redmond, WA, USA) document containing emerging themes from each transcript, to provide a data trail. The team met regularly to discuss their own emergent codes, to develop a provisional coding framework, to discuss alternative explanations of interpretations and to ensure that the emerging codes remained grounded in the original data for purposes of validity. This approach to analysis meant that during the constant comparison of new data, the provisional framework was amended and re-shaped to enable the introduction of new codes, and allowed for the removal of other codes that became superfluous over the course of the analysis. The resultant framework contained only those codes agreed on by the whole analysis team. Previous iterations of the coding framework were stored for purposes of transparency and the research team agreed as a whole when data saturation had occurred and no new themes were emerging from the data. In order to further strengthen the validity of the qualitative findings, the final coding framework was presented to the wider study team, which was asked to comment on whether the framework seemed grounded in the data, on any omissions in the framework or any ambiguities.

Key findings

The combined data from studies 1 and 2 were divided into separate categories for user and carer data and health professional data.

Health professionals

A clear training need was identified by health professionals, with strong support for the idea of user and carer involvement in that training, and for whole-team training for greater impact. A range of barriers to service user involvement were identified, including individual barriers, such as skills deficits and staff understanding of user-involved care planning, and organisational barriers, including workload/resource

pressures, the current key performance indicator/target culture of the NHS and difficulties balancing involvement with risk management.

Service users and carers

In accordance with the professional data, users and carers identified a need for training for all mental health staff, but there was a feeling that senior clinicians might benefit most. There were suggestions that training should prioritise skills in active listening and communication, assertiveness and time for reflection. Participants believed that the training should be mandatory, accredited and updated regularly, and should be co-delivered in order to value the expertise of service users and carers. Potential barriers to effective training were also raised, including staff workload and attitude, lack of accountability and reluctance among service users and carers to be involved as trainers. Issues around care plans also emerged, where care plans were seen as meaningless, not tailored to individuals and not taking into account service users' and carers' wishes, experiences or needs. Participants felt that good involvement is facilitated by good relationships with and between staff, effective communication, partnership working and allowing sufficient time during care planning. Barriers to involvement were highlighted as frequent staff changes, workload, lack of knowledge about services by all parties, unhelpful staff attitudes and episodes of severe illness.

Outputs

A full description of the methods, analysis and results have been published in Bee *et al.*,[24] Cree *et al.*[17] and Grundy *et al.*[16] (see *Appendix 2*).

Strengths and limitations

We examined care planning issues with contemporary mental health services in depth across a large sample and from multiple stakeholder perspectives, maximising the transferability of our findings. We included service users and carers in analysis (independent coders) and presented our coding manuals to the SUCAG to optimise the rigour of our analysis. It is likely that the health professionals who took part in these studies were those who were motivated to achieve 'good' care planning and/or were open to organisational and individual change. The data also reflect only the views of health professionals within only two NHS trusts and may not be generalisable to other individuals, settings or localities. In terms of service user and carer data, we interviewed a self-selected sample of participants, many of whom had particularly strong views on the shortcomings of the care planning process. Despite efforts to recruit directly from black, Asian and minority ethnic (BAME) third-sector organisations, there was only a small minority of participants from BAME groups.

What the studies add

Health professional data show that a combination of individual and organisational factors currently hinder successful service user and carer involvement in care planning, and highlight a clear need to deliver training to increase the quality and consistency of care planning procedures. The studies also draw attention to the fact that service users and carers are concerned about the way in which care plans are created and implemented, and that there is a shared perception between service users and carers of a reluctance among health professionals to involve them in the care planning process.

Scoping review of training

Building on the evidence gathered for training content, a scoping review was conducted to identify relevant work that could inform the development, delivery and implementation of the training courses. Three key reviews were identified.[28–30] The exercise produced a number of key findings relevant to the development of the training programme, including that small interactive groups are more effective than large didactic groups; educational outreach (supervision) is effective; improving collaboration between health professionals might be helpful; multifaceted interventions are likely to be better than single-strand intervention; and providing patient materials may help implementation.

Data synthesis

A synthesis day was held with all study applicants and researchers in November 2013.

The two key aims of the synthesis day were to:

1. synthesise the evidence from workstream 1 to develop the training intervention for health professionals
2. develop a 'train the trainers' course for service users and carers to co-deliver the training intervention.

Structured summaries of key findings from the systematic review, focus groups and interviews with service users, carers and health professionals, and from the scoping review of training interventions, were distributed by study leads to the group (see *Appendix 2*). Our synthesis (*Figure 2*) followed a similar format to formats of previous studies, where we successfully synthesised a variety of data sources.[31–33] A group discussion involved tabulating key evidence statements within a matrix where each row referred to the results from each dataset and each column represented one of the core training components for both the training intervention and the 'train the trainers' course (see *Appendix 2*).

Training intervention for health professionals

The core training components included the content, attendance, duration, delivery mode, resources needed and system requirements that we wished to address. The matrix provided the platform for a structured discussion between the programme team to derive the final training intervention and 'train the trainers' course. Those components that did not provide evidence or were ambiguous were discussed by applicants in small teams until a consensus was reached.

The training intervention is detailed in accordance with the Template for Intervention Description and Replication (TIDieR) guidelines in *Box 1*.[34]

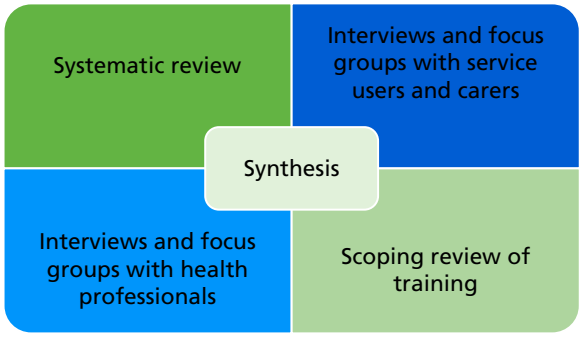

FIGURE 2 Synthesis of multiple data sources.

BOX 1 The TIDieR guidelines for development and replication of the training intervention

Why: our aim was to co-develop, co-produce and co-deliver (with service users/carers) a best-evidence, acceptable and feasible training programme for mental health professionals to enhance user and carer involvement in care planning. Two reviews were conducted, including a narrative synthesis (Bee *et al.*[5]), which examined how user-involved care planning is operationalised within mental health services and to establish where, how and why challenges to user involvement occur; and a scoping review of training reviews and interventions that change clinician behaviour. In addition, focus groups and individual interviews with service users, carers and health professionals were conducted to ascertain training content and delivery requirements and to determine the priorities and components of adequate user and carer involvement in care planning. The evidence from the reviews and qualitative data were synthesised to develop and design the training.

What: a range of training materials have been developed for the training, including Microsoft PowerPoint® (Microsoft Corporation, Redmond, WA, USA) slides, case scenarios, audio-recordings from health professionals, service users and carers and a trainer's manual.

Who: the synthesis identified that the training should be multidisciplinary, including all health professionals and psychiatrists. Team training was seen as optimal and, as far as possible, teams will be trained together. The training will be delivered by two of the co-applicants (both academics with teaching experience) and three or four service users and carers who have attended a 4-day 'train the trainers' course.

How: the synthesis indicated that training should include a range of formats: face to face, self-directed learning and follow-up supervision. The consensus exercise indicated a minimum of 15 hours and maximum of 30 hours. The course will run for 2 days (12 hours) plus 6 hours' follow-up supervision and 8 hours' self-directed learning (optional). Hence, each health professional will receive 18 hours of facilitated training and an additional optional 8 hours' self-directed learning.

Where: consensus was reached that the training venue should be outside the clinical area, geographically convenient, provide good catering and in a venue with appropriate training resources.

When and how: the training will be delivered to each cluster randomised to the training intervention over 2 days. In recruiting teams, we ask that 80% of the care co-ordinators within each team attend the training. The training will be delivered within 6 weeks of service users being recruited into the trial.

Tailoring: the intervention has been tailored for health professionals.

Modifications: only minor modifications will be made in the light of feedback during the trial. If the trial is successful and we implement the training across other NHS trusts, modifications will be made in the light of feedback collected from the process evaluation.

How well: fidelity of the training has been ensured by the careful development and synthesis work described earlier, the 'train the trainers' course, the development of a detailed manual and the delivery of training by the same groups of trainers.

The core components of the training were a training package including a training manual, training materials, presentations, and group exercise materials consisting of 2 days' face-to-face training (12 hours in total), an 8-hour optional self-directed learning package and 6 hours' supervision per team in the 6 months post training.

The 2-day training intervention included interactive presentations, audio-visual clips, small group exercises, skills practice exercises (including role play), live demonstrations of good practice, and working with anonymised care plans or anonymised examples from professionals' caseloads. We wanted to move away from the 'sharing personal stories' model of user/carer 'involvement' in delivering training; thus, although the academic researcher was the lead facilitator, the service users and the carers facilitated group work, shared both positive and negative experiences of care planning and shared ideas around good and poor practice with the wider group throughout the 2 days.

The training team consisted of two academic researchers, six service users and one carer. We delivered the initial training as a whole team to ensure consistency; subsequent training sessions comprised one academic researcher and two or three service users and carers. Over the duration of the study, some of the service users and carers took leading roles in the training. The training was designed to be a co-produced and co-delivered training resource.

'Train the trainers' course

The synthesis contributed to the development of the 'train the trainers' course. A 4-day course was designed to train service users and carers to deliver the training course to health professionals. The underlying philosophy of the programme was participatory learning and andragogy (adult learning) and aimed to enable participants to understand the principles of training and identify the attributes and values of an effective trainer. The training focused on core educational principles of delivering high-quality training, including facilitating small and large groups, engaging and empowering trainees and maximising the use of training materials. The fourth day of training included a review of the EQUIP professional training intervention for health professionals and an opportunity to practice presentation and facilitation skills.

In addition to our three service user and carer co-applicants, we recruited six service users and carers from our SUCAG with the aim of having a core team of six trainers and three reserves in case of sickness/absence. The course was delivered by the study team in June 2014 and incorporated 2 days of educational principles, 1 day of micro-teaching with peer feedback and a final day focusing on delivering the training intervention for health professionals. (Training materials are available on request from the authors.)

Evaluation of the 'train the trainers' course

The aim of the study was to obtain views from service users and carers who attended the 'train the trainers' course 1 year following completion of the course, when participants had had exposure of delivering the training. In particular, the team wanted to elicit feedback on training facilitation, content and preparedness for undertaking a trainer role on the EQUIP care planning training intervention for mental health professionals.

Methods

Individual semistructured interviews to explore participants' views on training acceptability were used. Letters of invitation to take part in the evaluation were sent to all nine trainees approximately 7 months after the completion of training. Participants had to opt in (by e-mailing or phoning). All nine trainees agreed to take part and provided written informed consent. Interviews were digitally recorded and transcribed verbatim. Of the nine participants, there were six service users (four female, two male) and three carers (two female, one male). Transcripts were analysed independently by two members of the trial team using thematic inductive coding of themes emerging to uncover meaning in participants' accounts of their involvement in the training process.[35] The team met to review themes and reach agreement on the coding of the data and the overarching themes.

Key findings

Course content was rated highly but may benefit from review and/or extension to allow the range of topics and resulting professional training programme to be covered in more depth. Trainees who delivered the training intervention to health professionals were positive about their support experiences, preparedness and personal impacts. Service users and carers wanted to gain new skills and confidence in presentation/facilitation as well as to make a difference to health-care practice. We also found that service users desired different levels of involvement in training facilitation – some wanted to take a more active role than others.

Outputs

A full description of the methods, analysis and results has been published in Fraser *et al.*[36] (see *Appendix 2*).

Study 3

The aim of study 3 was to co-develop, with service users and carers, a PROM to assess user/carer involvement in mental health-care planning and an audit tool for mental health services.

Patient-reported outcome measure

We undertook a systematic review reporting the use, development and/or validation of user- and/or carer-reported outcome measures of involvement in mental health-care planning.[37] The review revealed a lack of care planning measures that are able to meet service user nominated acceptability criteria alongside published standards for psychometric quality. Our aim was to co-develop a PROM to assess user and carer involvement in care planning and the SUCAG suggested that the measure should include the following attributes: suitable for use in the UK; developed via service user and carer collaboration; available in a self-report format for both service users and carers; rated by both service users and carers; based on a social and recovery model; continuous rather than a dichotomous scale; and between 12 and 15 items long.

Audit tool

We developed an audit tool to inform clinicians, services, auditors and researchers who want to quantify levels of user and carer involvement in care planning.

Methods

Potential PROM items were generated from data collected in workstream 1 (studies 1 and 2); 70 candidate items were developed. Face validity was examined with a mixed sample of 16 members of the SUCAG using cognitive interviewing. Nine items were removed because the SUCAG found their language or wording unclear or hard to understand.

The remaining 61 items constituted the nascent scale. Members of the SUCAG were also asked to comment on potential response formats. Consensus was reached for a five-point Likert scale with named anchors of ‘strongly disagree’ and ‘strongly agree’ and a middle neutral value with the label ‘neither agree nor disagree’.

We recruited self-identified service users with severe and enduring mental health problems and carers to complete the emerging PROM, using multiple recruitment strategies (including advertising on NHS trust intranets, newsletter and press releases; posters displayed on trust premises, local trust-based and third-sector study advocates, via Twitter and re-tweeted by local and national mental health charities across the UK and local and national service user and carer forums). Data were collected using online (SelectSurvey version 4.5; ClassApps, Kansas City, MO, USA), postal and face-to-face modalities.

In total, 402 participants completed the 61-item PROM. A randomly selected sample of the 402 were approached to undertake a second completion 4 weeks after baseline, to assess test–retest validity, and 59 test–retest PROMs were completed.

For Rasch analysis, a minimum sample size of 250 allows for > 99% confidence that item calibrations are stable to within ± 0.5 logits, irrespective of scale targeting. This minimum sample size was also deemed sufficient. Prior to statistical analysis, data were double entered and a 5% accuracy check was made. Less than 0.1% errors were detected during the double-entry procedure.

Psychometric and statistical analysis of the data were conducted, involving exploratory factor analysis, Mokken analysis,[38] Rasch analysis,[39] category threshold analysis, differential item functioning, local dependency, scale reliability, unidimensionality and test–retest reliability. An iterative process of item removal reduced the remaining 61 items to a final 14-item scale (*Table 1*). The final scale has acceptable scalability ($H_0 = 0.69$), reliability ($\alpha = 0.92$), fit to the Rasch model [$\chi^2(70) = 97.25$, $p = 0.02$], and no differential item functioning or locally dependent items. Scores remained stable over the 4-week follow-up period, indicating good test–retest reliability.

For the audit tool (*Table 2*), we completed a three-round consensus exercise with our SUCAG ($n = 16$) and reduced the 61 candidate PROM items to form a shorter six-item audit tool. In round 1, items were presented to the SUCAG members ($n = 16$), who were each asked to select the top 10 PROM items that they felt were most important to include in an audit tool. A total of 27 items were identified by the group. In round 2, these 27 items were discussed, with individuals providing verbal reasoning for their choices. The 27 items were then re-rated for importance based on the group discussion, reducing the pool down to 10 items. In round 3, these 10 items were identified and discussed further until consensus was reached on six audit tool priorities. Psychometric assessment assessed the performance of the six items identified by the SUCAG using a combination of classical test, Mokken and Rasch analyses. Test–retest reliability was calculated using *t*-tests of interval level scores between baseline and 2- and 4-week follow-up.

Key findings

The 14-item PROM 'Enhancing the Quality of User and Carer Involvement in Care Planning (EQUIP)' scale displays excellent psychometric properties and is capable of unidimensional linear measurement. The scale is short, user- and carer-centred and will be of direct benefit to clinicians, services, auditors and researchers wishing to quantify levels of user and carer involvement in care planning (see *Table 1*). A six-item audit tool was also developed for NHS trusts (see *Table 2*).

TABLE 1 The final 14-item PROM

Item	Completely disagree		Neither agree nor disagree	Completely agree	
1. The care plan has a clear objective	0	1	2	3	4
2. I am satisfied with the care plan	0	1	2	3	4
3. I am happy with all of the information on the care plan	0	1	2	3	4
4. The contents of the care plan were agreed on	0	1	2	3	4
5. Care is received as it is described in the care plan	0	1	2	3	4
6. The care plan is helpful	0	1	2	3	4
7. My preferences for care are included in the care plan	0	1	2	3	4
8. The care plan is personalised	0	1	2	3	4
9. The care plan addresses important issues	0	1	2	3	4
10. The care plan helps me to manage risk	0	1	2	3	4
11. The information provided in the care plan is complete	0	1	2	3	4
12. The care plan is worded in a respectful way	0	1	2	3	4
13. Important decisions are explained to me	0	1	2	3	4
14. The care plan caters for all the important aspects of my life	0	1	2	3	4

TABLE 2 The EQUIP audit tool

Item	Completely disagree		Neither agree nor disagree	Completely agree	
1. I am satisfied with the care plan	0	1	2	3	4
2. My preferences for care are included in the care plan	0	1	2	3	4
3. The care plan helps me to manage risk	0	1	2	3	4
4. The information provided in the care plan is complete	0	1	2	3	4
5. Important decisions are explained to me	0	1	2	3	4
6. The care plan caters for all the important aspects of my life	0	1	2	3	4

Strengths and limitations

We undertook a stringent, methodological process leading to an initial PROM measure of 61 items, developed in conjunction with service users and carers, and reduced to a 14-item psychometrically validated PROM. Measure length and ease of completion were identified as key user-nominated attributes for PROM acceptability. However, the utility of any measure depends on its validity, reliability, sensitivity and feasibility of completion and a trade-off between these criteria is often necessary. It is possible that some concepts that were originally conceived as important to service users during item generation were not adequately represented by the items retained in the final measure. This accepted, the final measure encompassed a breadth of items that represented a multiplicity of user responses. The attributes selected as most important for the audit tool were chosen by our SUCAG and may lack a diverse or representative sample of individuals using secondary care mental health services.

What this study adds

Current measures, such as those used by the UK CQC, focus on objective indicators of care planning administration rather than those aspects of care planning that service users value most. Our 14-item PROM 'Enhancing the Quality of User and Carer Involvement in Care Planning (EQUIP)' addresses this gap. The scale is short, user- and carer-centred and will be of direct benefit to clinicians, services, auditors and researchers wishing to quantify levels of user and carer involvement in care planning.

Outputs

The systematic review reporting the outcome measures of involvement in mental health-care planning has been published in Gibbons *et al.*[37] (see *Appendix 2*).

The description of analysis, methods and results of the PROM has been published in Bee *et al.*[40] (see *Appendix 2*).

Study 4

The aim of study 4 was to use a stated preference survey to estimate the strength of user/carer preferences and weights for key items included in the audit tool.

Methods

We used a binary discrete choice experiment with five attributes (i.e. whether or not preferences for care are included in the care plan; whether or not the care plan helps me manage risk; completeness of the information in the care plan; whether or not important decisions are explained to me; and whether or not all important aspects of my life are catered for) and an additional attribute describing the time per person spent

on care planning related activities. Each attribute had five levels. Each level described how the service might be described by service users, from completely disagree (the reference level) to completely agree. *Table 3* shows an example choice question; 13 choice questions were designed, with each choice question describing two alternative care planning approaches for participants to choose their preferred option.

Service user and carer participants were recruited from adult secondary care mental health services in two NHS trusts, and online via social media. Participant characteristics were summarised with descriptive statistics. The analyses included all participants who completed one or more choice set. For the analysis, the completely disagree level of each attribute was used as the reference level for each of the audit tool attributes. This gives an indication of the value to participants of moving from the worst to an improved level of involvement in the care planning process.

This first step was to summarise and describe the data and inform further analysis. Accordingly, it was hypothesised that higher levels for the audit tool attributes (e.g. agree or completely agree) would be preferred to lower levels (e.g. disagree or completely disagree). In contrast, it was thought that participants would prefer to spend less rather than more time per month on care planning activities. A conditional logit regression using maximum likelihood estimation was used as the starting point for the analysis.[41,42] However, participants' preferences may vary because of factors that are observed, such as sociodemographic characteristics, type of respondent (service user or carer), design factors (e.g. postal vs. online survey), or because of unobserved factors. To account for this, a random-effects, mixed logistic regression model was used for the main analysis.[43] The analysis treated all attributes as random.

A marginal rate of substitution was calculated using the time spent per month on care planning related activities to estimate the amount of time each person is willing to trade to gain their preferred levels of each audit tool attribute.

Stata® version 15 (Stata Corp LP, College Station, TX, USA) was used for all the analyses reported here. The mixed logistic regression used the published mixlogit and wtp (delta) user commands developed for Stata.[44,45]

Key findings

We recruited 232 participants, of whom 89% completed all choice questions. Most responses were from service users ($n = 132/215$, 61%), carers ($n = 49/215$, 23%) and people identifying themselves as both service users and carers ($n = 34/215$, 16%). Seventeen participants did not report if they were services users or carers. The mixed logit regression results are summarised in *Table 4*.

TABLE 3 Example question

Which care plan do you prefer? (tick one)	Care plan A	Care plan B
My preferences for care are included in the care plan	Completely disagree	Completely agree
The care plan helps me to manage risk	Neither agree nor disagree	Disagree
The information provided in the care plan is complete	Completely agree	Agree
Important decisions are explained to me	Neither agree nor disagree	Disagree
The care plan caters for all the important aspects of my life	Agree	Neither agree nor disagree
The average time you spend each month to prepare for, attend or follow up on care planning meetings is . . .	2 hours	4 hours

TABLE 4 Coefficients and marginal rate of substitution, mixed logistic regression

Attribute	Coefficient (SE)	*p*-value	MRS (95% CI)
My preferences for care are included in the care plan			
Completely disagree	Reference level		
Disagree	–0.539 (0.080)	< 0.001	–4.6 (–7.9 to –1.4)
Neither agree nor disagree	0.102 (0.069)	0.141	0.9 (–0.4 to 2.2)
Agree	0.567 (0.083)	< 0.001	4.9 (1.4 to 8.3)
Completely agree	0.797 (0.103)	< 0.001	6.8 (2.1 to 11.5)
The care plan helps me to manage risk			
Completely disagree	Reference level		
Disagree	–0.508 (0.076)	< 0.001	–4.4 (–7.7 to –1.0)
Neither agree nor disagree	0.209 (0.082)	0.011	1.8 (0.2 to 3.4)
Agree	0.532 (0.083)	< 0.001	4.6 (1.3 to 7.9)
Completely agree	0.484 (0.099)	< 0.001	4.2 (0.4 to 7.9)
The information provided in the care plan is complete			
Completely disagree	Reference level		
Disagree	–0.116 (0.071)	0.102	–1.0 (–2.3 to 0.3)
Neither agree nor disagree	–0.002 (0.077)	0.979	0.0 (–1.3 to 1.3)
Agree	0.115 (0.083)	0.165	1.0 (0.0 to 2.5)
Completely agree	0.188 (0.077)	0.015	1.6 (0.1 to 3.1)
Important decisions are explained to me			
Completely disagree	Reference level		
Disagree	–0.230 (0.070)	0.001	–2.0 (–3.7 to –0.2)
Neither agree nor disagree	0.077 (0.064)	0.227	0.7 (–0.5 to 1.8)
Agree/completely agree	0.577 (0.076)	< 0.001	4.9 (1.6 to 8.3)
The care plan caters for all the important aspects of my life			
Completely disagree	Reference level		
Disagree	–0.216 (0.070)	0.002	–1.9 (–3.6 to –0.1)
Neither agree nor disagree	0.049 (0.063)	0.436	0.4 (–0.7 to 1.5)
Agree/completely agree	0.519 (0.079)	< 0.001	4.5 (1.2 to 7.7)
Average time you spend each month to prepare for, attend or follow up on care planning meetings			
Time	–0.002 (0.001)	0.005	Not applicable

CI, confidence interval; MRS, marginal rate of substitution; SE, standard error.

The data suggested that preferences were strongest for the attribute 'my preferences for care are included in the care plan', with service users prepared to spend 5 hours [95% confidence interval (CI) 1 to 8 hours] and 7 hours (95% CI 2 to 12 hours) per month for improvements compared with the reference level. The least preferred attribute was whether or not the information included in the care plan was complete, with participants willing to spend 1.5 hours (95% CI 0.1 to 3.0 hours) for improvements, compared with the reference level.

Strengths and limitations

Service users and carers were involved in the design of the discrete choice experiment, survey materials and recruitment. Our recruitment methods increased the chance of self-selection into the study and may reduce the representativeness of participants and we used analysis methods to help account for variation in participants' preferences because of unobserved factors or individual characteristics. In addition, survey respondents were based in the UK and were predominantly female and white British. Thus, the results may not be generalisable within and outside the UK. We used a main effects design that means that important interactions between the study attributes were not accounted for, reducing the robustness of the results.

What this study adds

To our knowledge, this is one of the first large, full-profile, discrete choice experiments conducted with people with serious mental illness. The study results demonstrated that participants preferred care plans that emphasised their involvement by including their preferences, helping them to manage risk, catering for all of the important aspects of their life and by having important decisions explained to them. The completeness of information included in the care plan was the least preferred attribute. The marginal rates of substitution suggested that service users are willing to spend time for improvements to the way in which they are involved in their care planning. Our findings could be used to help services target improvements in care planning to the aspects most important to service users.

Outputs

The full results of the stated preference survey are reported in *Appendix 2*.

Workstream 2: evaluation

Study 5

The aim of workstream 2 (study 5) was to evaluate the clinical effectiveness and cost-effectiveness of a training intervention to enhance service user and carer involvement in care planning in secondary care mental health services.

Methods

We conducted a pragmatic cluster trial of the clinical effectiveness and cost-effectiveness of the training intervention to enhance service user- and carer-involved care planning compared with controls in UK NHS community mental health services. The trial used cohort and cross-sectional samples to reduce risks to recruitment and retention. The cluster cohort was recruited at baseline and followed over the 6 months of the trial, whereas the cluster cross-section was recruited at the end of the trial. Consenting service users cared for by each community mental health team (CMHT) were recruited and carers were recruited from consenting service users. Each CMHT was randomised to either intervention (training in care planning) or control (usual-care planning). The CMHTs randomised to intervention received the training package.

We recruited service users and carers from CMHTs between July 2014 and December 2015 from 10 NHS trusts across the UK. Service users were aged $\geq$ 18 years with a severe mental illness under the care of participating CMHTs. CMHTs screened lists and excluded patients who were not deemed to have capacity to provide fully informed consent or who were too unwell at the time of recruitment. The primary outcome was patient self-reported 'autonomy support' measured using the Health Care Climate Questionnaire (HCCQ-10).[46] The HCCQ-10 is a self-report scale based on self-determination theory and measures 'autonomy support', defined as patient perceptions of the degree to which they experience their health professionals as supporting choice and ensuring that their behaviour (and behaviour change) is congruent with their values. The scale has 10 items, examples of which include 'I feel that my mental health-care provider team has provided me with choices and options' and 'My mental health-care provider team has worked with me to develop a mental health-care plan'. Items are scored on a seven-point scale from 'strongly disagree' to 'strongly agree'. An overall score is calculated as the mean of the items (expressed out of 100), with a higher score indicating greater 'autonomy support'.

Secondary outcomes included patient self-reported involvement in decisions (EQUIP PROM);[40] satisfaction with services [Verona Service Satisfaction Scale (VSS54)];[47] side effects of antipsychotic medication [Glasgow Antipsychotic Side Effects Scale (GASS)];[48,49] well-being [Warwick–Edinburgh Mental Wellbeing Scale (WEMWBS)];[48] recovery and hope [Developing Recovery Enhancing Environment Measure (DREEM)];[50] anxiety and depression [Hospital Anxiety and Depression Scale (HADS)];[51] alliance and engagement [California Psychotherapy Alliance Scale (CALPAS)];[52] quality of life [World Health Organization Quality of Life (WHOQOL) questionnaire];[53] carer satisfaction [Carer and User Expectations of Services (CUES)];[54] quality-adjusted life-years (QALYs); and use of services. Measures were completed at baseline (pre training) and at 6 months post training (cohort sample), and at 6 months post training only (cross-sectional sample).

Outcomes for the cross-sectional sample included the HCCQ-10[46] and the PROM.[40] Carer measures included the EQUIP PROM[40] and WHOQOL[53] and carer satisfaction was measured using the Carers' and Users' Expectations of Services – Carer version (CUES-C).[54] A summary of outcome measures, including scoring ranges, can be found in *Table 5*.

TABLE 5 Summary of primary and secondary outcome measures

Outcome measures		Baseline Cohort design	6-month follow-up Cross-sectional sample
Primary outcome measure	Autonomy support	HCCQ-10[46] • Range 0–70 • Higher score indicating greater 'autonomy support'	HCCQ-10
Secondary outcome measures	User and carer involvement	EQUIP PROM[40] • Range 0–244 • Higher score indicates higher involvement	EQUIP PROM (short version) • Range 0–44
	Satisfaction	VSSS-54[47] • Range 0–21 • Higher scores denote greater satisfaction	
	Medication side effects	GASS[48] • Range 0–66 • Higher scores denotes higher severity of side effects	
	Well-being	WEMWBS[49] • Range 14–70 • Higher score indicates better well-being	
	Recovery and hope	DREEM[50] • Range 24–120 • Higher scores correspond to lower or less positive rating	
	Mental health symptoms	HADS[51] • Range 0–42 • Higher scores indicate higher levels of anxiety and depression	
	Alliance/ engagement	CALPAS-12[52] • Range 12–84 • Higher scores indicate higher levels of alliance and engagement	
	Quality of life	WHOQOL-BREF[53] • Range 1–5 • Higher score indicates higher quality of life	

To recruit service users into the cluster cohort, clinical studies officers (CSOs) sent out an introductory letter, participant information sheet and consent to contact form. On receipt of the consent to contact form, service users were invited to interview to complete baseline measures. Consenting service users were asked to nominate a carer to be included in the study who, if nominated, was provided with a questionnaire pack (including introductory letter, information sheet, questionnaire, prepaid envelope and consent to contact at 6-month follow-up form).

Service users were recruited to the cluster cross-section by a postal survey, distributed by CSOs to all service users in CMHTs (excluding those already in the cluster trial) recruited to the cluster cohort 6 months following randomisation.

Following recruitment of service users and carers, clusters were allocated randomly to either intervention or usual-care by the clinical trials unit of the Manchester Academic Health Science Centre.

The trial protocol was published[55] (the original trial protocol and a summary of amendments can be found in *Appendix 3*).

Intervention

All consenting CMHTs allocated to the intervention received the training intervention. We asked that at least 80% of staff designated as 'care co-ordinators' (i.e. those with a caseload) committed to attending the training. Training was delivered within 6 weeks of service users being recruited into the trial. Clusters allocated to the control condition of 'usual practice in care planning' did not have access to the training intervention training.

Sample size and statistical methods

The original sample size calculation was for 24 clusters and 480 patients. Recruitment issues identified early in the trial meant that a decision was made to increase the number of clusters to 36 to ensure sufficient power. The recruitment methods used in EQUIP meant that the proportions of patients responding to the study was variable within sites (from 5% to 30%) and difficult to predict. Therefore, increasing the numbers of clusters to 18 meant that recruitment of more patients than the planned 480 was likely, unless specific measures were taken to reduce the numbers of patients per site (e.g. sampling patients within clusters, or limiting the numbers of patients per cluster). Such additional measures would have proven difficult in practice. Therefore, the decision to increase the number of clusters to 36 led to recruitment of 609 patients. The low-risk and non-invasive nature of the intervention and because the cluster design meant that all patients were exposed whether or not they formally participated in the trial means that it is unlikely that any participants had faced additional risk of harm because of the decision to increase cluster numbers and the subsequent increase in the total sample size.

We wrote to the Research Ethics Committee outlining the recruitment numbers at the end of the trial and the committee raised no issues, but we accept that this issue should have been stated explicitly to the Research Ethics Committee when we raised the cluster numbers.

The Research Ethics Committee's response was as follows:

> *The Committee has reviewed your letter regarding the over recruitment into this study. Although they acknowledged that nothing could be done since the study has been declared closed, they pointed out that it was not clear from your letter why the cluster was increased. They stated that whilst the design meant that the numbers in each cluster were difficult to control, the CI [chief investigator] had overall responsibility of the study and should have been aware of the overall recruitment and when a possibility of over recruitment became apparent, the REC [Research Ethics Committee] should have been notified immediately. They concluded that although no actual harm had occurred at this time, they strongly advised that if this happens in the future, you must notify the REC immediately the participant numbers are likely above what had been approved by the REC and submit an amendment.*
>
> *National Research Ethics Service Committee Northwest Preston (Health Research Authority), 2019, personal communication. Reproduced with permission from the Research Ethics Committee (25 September 2019)*

The primary outcome was the HCCQ-10,[46] but data on the use of this scale by people with severe mental illness were limited, so we used a standardised effect to calculate sample size for the cluster trial. Twelve clusters per arm and a mean of 20 service users per cluster (total sample size of 480 participants) would have > 80% power to detect a standardised effect size of 0.4. This assumes an intracluster correlation coefficient (ICC) of 0.05 and an 80% follow-up rate, providing 384 participants with complete data in the analysis. For the cross-sectional study, we required the same number of patients in each cluster.

Analysis was completed using Stata version 13 and followed a statistical analysis plan prepared prior to analysis and approved by the independent Programme Steering Committee. The plan identified the cluster trial as the primary analysis, with the cluster cross-section and combined analyses to be presented as secondary analyses. For the cluster trial, intervention effects were estimated using a linear mixed model with a random intercept for teams. Analysis of outcomes followed intention-to-treat principles with outcome data included for all patients irrespective of receipt of the intervention or completion of care planning during the time scale of the trial. The pattern of missing data was assessed in terms of baseline characteristics of service users to check for differential non-response. Predictors of non-response were included as covariates in each model to satisfy the missing at random assumption of maximum likelihood used in estimating linear mixed models. Missing baseline data for the cohort sample were cluster mean imputed.

Participant flow

Participant flow for the cluster trial and cross-sectional sample is shown in *Figure 3*. During recruitment, the number of service users per cluster was smaller than estimated in the sample size calculation. We increased the number of clusters from 12 to 18 per arm to ensure sufficient power, and 36 teams were randomised to either the intervention ($n = 18$) or the usual-care ($n = 18$) group. There was appreciable uncertainty regarding the effect size for the outcome, which is indicated by the use of a standardised rather than absolute effect size and also the adoption of an ICC of 0.05. Given that there was minimal cost to continuation, it seemed appropriate to continue recruitment of centres rather than termination to protect the power of the trial against the ICC being larger than expected. The Programme Steering Committee, Research Ethics Committee and NIHR approved continued recruitment beyond the target size. In total, 604 service users and 90 carers were recruited to the cluster cohort. Ten out of the 18 CMHTs demonstrated ≥ 80% attendance of care co-ordinators at the training (range 48–100%). Retention at the 6-month follow-up for service users in each CMHT ranged from 76% to 93%, with an overall mean of 82% ($n = 497$). Retention of carers was limited, ranging from 0% to 100% between clusters, with an overall mean of 56% ($n = 50$). For the cross-sectional study, 682 service users were recruited [mean number per CMHT was 19.5 service users, standard deviation (SD) 14.0 service users].

Demographics

Combining the cluster trial and cross-sectional samples ($n = 1286$), 58% of service users were female, 48% were aged between 45 and 64 years, 38% were aged between 25 and 44 years, 87% described themselves as white and only 13% were employed (*Table 6*). Demographics were broadly similar between the cluster cohort and cross-sectional samples and between intervention and usual care (*Tables 6* and *7*). Of the 90 carers in the cluster trial, just over half were female and most were white (*Table 8*).

Cluster trial (service users)

Primary outcome Health Care Climate Questionnaire (cluster cohort)

The HCCQ-10[46] was the primary outcome measure. High scores represent higher appraisals of care. The mean and SD in the intervention and usual-care group are given in *Table 9* with the adjusted mean difference and 95% CI. Results show no difference in HCCQ-10 scores between intervention and usual care at 6 months. The ICC indicates that approximately 2% of the variation of HCCQ-10 at 6 months is between teams, showing little difference in HCCQ-10 scores between teams.

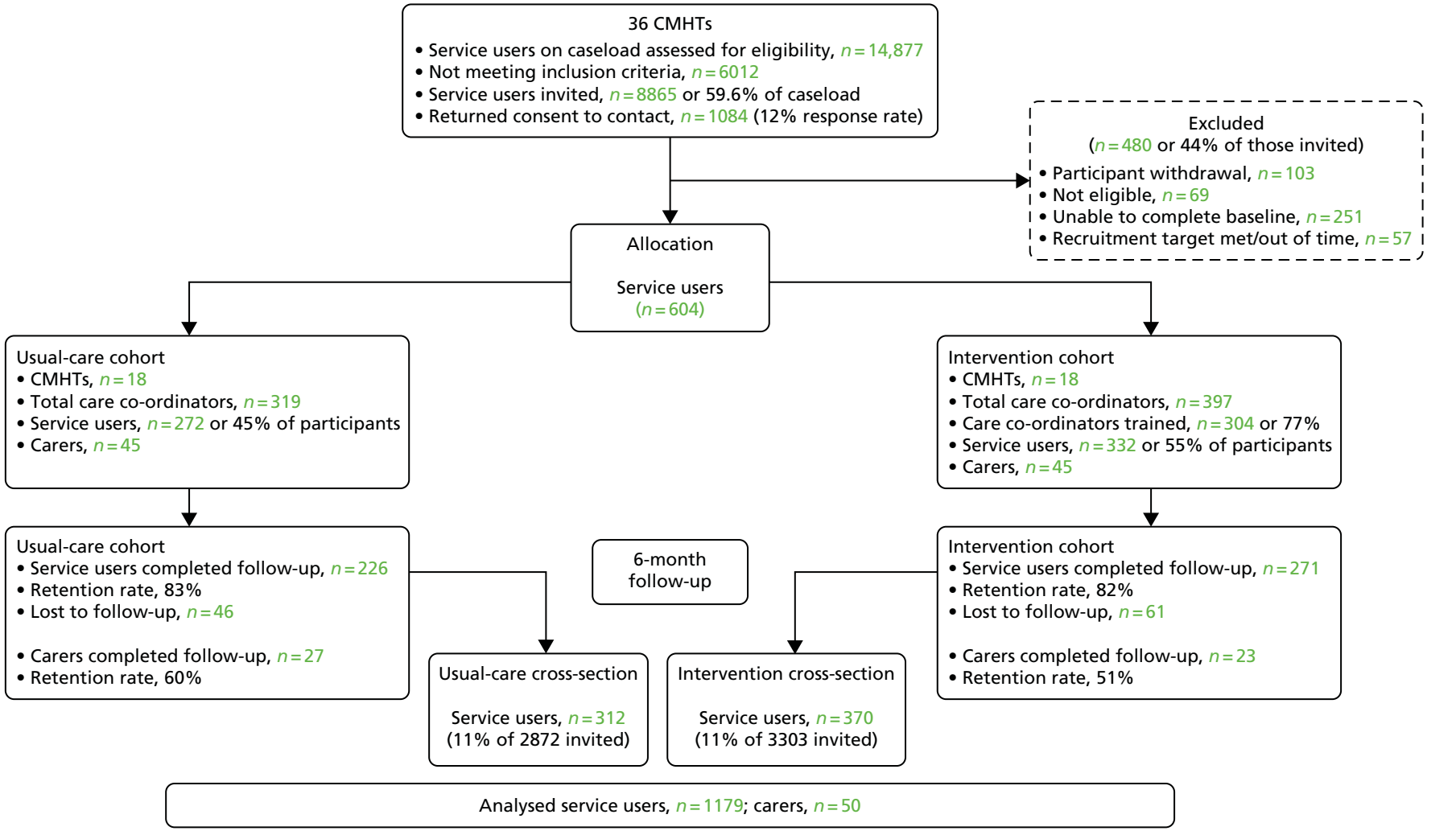

FIGURE 3 The Consolidated Standards of Reporting Trials (CONSORT) flow diagram for cluster randomised controlled trial and cluster cross-section.

TABLE 6 Demographics of service users in the cluster cohort and cross-sectional study

		Cohort			
		Usual care ($N = 271$)		Intervention ($N = 333$)	
Demographic variable		*n*	%	*n*	%
Gender	Female	156	58	199	60
	Non-female	107	39	128	38
	Missing	8	3	6	2
Ethnic group	White	232	86	295	89
	Non-white	33	12	32	10
	Missing	6	2.	6	2
Education	Secondary school	108	40	129	39
	Higher education	153	56	182	55
	Missing	10	4	22	7
Accommodation	Owner-occupier	85	31	97	29
	Other	176	65	227	68
	Missing	10	4	10	3
Living arrangements	Alone or with a pet	191	70	225	68
	With someone else	75	28	102	30.63
	Missing	5	2	6	2
Employment	Employed	37	14	45	14
	Other	230	85	281	84
	Missing	4	1	7	2

TABLE 7 Demographics of service users in the cross-sectional study

		Cross-sectional			
		Usual care ($N = 309$)		Intervention ($N = 373$)	
Demographic variable		*n*	%	*n*	%
Gender	Female	172	56	225	60
	Non-female	131	42	141	38
	Missing	6	2	7	2
Ethnic group	White	275	89	314	84
	Non-white	28	9	45	12
	Missing	6	2	14	4
Education	Secondary school	147	48	167	45
	Higher education	112	36	151	40
	Missing	50	16	55	15

TABLE 7 Demographics of service users in the cross-sectional study (*continued*)

		Cross-sectional			
		Usual care (*N* = 309)		Intervention (*N* = 373)	
Demographic variable		*n*	%	*n*	%
Accommodation	Owner-occupier	84	27	113	30
	Other	217	70	246	66
	Missing	8	3	14	4
Living arrangements	Alone or with a pet	164	53	197	53
	With someone else	142	46	170	46
	Missing	3	1	6	2
Employment	Employed	40	13	55	15
	Other	265	86	306	84
	Missing	4	1	12	3

TABLE 8 Demographics of carers in the cluster cohort study

		Cohort			
		Usual care (*N* = 44)		Intervention (*N* = 46)	
Demographic variable		*n*	%	*n*	%
Gender	Female	22	50	25	54.35
	Non-female	22	50	20	43.48
	Missing	0	0	1	2.17
Ethnic group	White	39	89	40	87
	Non-white	5	11	6	13
	Missing	0	0	0	0
Education	Secondary school	17	39	20	43
	Higher education	22	50	23	50
	Missing	5	11	3	7
Accommodation	Owner-occupier	25	57	32	70
	Other	19	43	14	30
	Missing	0	0	0	0
Living arrangements	Alone or with a pet	13	30	14	30
	With someone else	31	70	31	67
	Missing	0	0	1	2
Employment	Employed	15	34	23	50
	Other	29	66	22	48
	Missing	31	70	1	2

TABLE 9 Primary outcome (HCCQ-10) (cluster trial)

Time point	Usual care			Intervention			Adjusted[a] mean difference (intervention – usual care)	95% CI	*p*-value	ICC
	Mean	SD	*n*	Mean	SD	*n*				
Baseline	5.06	1.66	271	5.27	1.48	334				
6 months	4.93	1.78	226	5.01	1.70	270	–0.064	–0.343 to 0.215	0.653	0.02

a Adjusted for baseline HCCQ-10, time using NHS services, gender, ethnicity and age.

Secondary outcomes (cluster trial)

The results of the secondary outcomes (*Table 10*) in the cluster trial showed no significant difference between the intervention and usual care at 6 months, except for VSSS-54. The adjusted mean difference indicates that the intervention group had higher (meaning more satisfied) VSSS-54 scores than the usual-care group, which showed a small, statistically significant difference at the 5% level. The 95% CIs are wide and, therefore, the true effect is potentially negligible. With all secondary outcomes, the ICC demonstrates very little variation between CMHTs.

Cluster trial (carers)

The three outcomes completed by carers were the 14-item EQUIP PROM, WHOQOL and CUES-C. The results showed no significant difference in PROM or CUES-C scores between intervention and usual care at 6 months. There was a slight difference in WHOQOL scores, indicating that the intervention improves quality of life by approximately half a unit on the 1–5 scale (0.484), but the CI for this estimate is wide, suggesting potentially negligible difference. Controlling for baseline variables, the between-cluster variation in all three measures is negligible and so the ICC is effectively zero, showing no difference between CMHTs (*Table 11*).

Outcomes for cross-sectional study

The two outcomes completed by service users and carers were the HCCQ-10 and the PROM. Results show no significant difference in the HCCQ-10 and the PROM between intervention and usual care at 6 months. The mean and SD in the intervention and usual-care group are given in *Table 12* with the adjusted mean difference and 95% CI. Controlling for baseline variables, the between-cluster variation in all three measures is negligible and so the ICC is effectively zero, showing no variation between CMHTs.

Key findings

The results showed no statistically significant difference in HCCQ-10 scores between the intervention and usual care at 6 months. The ICC indicates that only 2% of the variation of HCCQ-10 at 6 months was between teams.

The results of the 'cluster cross-section' and combined analyses were similar to the primary analysis, with no statistically significant difference on the primary outcome between the intervention and usual care at 6 months. Analyses of secondary outcomes in the 'cluster cohort' found a significant effect on a single outcome of service satisfaction. However, the 95% CIs are wide and, therefore, the true effect is potentially negligible. In terms of opportunities to use the training in routine contacts with patients, data from patient self-report suggested that 79% of patients providing data saw their CMHT during the 6-month follow-up, with a mean of 12.3 contacts. Our intervention to improve user- and carer-involved care planning in community mental health services was well attended and acceptable to staff, but had no significant effects on patient perceptions of autonomy support, or other outcomes.

Cost-effectiveness

An economic evaluation was integrated into the clinical trial to assess whether or not the EQUIP training intervention was cost-effective at each of the different levels that decision-makers may be willing to pay in order to gain 1 unit of health benefit.

TABLE 10 Secondary outcomes (cluster cohort)

Outcome	Time point	Usual care			Intervention			Adjusted[a] mean difference (intervention – usual care)	95% CI	*p*-value	ICC
		Mean	SD	*n*	Mean	SD	*n*				
PROM[a]	Baseline	22.81	8.78	271	22.07	8.58	334				
	6 months	21.64	11.18	152	21.32	9.62	193	0.396	–1.817 to 2.609	0.726	0.05
HADS-A (anxiety)[a,b]	Baseline	11.37	5.36	271	12.23	5.18	334				
	6 months	10.85	5.86	171	12.10	5.37	209	0.430	–0.334 to 1.194	0.270	0.00
HADS-D (depression)[a,b]	Baseline	9.19	5.31	271	10.03	5.18	334				
	6 months	8.91	5.83	171	9.81	5.49	209	–0.001	–0.861 to 0.858	0.998	0.00
VSSS-54[a,b]	Baseline	3.58	0.62	271	3.53	0.61	331				
	6 months	3.53	0.80	155	3.51	0.72	192	0.120	0.001 to 0.239	0.049	0.01
CALPAS[a,b]	Baseline	4.98	1.27	271	5.06	1.19	334				
	6 months	4.87	1.45	151	4.81	1.38	192	–0.010	–0.259 to 0.239	0.935	0.01
GASS	Baseline	17.73	10.37	271	18.30	8.93	334				
	6 months	17.80	11.57	114	19.80	10.28	144	1.316	–1.075 to 3.708	0.281	0.05
WHOQOL[a]	Baseline	3.03	1.02	271	3.04	1.05	334				
	6 months	3.20	1.19	157	3.16	1.11	201	0.024	–0.170 to 0.218	0.808	0.00
DREEM[a]	Baseline	39.20	12.32	271	38.81	11.86	334				
	6 months	41.07	13.78	161	38.83	13.29	204	–0.661	–2.600 to 1.278	0.504	0.002

All secondary measures adjusted for baseline, time using NHS services, gender and ethnicity, accommodation and age.
a Measures additionally controlled for accommodation to satisfy MAR assumption.
b Measures additionally controlled for age to satisfy MAR assumption.

TABLE 11 Carer outcomes (cluster cohort)

Outcome	Time point	Usual care			Intervention			Adjusted[a] mean difference (intervention – usual care)	95% CI	*p*-value	ICC
		Mean	SD	*n*	Mean	SD	*n*				
PROM	Baseline	19.48	10.96	44	20.97	12.64	20				
	6 months	16.45	10.86	46	20.10	8.00	22	0.392	–5.676 to 6.460	0.899	0.00
WHOQOL	Baseline	3.45	0.90	44	3.69	0.81	46				
	6 months	3.27	1.15	26	3.91	1.00	23	0.484	0.009 to 0.959	0.046	0.00
CUES-C	Baseline	24.68	8.02	44	24.67	8.28	46				
	6 months	24.12	9.97	26	22.71	9.08	24	–0.972	–4.4383 to 2.440	0.577	0.00

TABLE 12 Outcomes for cross-sectional study

Outcome	Time point	Usual care			Intervention			Adjusted[a] mean difference (intervention – usual care)	95% CI	*p*-value	ICC
		Mean	SD	*n*	Mean	SD	*n*				
HCCQ-10	6 months	5.10	1.72	284	5.08	1.72	344	–0.132	–0.511 to 0.247	0.495	0.05
PROM	6 months	25.25	13.60	242	25.62	13.46	309	–0.691	–4.068 to 2.686	0.688	0.07

Methods

Service use data were collected at baseline and the 6-month follow-up for all service users who participated in the cluster trial, as were health status data [EuroQol-5 Dimensions, five-level version (EQ-5D-5L)]. The service use data were collected using a survey adapted for the EQUIP trial. The service use data were combined with published national unit costs to estimate costs.[56,57] The costs of delivering the intervention were estimated from the costs incurred in the trial and the number of people trained. They included the costs of health-care professionals' time to attend the training and the costs of trainers' time to deliver the training. The costs of consumables and room hire were also included. The QALYs were estimated by combining the EQ-5D-5L data with UK-specific utility weights using the crosswalk methodology recommended by NICE at the time of the evaluation.[58,59] The analysis used the perspective of the NHS and social care (costs) and service users (QALYs). The time horizon for the primary analysis was the 6-month follow-up point of the trial. Analysis of the economic data was based on intention-to-treat principles, and missing data (owing to incomplete observations and missing follow-up) were imputed using multiple imputation. Regression analyses were used to estimate the net costs and outcomes of the EQUIP training intervention, adjusting for participant sociodemographic characteristics and team cluster (baseline covariates) that may influence costs and QALYs. A generalised linear regression model, with a gamma distribution and log-link, was used to account for the skewed nature of the cost data. An ordinary least squares regression model was used to estimate net QALYs. This required the assumption that the QALY data were normally distributed, which was tested in the sensitivity analysis. The net cost and QALY were bootstrapped to estimate the probability that the EQUIP training intervention was cost-effective at different hypothetical amounts decision-makers may be willing to pay to gain an additional QALY. Sensitivity analysis explored the relative cost-effectiveness of the training intervention if different choices were made about the study methods. These included using different measures of benefit, alternative estimates of the unit cost of the intervention, complete-case analysis and the use of a beta distribution to estimate net QALYs.

Key findings

Eighty-two per cent of service users completed follow-up (497/604). A total of 581 service users (581/604; 96%) completed the EQ-5D-5L at baseline and 537 (89%) had sufficient service use data to estimate baseline costs. At the 6-month follow-up, 442 service users (73%) had complete EQ-5D-5L data and 334 (55%) had complete service use data. Overall, 322 service users (53%) had complete baseline and 6-month follow-up cost, utility and QALY data (see *Appendix 3* for further detail). There were no differences between participants with complete and missing data on all but two of the sociodemographic variables. These were whether or not the service user had one or more than one diagnosis (chi-squared test; $p = 0.033$) and whether or not the participants lived in accommodation that they owned (chi-squared test; $p < 0.001$). The rate of missing data did not appear to differ between the intervention and usual-care groups. *Tables 13* and *14* summarise the EuroQol-5 Dimensions (EQ-5D) data and costs of services used.

There was no indication that the number of people using a service and the average cost per person differed between groups at baseline or follow-up. Wide 95% CIs indicated a high level of variation in the average costs per person.

The net costs and QALYs are shown in *Table 15* (primary analysis and sensitivity analyses using the QALY as the measure of health benefit). There was no evidence that the costs or health benefit differed between the training intervention and usual care. The primary analysis, using a willingness-to-pay threshold of £15,000 per QALY, indicated that there was a net saving of £3600 per QALY lost associated with training. Whether or not the savings offset the QALY loss depends on the decision-makers' willingness to pay to gain 1 QALY. If decision-makers are willing to pay £5000–15,000 to gain 1 QALY then the probability that the training intervention was cost-effective was between 0.29 and 0.49. The probability ranged between 0.09 and 0.75 in the sensitivity analyses using the QALY.

Outputs

A full description of the protocol has been published in Bower *et al.*[55] (see *Appendix 3*).

TABLE 13 The EQ-5D ratings (participants with complete cost and QALY data)

	Usual care ($n = 146$)		EQUIP ($n = 176$)	
Outcome	Frequency	%	Frequency	%
No problems with mobility				
Baseline	91	62	100	57
Follow-up	85	58	97	55
No problems with self-care				
Baseline	99	68	117	67
Follow-up	101	69	108	61
No problems with usual activity				
Baseline	66	45	68	39
Follow-up	66	45	62	35
No problems with pain or discomfort				
Baseline	70	48	69	39
Follow-up	69	47	74	42
No problem with anxiety or depression				
Baseline	38	26	50	28
Follow-up	52	36	33	19

TABLE 14 Mean cost per person, by cost category (participants with complete cost and QALY data) (2015–16 Great British pounds)

	Cohort, mean (95% CI)	
Cost category	Usual care	EQUIP
Primary care services		
Baseline	£164 (£131 to £196)	£157 (£131 to £182)
Follow-up	£140 (£113 to £168)	£158 (£128 to £188)
Community-based services		
Baseline	£692 (£590 to £794)	£601 (£504 to £698)
Follow-up	£559 (£456 to £661)	£523 (£425 to £621)
Social care services		
Baseline	£28 (£10 to £45)	£71 (£40 to £103)
Follow-up	£42 (£16 to £68)	£41 (£19 to £64)
Accident and emergency		
Baseline	£73 (£15 to £132)	£30 (£17 to £44)
Follow-up	£49 (£20 to £78)	£30 (£14 to £47)
Hospital outpatient services		
Baseline	£241 (£184 to £297)	£314 (£243 to £385)
Follow-up	£247 (£181 to £313)	£216 (£157 to £276)
Hospital day services		
Baseline	£240 (< £1 to £563)	£612 (£17 to £1207)
Follow-up	£5 (< £1 to £16)	£18 (< £1 to £43)

TABLE 14 Mean cost per person, by cost category (participants with complete cost and QALY data) (2015–16 Great British pounds) (*continued*)

Cost category	Cohort, mean (95% CI)	
	Usual care	EQUIP
Hospital inpatient stay (≥ 1 night)		
Baseline	£154 (£83 to £225)	£86 (£44 to £128)
Follow-up	£128 (£38 to £218)	£73 (£30 to £117)
EQUIP training intervention	£0.00 (£0.00)	£23 (not applicable)

TABLE 15 Net costs and QALYs and probability that the EQUIP intervention is cost-effective

Analysis	Net cost[a,b] (5th percentile; 97.5th percentile)	Net QALYs[a] (5th percentile; 97.5th percentile)	ICER (£/QALY)	Probability that EQUIP is cost-effective if WTPT =	
				£5000/QALY	£15,000/QALY
Primary	–£54 (–£193; £84)	–0.014 (–0.034; 0.005)	£3600 saving per QALY lost	0.16	0.41
Complete case	–£96 (–£310; £117)	0.004 (–0.021; 0.029)	EQUIP dominates	0.80	0.75
Costs of EQUIP intervention					
£0	–£79 (–£217; £60)	–0.014	£5643 saving per QALY lost	0.52	0.20
£29	–£35 (–£176; £106)	(–0.034; 0.005)	£2500 saving per QALY lost	0.32	0.13
£57	–£5 (–£146; £136)	–0.014	£357 saving per QALY lost	0.21	0.09
Beta distribution for QALYS	–£54 (–£193; £84)	–0.041 (–0.10; 0.014)	£1317 saving per QALY lost	0.56	0.17
New value set for EQ-5D-5L	–£54 (–£193; £84)	–0.003 (–0.020; 0.013)	£18,000 saving per QALY lost	0.75	0.65

ICER, incremental cost-effectiveness ratio; WTPT, willingness-to-pay threshold to gain 1 QALY.
a Unless stated otherwise, net costs and health benefits adjusted for baseline covariates using imputed data, bootstrapped 10,000 times.
b Costs given in 2015–16 Great British pounds.

A full description of the methods, analysis and results of the cluster randomised controlled trial (RCT) has been published in Lovell *et al.*[60] (see *Appendix 3*).

A full description of the methods, analysis and results of the cost-effectiveness has been submitted.

Delivery and acceptability of the training intervention

Training was delivered to 18 CMHTs in 10 NHS trusts. Owing to service need and the logistics of taking an entire team out of usual work for 2 days, most teams were divided and the training was delivered twice. In total, 350 health professionals (249 female, 101 male) attended the training, ranging from 4 to 39 trainees (mean 19.44 trainees) at each 2-day session. CMHTs teams consisted of 304 care co-ordinators (mainly nurses, occupational therapists and social workers); the remaining 46 were students, support workers and clinical managers. Although psychiatrists were invited, none attended.

We used the Training Acceptability Rating Scale (TARS-1[61] and TARS-2[62]) to evaluate the acceptability of the training, with six self-report items assessing general acceptability, perceived effectiveness, negative side effects, appropriateness, consistency and social validity. Items were rated on a six-point Likert scale, from 'strongly disagree' (score 1) to 'strongly agree' (score 6). TARS-2 assesses attendees' overall impressions of the impact of the teaching process and its outcomes and consists of nine items, rated on a four-point scale from 'not at all' (score 0) to 'a great deal' (score 3). TARS-2 also includes three open-ended questions asking about the 'most helpful' part of the training, any 'recommended changes' and 'any other comments'. Questions 1–6 were summed to calculate an overall acceptability score (range 6–36), and questions 7–15 were summed to calculate a perceived impact score (range 0–27). The overall TARS score was calculated by summing the responses to questions 1–15 (possible range 6–63).[63,64]

Analysis

Descriptive statistics were used for the TARS results and open-ended comments were analysed using content analysis.[65]

Findings

The results demonstrated high levels of satisfaction/acceptability of the training, with the median overall TARS score as 56 out of 63, median 'acceptability' score as 34 out of 36 and median 'perceived impact' score as 22 out of 27 (*Table 16*). Open-ended comments reflected six qualitative themes: the value of the co-production model, time to reflect on practice, delivery preferences, comprehensiveness of content, need to consider organisational context and emotional response (with six people commenting that they did not find the training helpful). The co-production model was key to the training intervention, and 102 participants commented on the value of the service user and carer contribution to the training, in terms of the value of their shared experiences, perspectives and insights, and appreciating them as facilitators. Participants appreciated the opportunity to take 'time out' to reflect on practice ($n = 50$).

All teams were provided with supervision: 2 half-days of 3 hours in the 6 months following the training. Overall, supervision was poorly attended, with < 50% of the original professionals attending. Supervision for those who did attend focused on practice changes that they had made (e.g. including carers in the care plan and writing the service user's perspective into the care plan) and difficulties encountered when they tried to include some service users in their care plan. Although all of the health professionals were sent the 8-hour optional self-directed learning package, only one individual reported looking at this. Reasons for not looking at the self-directed learning included 'being too busy', 'wanted to look at it but dropped off to do list', 'forgot' and 'don't like e-learning'.

Outputs

A full description of methods, analysis and results has been published in Grundy *et al.*[23] (see *Appendix 3*).

Strengths and limitations

The study achieved the required sample size in both the cluster trial and the cross-sectional sample and we achieved a high follow-up rate (82%). Our comprehensive outcome assessment increases confidence that our observed lack of effect is robust. Our pragmatic design was intended to improve service user and carer involvement in routine mental health services. Our intervention was delivered in 18 CMHTs across 10 NHS trusts with over 300 care co-ordinators. However, our volunteer sites may not be fully representative of the

TABLE 16 The TARS summary scores

Outcome	*n*	Median	Interquartile range	Range
Total 'acceptability' questions 1–6 (score 1–36)	289	34	31–36	6–36
Total 'perceived impact' questions 7–15 (score 0–27)	301	22	19–25	4–27
Total TARS questions 1–15 (score 6–63)	283	56	51–61	24–63

wider population, and we lacked data by which to compare our participants with the eligible population. A known risk to cluster trial validity is professionals recruiting differently depending on allocation. To reduce risk, we selected patients via existing registers and invited patients before revealing allocation to teams. Practitioners could potentially exclude patients after invitation, although this involved a small proportion of service users and did not differ between arms. Measures of service use and contact with professionals were based on self-report, and such measures may not always agree with other sources, such as service records. Limitations that are specific to the economic evaluation suggest additional uncertainty about the relative cost-effectiveness of the training intervention. Changes in care planning reflect a change in process, which may in turn lead to changes in health and other resource use. However, the 6-month follow-up of the study may be too short for the training to feed through to changing either use of services and costs or overall health and QALYs. There was insufficient evidence to support modelling work to extrapolate from the trial to longer time periods.

The measure of health benefit for the primary analysis was the QALY, which is widely used in mental health trials comparing different types of treatment or patient management. However, it may not be an appropriate measure to detect changes in care planning processes and any indirect impact on subsequent health.

What this study adds

Despite a high level of attendance and satisfaction with the training intervention, no significant effect was found on the primary outcome (perceptions of autonomy support) or other outcomes. There was no evidence that the costs or health benefit differed between the training intervention and usual care. The primary and sensitivity analyses suggested that the probability that the intervention was cost-effective was between 9% and 75% for those analyses using the QALY as the measure of health benefit. Embedding service user and carer involvement in care planning may require considerably greater investment of resources. Benefits for service users may be apparent only over the longer term.

Workstream 3: implementation

The aim of workstream 3 (studies 6 and 7) was to understand the contextual, individual and organisational barriers and facilitators and examine the processes involved in the development and use of service user- and carer-involved care planning.

This work package consisted of two studies (6 and 7), which were designed to:

- understand the perspectives of professionals, service users and carers about the influences that inhibit or promote user involvement and integration of care planning into clinical settings
- explore and assist with explaining the impact of the novel training intervention in enhancing user involvement in care planning in mental health settings.

An exploration of the existing operationalisation of care planning and potential barriers to the implementation of the training intervention was undertaken prior to the development of the intervention. This was done so that views and arrangements related to existing practices could create the foundation on which to build an intervention likely to fit best with the work and organisation of pre-existing day-to-day practice.

Theoretical framework

Both studies in the workstream were carried out sensitised by implementation theory concepts informed by normalisation process theory (NPT) (*Figure 4*).

Investigations of successful implementation require an approach that understands both complex interventions and their contexts prior to the development of trials to test effectiveness.[67,68] Implementation theory allows researchers to identify factors that 'promote and inhibit the routine incorporation of complex interventions into everyday life'.[67] It focuses on the work that people do to ensure that interventions become adopted, normalised and embedded. NPT is one of a range of theories that offer a heuristic framework within which to optimise the development of a trial intervention applicable to three stages:[66]

1. designing an intervention
2. describing the context within which an intervention is located and implemented
3. supporting the retrospective interpretation of the implementation of an intervention.

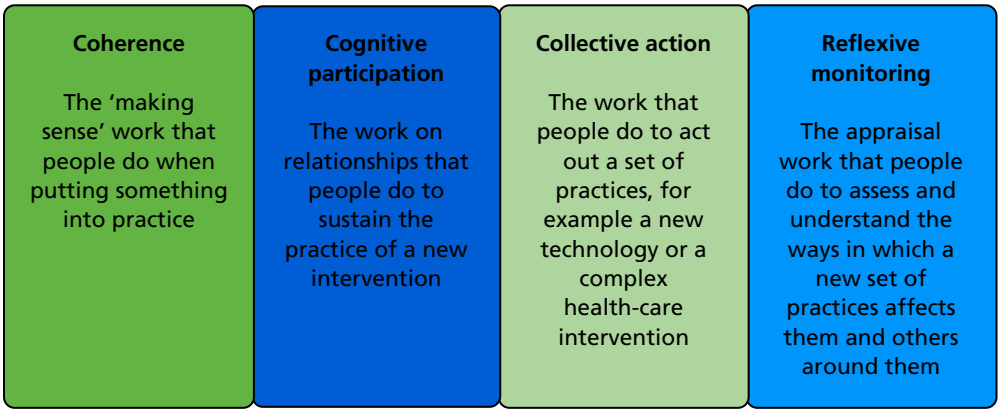

FIGURE 4 Description of NPT components.[66]

Other implementation theories were used at the explanatory analysis point; these included Concepts from the Consolidated Framework for Implementation Research (CFIR), which were useful in exploring outer setting and contextual variables relevant to a rapidly changing mental health context. Of most relevance were theories relating to how social networks and relational work explained the personal care options and management leveraged by users, which lay outside the care planning arrangements and ethos of formal clinical settings.[69] The notions of navigation, negotiation and collective efficacy were relevant to understanding the nature of management work undertaken in users' own personal communities.[70]

Study 6

Pre-implementation exploration of the environmental influences

To explore the distal political, economic, policy and clinical environments, we conducted semistructured interviews with key informants involved locally and nationally in mental health policy, practice and research. This was designed to elicit key informants' perspectives on the state and progress of user involvement in mental health planning and practice. We also carried out a mapping exercise of the contemporary organisational structures and care planning policies. This broader picture was intended to complement analysis undertaken in workstream 1, which was designed to explore current care planning with service users, carers and health professionals with direct involvement in care planning. This was predicated on the notion that key informants would have access to insider policy and practice information, relationships and opinions likely to be relevant in the development and evaluation of the trial being undertaken in workstream 2 to test the effectiveness of a training intervention for mental health professionals (see Brooks *et al.*[66]). We referred to the NPT toolkit framed as a set of propositions to guide the stakeholder interviews (www.normalizationprocess.org/npt-toolkit.aspx; accessed 15 June 2015). We then used NPT as a coding frame[67] adapted from the RESTORE[71] and EUWISE[72] projects to conduct analysis.

Mapping exercise

Aim

To understand the pre-existing organisational structures and care planning related policies in place at all levels within the organisation.

Objectives

To understand the operationalised pre-existing arrangements and views of care planning by undertaking a mapping exercise through:

- analysing trust documents relevant to care planning
- exploring audits related to care planning
- identifying how care planning activities are recorded (e.g. Amigos in Manchester and Rio in Nottingham – patient record systems)
- reviewing service user experience from surveys and committee and audit minutes.

Method and analysis

Two reports of findings were produced from documentary analysis of the above sources (see *Appendix 4*). Additionally, EQUIP team members met to discuss and interpret policies, procedures, documentation and information technology systems used for care planning. Additional mapping exercises were undertaken for a number of additional sites as the number of recruitment sites included in the trial increased over the course of the trial (see *Appendix 4*).

Stakeholder interviews

Aim

To explore stakeholder views of care planning and expectations of individual and organisational 'barriers' to and 'facilitators' of service user- and carer-involved care planning prior to the development of the training (herein referred to as stakeholder interviews).

Objectives

To identify stakeholder understandings of contemporary arrangements for care planning through interviews with key informants exploring the:

- potential facilitators of and barriers to the implementation of service user- and carer-led planning within mental health services
- feasibility of a social network mapping method for tracking the processes of change associated with service user- and carer-involved care planning.

Methods and analysis

Prior to the commencement of the trial (study 5, workstream 2), we worked with investigators in workstream 1 to develop the content of the training. We analysed interview transcripts of participants (health professionals, service users and carers) to identify potential 'barriers' to and 'facilitators' of service user-/carer-involved care planning.

Additional interviews allowed for the incorporation of the views of key informants not included in workstream 1 (stakeholders outside the trusts and high-level managers within the trusts). A focus of these interviews was the feasibility of delivering a user- and carer-led training package to improve service user and carer involvement in care planning.[66] This feasibility related specifically to their experience of:

- understanding user involvement and participation
- multidisciplinary perspectives
- knowledge and experience of care planning
- resource allocation
- official policy catalysts
- organisational cultural acceptance
- organisation resistance and facilitation.

Interviews were carried out face to face or via the telephone. Interviews were digitally recorded and transcribed verbatim. Participants were recruited from prominent knowledge positions, including high-level NHS managers, subject-relevant academics and policy-makers, and were selected on the basis that they were likely to be immersed in critical understanding of contemporary care planning and user involvement in mental health care. Participants were identified through purposive and snowballing sampling starting from a list of national key contacts developed by the applicants. We asked the respondents interviewed for names of other potential interviewees. Sampling continued until theme saturation occurred. Saturation was considered sufficient after 13 interviewees were recruited.

The starting focus of analysis was the summative perspectives of key stakeholders collected as part of workstream 1. Data were analysed using framework analysis. The transcripts were coded independently by two researchers using adaptive theorising and sensitising concepts from NPT. Analysis of interview data and snowball sampling were conducted in accordance with the constant comparative method. Analysis was carried out concurrently with data collection and sampling in line with iterative constant comparison.

The data collected and findings produced were designed to complement the mapping exercise described in aim 1 (to understand the pre-existing organisational structures) and data collected in workstream 1 as well as feeding into the development of the trial to be undertaken within workstream 2. Themes that

arose in interviews were later compared with those in study 7 of the actual barriers and facilitators encountered during the roll-out, implementation and embedding of the new care planning practices at baseline and 6 and 12 months post training.

Key findings

The framework analysis undertaken in workstream 1 illuminated the likely barriers to and facilitators of implementing the proposed training from the point of views of professionals, service users and carers immediately involved within care planning. The stakeholder findings sensitised by and interpreted with reference to implementation theory incorporated wider environmental views of key informants with broader knowledge, which further expanded on the list of potential barriers and facilitators that were likely to have an impact on the implementation of the intervention.

All stakeholders supported the need for training to improve involvement in care planning and considered such a view to be normative. Any potential problems that were likely to arise were predicted to be related to the implementation at meso and organisational levels. The preoccupation with recording processes and lack of ability to do this in a minimally disruptive manner were viewed as potentially taking precedence over the competing imperatives to ensure patient centeredness.

Interview data from workstream 1 highlighted the importance of interpersonal relationships between health professionals and service users while concomitantly acknowledging that current resource and workload challenges make developing these relationships difficult and seemingly less of a priority. Interviews with key informants further supported the centrality of relationships and relational work and flagged how this could be downplayed through attempts at practice standardisation in a climate of limited resources.

The identification of outer setting factors (the economic, political and social context in which an organisation resides) was less prominent in accounts from workstream 1 than a focus on inner setting features that needed to be changed. The structural, political and cultural contexts were not seen as a primary concern. By contrast, interviews with key informants illuminated the relevance of these contexts and described the impact of the historical legacy of care planning and, given their distance from services, these stakeholders seemed more able to comment critically on cultural impediments to change within services.

Outputs

A full discussion of findings from the mapping exercise and key stakeholder interviews has been published in Brooks *et al.*[66] (*see Appendix 4*).

What this study adds

This study added to existing data by highlighting the potential impact of organisational bureaucracy and the cultural history of mental health services in the implementation of the proposed intervention.

Study 7

Process evaluation

A process evaluation of the training programme delivered as part of the trial was considered appropriate because successful implementation of the training intervention implicated a range of explanatory factors, including the integrity of the intervention and the acceptability of the intervention to both clinicians and service users, which is absent from the traditional outcomes of trials.[73]

The process evaluation was designed to explore how far the training intervention had been taken up and implemented into the daily work of the health professionals who attended training and what the consequences of this uptake had been. It aimed to complement and supplement the evidence provided by the cluster trial as recommended by the Medical Research Council (MRC) framework for evaluation of complex interventions.[74]

The objectives were to examine how:

- the training for service user- and carer-involved care planning and its principles had an impact on, and was incorporated into, existing routine clinical practices
- care planning training influenced the way in which professionals related to, communicated with and negotiated therapeutic options with users
- care planning training and arrangements had an impact on existing methods of coping, self-care and the development of service user expertise and how it shaped and transformed relationships between service users and professionals
- the impact of training on service users' perceptions of networks, a sense of control, security and identity compared with previous care planning practices
- service users perceived preparation and support arrangements for engaging with the form and content of the new system of care planning.

Methods and analysis

Semistructured interviews were undertaken with service users ($n = 29$), carers ($n = 4$) and mental health professionals ($n = 21$) from both the usual-care and intervention arms of the RCT at three time points (baseline, 6 months and 12 months post intervention). Participants were eligible for the study if they were service users, carers or professionals from the CMHTs included in the RCT sites. Service users were invited to take part via written invitation including an information sheet and consent to contact form. Eligible staff members were approached by e-mail. Included service users were asked to identify eligible carer participants. Interviews aimed to obtain in-depth data on the experience of utilising and receiving the EQUIP intervention and identify changes to practice over time. Service users involved in the study also completed 'ego' network mapping at the beginning of baseline interviews to develop an understanding of the impact of social networks in the management of mental health and to examine the role of care planning over time within those networks (*Figure 5*).

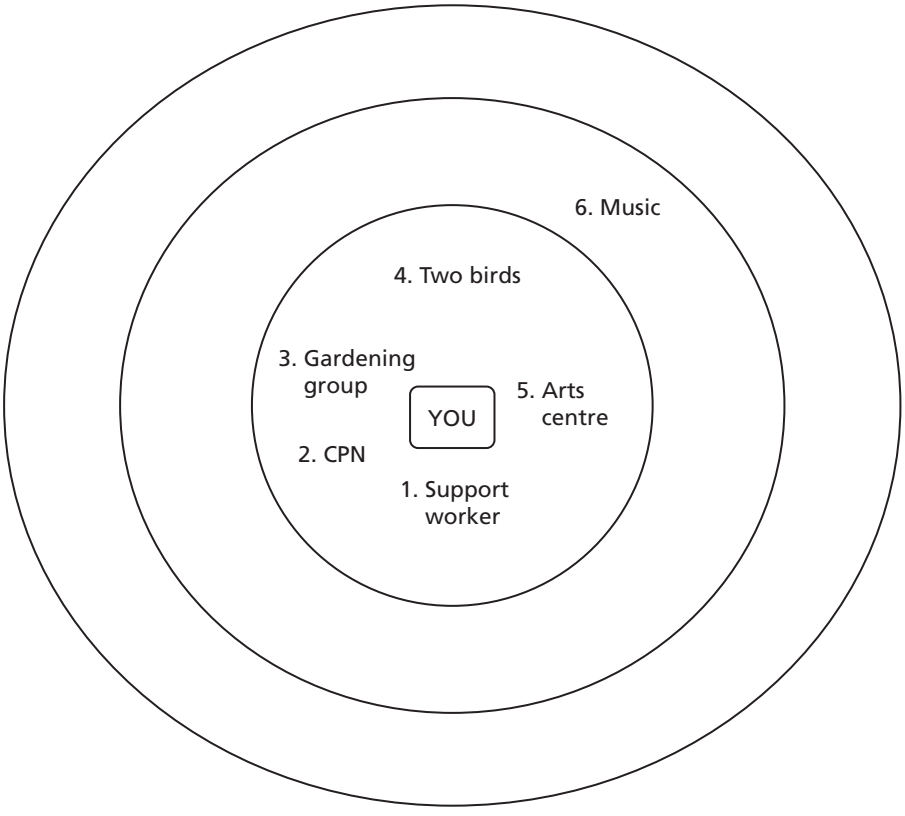

FIGURE 5 Example 'ego' net.[75]

Service users included in the process evaluation were invited to have a care planning meeting observed and to complete a diary over the 12-month follow-up period. Two service users returned completed diaries and one consented to have a care planning meeting observed. The main reason for these low levels of uptake was that most participants reported that insufficient care planning activity took place over the 12-month period to warrant participation in such activities.

Interviews and observations were digitally audio-recorded and transcribed verbatim before being analysed thematically using NVivo software (QSR International, Warrington, UK). Iterative modifications were made to the initial framework through the removal of duplicate codes, recategorisation and the addition of new codes.

Participants who took part in the study were:

- 29 service users from five trial sites – 55% ($n = 16$) were female and 62% ($n = 18$) were from the intervention arm of the trial
- four carers from three trial sites – 50% were female ($n = 2$) and 75% ($n = 3$) were from the intervention arm of the trial
- 21 professionals from four trial sites – 86% ($n = 18$) were female and 90% ($n = 19$) were from the intervention arm of the trial.

Key findings

Baseline data

Despite a general awareness of the care planning process, most service users and carers had not seen their care plan or been involved in its development. Care plans and care planning were characterised by a failure to meet the complexity of mental health needs including the holistic and broader contextual and environmental influences having an impact on a person's ability to manage their condition and against the backdrop of the potential coercive elements of mental health services.

Current definitions of care planning (e.g. NICE guidelines[14]) focus on the inclusion of patient experience in the delivery of mental health care. However, current organisational imperatives relating to quality assessment failed to address this sufficiently, which meant that current care planning processes were interpreted as fulfilling one organisational need (e.g. measuring organisational targets) at the expense of undertaking the purported aim of care planning relating to choice, need and the everyday means of managing mental health.

The personal network analysis of users revealed a range of imaginative and complex arrangements implicating a wide range of network members, organisations and valued personal activities, which provided the bases and resources for managing mental health. In general, these resources were invisible in accounts of the processes and outcomes of descriptions of care planning arrangements within services.

Care plans rarely featured in individuals' specification of their networks of self-management support. All stakeholder groups felt that care plans were of most relevance to the professionals and health systems in which they were based. Care planning processes prioritised organisational and risk agendas, which further distanced care plans and care planning from the everyday lives of service users.

Potential strategies to reorient care plans to the priorities and everyday lives of service users included the use of evidence-based tools designed to prompt discussion about harnessing resources to self-manage and the separation of risk management and needs elicitation activities. Social network mapping interventions that reveal the everyday and preferred means of managing the relationships and resources likely to support people might be more a more appropriate means of planning for the management for mental health than current care planning processes.

Outputs

A full discussion of findings from baseline data has been published in Brooks *et al.*[75] (see *Appendix 4*) and Brooks *et al.*[76] (see *Appendix 4*).

Longitudinal process evaluation

The findings from the process evaluation were, on the whole, consistent with the lack of effect found in the parallel cluster trial and the potential barriers identified at baseline. Data from the concurrent process evaluation illuminated a lack of organisational readiness and support for implementation and insufficient consideration of the required type of range of relational work associated with the intervention. This was further reinforced by the context in which the intervention was implemented, which diminished the initial enthusiasm for training as reported by front-line professionals. These wider contextual factors were not the focus of intervention design or implementation.

The professionals included in the study were positive about the training intervention and particularly valued the service user and carer input into the training design and delivery. They described how the training initially strengthened moral values about the need to involve service users and carers in the care planning process and increased motivation for change. Through delivering training at a team level, cohesion within teams was also promoted. However, a lack of continuity of care and resource limitations both within and outside health services reduced the possibility of sustaining and acting on such motivations, which meant that service users were unlikely to benefit from the professional training.

The process evaluation also demonstrated that, given the subtle nature of the changes in professional behaviour that were identified over the 12-month period, they may have gone unnoticed by service users (which was also reflected in the service user data). Such minor behavioural shifts were unlikely to have been sufficient to challenge entrenched practices and negative perceptions from both sides of the service user/professional dyad relating to health service relationships and health services more generally, which were identified at baseline.

A full discussion of findings from the longitudinal process evaluation can be found in *Appendix 4*.

Strengths and limitations

The workstream draws its strengths from the in-depth qualitative approach combined with the longitudinal design and theoretical underpinnings. Such methods allowed for anticipated implementation barriers to be explored in real time. However, there were a number of limitations. Participants included in all of the studies within the workstream self-selected themselves to take part in the study. Therefore, any data produced may not be generalisable to other mental health service users, carers or professionals. Furthermore, in study 7, only those service users who were involved in the trial were eligible to take part. As a result, those service users who were acutely unwell or were considered by professionals to not be suitable for the trial were ineligible. Despite recruitment endeavours to recruit carers, only four were recruited to study 7 (initial target was up to 10) and although carers' views coalesced with those of service users in the most part, their views may be under-represented in current reporting.

What this study adds

The training was a success in so far as it gained ideological buy-in from those charged with delivering user-centred care planning. However, there was a failure of training to become embedded and normalised in practice. This relates to a lack of organisational readiness to accept change together with an underestimation and lack of investment in the amount of relational work required to make it work. Even the changes that were observed over the 12-month period were too subtle to challenge the existing discontent with care planning as identified at baseline.

Care planning based on shared decision-making that is compatible with user and carer engagement and values is more likely to be achieved if delivered by peer support workers and occupational therapists whose values align more readily than those of existing care co-ordinators or nurses.

Care planning focused on managing mental health based on principles of connecting to others, and activities that are valued in people's everyday life, is likely to be a more effective and acceptable replacement for traditional care planning than modifying through training professional attitudes to user participation.

Workstream 4: dissemination

The aim of workstream 4 was to disseminate our findings, training intervention materials and patient-mediated resources produced during the programme to all relevant stakeholders using multiple methods. We disseminated our findings throughout the programme.

Our implementation strategy utilised a number of known effective mechanisms for the dissemination of findings, and activities occurred at local, regional, national and international levels via professional, service user and carer organisations, in health, social care and third-sector services. We have completed the following dissemination activities and developed patient-mediated materials and resources.

Publications and conferences

To date, 16 manuscripts have been published open access, in peer-reviewed journals with impact factors ranging from 1.827 to 7.06. An additional manuscript has been submitted. We have supported service users and carers to first author three publications by adopting a 'buddy system'. We have also presented findings from our programme at 22 local, 20 national and five international conferences.

Patient-reported outcome measure and audit tool

The EQUIP PROM and EQUIP audit tool were developed (see *Tables 4* and *5*) and have been made freely available for use via the University of Manchester Intellectual Property Click2Go portal. The audit tool is being used in three mental health NHS trusts.

Patient-mediated materials

We developed with service users and carers a range of information materials to facilitate service user- and carer-involved care planning including the following.

User and carer definition of care planning

A definition of care planning using a structured exercise was developed by the SUCAG:

> *A good care plan is one over which service users have a sense of ownership. It is interactive, person-centred and accessible in an understandable form. It provides recovery-focused individually relevant information, addresses current and future needs and sets out objectives that are achievable, time-bounded and regularly reviewed. All decisions are justifiable and health professionals are accountable for any identified support that is not received.*
>
> *EQUIP Advisory Group, 2015. Reproduced with permission from the Advisory Group (2015)*

This definition has been incorporated into the 'Willing Adopters' training and into the EQUIP cards.

Animations

Findings from the published work undertaken in workstream 1 were used to develop two animations to convey key messages to a lay audience. The two animations were created by a professional animator detailing the 10 Cs of care planning (http://research.bmh.manchester.ac.uk/equip/10Cs;[16] accessed 31 August 2019) and carers' perspectives on care planning (http://research.bmh.manchester.ac.uk/equip/mentalhealthcareplanning;[17] accessed 31 August 2019).

Enhancing the Quality of User and Carer Involvement in Care Planning cards

Using a structured session with our SUCAG, we defined five key questions that service users and carers could ask their care team about their care plan. The SUCAG felt that the most effective way of presenting this material was to produce a small pocket-sized fold-out card that contained the five questions and the definition of care planning. The cards are intended to be handy tools for service users and carers to refer to before and during a care planning meeting. Cards were designed utilising the same illustrations as in the animations for continuity. Details of how cards were disseminated are given in *Dissemination of materials*. Images of the cards can be found in *Appendix 5*.

Research methods course for service users and carers

In our Programme Development Grant (RP-DG-1209-10020) we developed a 6-day interactive research methods course, delivered over 6 months, for service users and carers to facilitate increased engagement in the research process. During the programme, we delivered the course twice with service user co-applicants, and our course has been cited as an exemplar of good practice by the Mental Health Research Network and published in the NICE shared learning database.[77] We completed a 6-day course during the programme. A further 6-day course and four 2-day courses were commissioned by the Mental Health Research Network, which were delivered in 2013/14 in London, Nottingham and Manchester. The 2-day course has subsequently been adopted and embedded by the Recovery College in Nottingham Healthcare Trust, and has been delivered by members of our team 16 times from 2012 to 2017, averaging seven participants per course. More widely, the course has been incorporated as a model of good practice in a number of NIHR and other funded grants. For example, we have adapted the training course for a Horizon 2020 bid and have trained PPI leads in Europe, who have cascaded the training to service users and carers with cognitive and sensory impairment. We have delivered a shortened version of our course to PPI members of a NIHR Research for Patient Benefit that aimed to improve care for young people with communication difficulties. We will be repeating the 6-day course for two funded NIHR Programme Grants for Applied Research, which we are leading or co-applicants for [RP-PG-1016-2001; enhancing the quality of psychological interventions delivered by telephone (EQUITy) and RP-PG-0216-20009; improving access to psychological therapy on acute mental health wards]. The training will also be delivered in 2018 as part of a MRC-funded bid in Indonesia and in Kenya and Tanzania as part of a funded NIHR Global Health grant.

Research methods book

The drive to enhance PPI in research means that members of the public are increasingly and actively involved in research projects. Well-planned and -resourced and meaningful involvement necessitates that these representatives achieve sufficient confidence, knowledge and skills to navigate the research process in an often short time period. To complement our research methods course, we are currently developing a research methods book, which is intended to provide a short but detailed overview of the main methods and applications of health services research. During the development of our course, we undertook a scoping search and could not find an appropriate and relevant textbook that aimed to provide in-depth research methods training to patient and pubic representatives. Our book aims to enable patient and public representatives to share a common language with academic research colleagues, and participate meaningfully and collaboratively in research projects.

The research book has been written by course facilitators (EQUIP programme co-applicants and researchers), including our service user and carer co-applicants. We have worked closely with our SUCAG to ensure that the right content, language and pitch are used. The book contains chapters detailing the research process, PPI, evidence synthesis and critical appraisal, quantitative research, qualitative research, health economics, measurement scale design and evaluation, research governance and ethics, and dissemination. Our book ties in with the designs of our other products by utilising illustrations from our EQUIP cards and animations. The book has been published and is available in hard copy (via Manchester University Press;

www.manchesteruniversitypress.co.uk/9781526136534/; accessed 31 August 2019) or as a free open-access download (www.manchesteropenhive.com/view/9781526136527/9781526136527.xml; accessed 31 August 2019).

'Willing Adopters'

Our aim was to support the roll-out of the training intervention (including all our training materials and resources) by inviting 10 NHS mental health trusts to become 'Willing Adopters'. We originally planned to provide up to 3 days (an initial 2 days with a 1-day follow-up meeting 6 months later) of consultation with the EQUIP training team via a dissemination/implementation workshop to trust staff and service user and carer co-facilitators. The 'Willing Adopters' intervention comprised:

- a 'train the trainers' course for health professionals (ideally those who have previously attended the training intervention) and a 'train the trainers' course for users and carers (recruited by the trust) to facilitate the course (all training materials including Microsoft PowerPoint, scenarios, digital clips, training manual, etc.)
- an interactive workshop with health professionals, managers and service users and carers focused on implementation and sharing of lessons learned from the training and workstream 3
- provision of all patient-mediated materials co-produced during the programme including the service user and carer definition of care planning, two animations to demonstrate the key components of service user- and carer-involved care planning; a pocket-sized leaflet with five key questions that service users and carers could ask health professionals about their care plan
- the EQUIP audit tool and guidance for use to measure the extent of user and carer involvement in care planning before and after training.

The EQUIP 'Willing Adopters' package was offered to all nine of the NHS mental health trusts that participated in the trial phase (two of the Manchester mental health trusts have merged). The package has been delivered at seven trusts, but the model of delivery has varied dependent on their needs. Owing to an underspend on the grant, we have secured an agreement with the NIHR for £50,000 to continue the implementation following the end of the programme.

Coventry and Warwickshire Partnership NHS Trust

There has been commitment from all levels including senior management since the training intervention was first delivered. The 'Willing Adopters' workshop was delivered to the trust in October 2016. Day 1 focused on orientation and implementation of the EQUIP programme for senior managers, health professionals and service user and carers. Days 2 and 3 delivered a hybrid of the training intervention and 'train the trainers' involving six service users and carers and six health professionals. However, neither health professionals nor service users and carers felt confident to deliver the training alone and we jointly delivered the 2-day training to two CMHTs. The trust training team has since delivered five training sessions to 82 staff working in CMHTs. The trust is using the EQUIP care planning audit tool to measure service user involvement in care planning. The trust planned to roll out the training to all older adults and learning disability teams in early 2018. To ensure further embedding, a session on enhanced user and carer involvement in care planning is to be incorporated into the trust staff induction programme. Ongoing support by the EQUIP team will continue to be provided via 2- to 3-monthly teleconferences.

South West Yorkshire Partnership Foundation Trust

A 2-day 'Willing Adopters' package was delivered to seven senior staff at the trust in March 2017. The trust was keen to embed the training via the Recovery College to maximise service user and carer input. The Recovery College involving nine health professionals and six service users received the 2-day training package in September 2017. A further implementation half-day was delivered in October 2017; plans are now afoot to roll out the training to both community and inpatient staff and intend to use the audit tool. The EQUIP team will provide continued support to the Recovery College.

Pennine Care NHS Foundation Trust

The 'Willing Adopters' package was delivered to the trust in July 2017. The trust requested that the training package be condensed to a 1-day version to minimise service disruption. Although committed, it was keen that the EQUIP team deliver the training, which has been delivered seven times to health professionals (with in excess of 250 staff attending) from a wide range of services, including community mental health, early intervention, inpatient, older people's, learning disability and children and young people's services. The trust has made significant progress with embedding service user- and carer-involved planning with considerable buy-in from senior management with away days with service users and carers focused on improving care planning. The trust developed and implemented a new care planning template.

Lincolnshire Partnership NHS Foundation Trust

The 'Willing Adopters' package was delivered to seven mental health staff, two service users and two carers at Lincolnshire Partnership NHS Foundation Trust. The trust adapted the training to include a local perspective including results from a community survey, and developed examples of good care plans and risk plans, which evidenced service user involvement. The trust has plans to roll out training to the CMHTs during 2018 and use peer workers to support care/safety planning within the teams.

Leicestershire Partnership NHS Trust

The 'Willing Adopters' package was delivered on 14 and 15 December 2017. The learning from EQUIP has been fed into a 1-year project on care planning and recovery, and this will result in a new approach for the trust, including training, care planning and tools for recovery.

Greater Manchester Mental Health NHS Foundation Trust

Manchester Mental Health Trust and Greater Manchester West NHS Foundation Trust merged, and are now the Greater Manchester Mental Health NHS Foundation Trust. We delivered the training to the usual-care group and two further CMHT teams, with a further training session delivered in February 2018. The trust distributed the EQUIP cards via the NIHR CRN CSOs and for a 1-month period in 2017 the trust included a card with every care planning appointment letter ($n = 2100$). Cards were also placed within clinic waiting rooms, handed out during appointments with service users by CSOs and made available to CMHT staff to hand out to their clients.

The trust has included 'user-involved care planning' in its quality account, incorporated it into its service user engagement plan, developed a new template for care planning, and are funding a band 4 role specifically designed for an individual with lived experience and to deliver and embed care planning training. We will deliver the training to this newly appointed person and clinical leads in October and will offer further bespoke training to the 'trainer'.

2Gether NHS Foundation Trust

The 2Gether NHS Foundation Trust was not part of the trial but contacted us following our dissemination and intends to use our materials and training.

Dissemination of materials

We used a systematic approach to dissemination activities in order to ensure comprehensive and thorough communication of our key messages and materials.

Phase 1 dissemination (August 2017) entailed of a mail-out of 50,000 EQUIP cards with an accompanying letter detailing information and web addresses of the animations. A total of 225 recipients were included in the phase 1 mail-out, including 70 chief executive officers of mental health NHS trusts, 61 CMHT managers, 14 third-sector organisations and 80 recovery colleges.

Focused distribution of EQUIP cards with Greater Manchester Mental Health Trust was via the NIHR CRN CSOs. Over a period of 1 month (September 2017), cards were included with care planning appointment letters by CMHT administration staff across the trust. A total of 2100 cards were distributed over a 4-week period. Cards were also placed within clinic waiting rooms, handed out during appointments with service users by CSOs and made available to CMHT staff to hand out to their clients.

Posters detailing the 10 Cs of care planning were displayed in clinic waiting rooms, and also in meeting rooms used for care planning appointments, at the request of the Greater Manchester Mental Health NHS Foundation Trust research champions. Playback of the two animations was arranged to take place on available monitors and interactive touch screens in clinic waiting rooms. Links to the animations were shared via the trust website, newsletters and e-mail to staff and service users who had provided contact details for such communication.

Phase 2 dissemination (November/December 2017) was focused on sharing the findings from workstream 2, and involved a mail-out to all of the trial participants and mental health trusts involved in the trial. Trial participants who requested to be informed of the research findings each received a lay summary of the results, details of how to view the animations and an EQUIP card. Staff involved in the trial also received a copy of the results, links to the animations and EQUIP cards to pass on to their clients.

Digital dissemination

Considerable effort was focused on digitally disseminating our findings. The digital campaign was launched on 13 July 2017 following a live Reddit Ask Me Anything (AMA) session, hosted by the EQUIP team.

Reddit Ask Me Anything

The live session was focused on the findings from workstream 1 (Grundy *et al.*,[16] Cree *et al.*[17] and Bee *et al.*[40]). The session generated a lot of interest, with an audience of 38,500 people and 7283 positive votes (i.e. people liked this work). The total reach of the AMA was 8.88 million people (data provided by Reddit).[78]

The National Institute for Health Research 'Let's Get Digital' competition

Both animations were submitted to the NIHR Let's Get Digital competition, with the carers' perspectives animation shortlisted and subsequently named as the winner of the video category. Following this success, the animation was presented to Google (Google Inc., Mountain View, CA, USA) at an event in London in November 2017.

Twitter and Facebook

A Twitter account (@Care_Plan) was created in 2013 and was used on an ad hoc basis to share work throughout the programme. Following the Reddit AMA and shortlisting for the NIHR award, a systematic approach to sharing the animations was employed to generate interest and increase the number of views.

Data from a search of keywords tweeted including 'user involvement', 'carer involvement', 'mental health, 'care planning' and 'service delivery' were provided by the University of Manchester library team, which allowed key Twitter accounts to be identified. Accounts were systematically selected based on relevance and number of followers. Direct contact with identified accounts involved tweets from the EQUIP account containing the EQUIP definition and links to the animations.

With support from the University of Manchester Digital Marketing Team in August 2017, we advertised via Twitter and Facebook to increase exposure to the two animations. Viewing metrics were monitored throughout the digital campaign to gauge reach and success of activity. Subsequent adjustments were made to the advertising strategy in real time based on these metrics. The results showed that the combined

number of views of both animations had exceeded 335,000, with viewer retention of 6.9%, which exceeds the current average duration of video viewing hosted on Facebook (5.5%). Final analytics revealed worldwide views in Europe, North America, Africa, Asia and Australasia, an audience age range between 13 and ≥ 65 years and a gender split, with female viewers accounting for > 75% of the total audience.

Key messages video

We consulted our SUCAG to determine how it would like to disseminate the key messages from the programme, and, following discussion, it was decided that a short animation would be the preferred method to communicate findings; it is available on YouTube (YouTube, LLC, San Bruno, CA, USA; www.youtube.com) and the EQUIP website: http://research.bmh.manchester.ac.uk/equip/mainfindings (accessed 31 August 2019).

Patient and public involvement video

In October 2017, a 2-day workshop was held with the production company Patient Voices (Landbeach, UK) to develop and film a short video about PPI involvement; this is available on the EQUIP website and YouTube (http://research.bmh.manchester.ac.uk/equip/resourcesandlinks/; accessed 31 August 2019).

Conference

We ran a joint service user and carer 1-day professional, national conference to disseminate our results to users, carers, mental health professionals and other key stakeholders on 13 April 2018. More than 70 people attended the conference [including NHS staff and research and development staff ($n = 34$), service user/carers ($n = 19$), academics ($n = 15$) and Katherine Horner (our NIHR programme manager)]. Five NHS trusts that had completed the 'Willing Adopters' training presented their progress towards good practice and implementation of service user- and carer-involved care planning. Evaluation of the conference found that 97.5% of respondents would attend/recommend the event to others if this kind of conference was available again. Aspects of the conference respondents enjoyed most were the sharing of good practice by the NHS trusts, opportunities to network and the animations (PPI, 10Cs and summary of findings).

Strengths and limitations of the programme

Key strengths of the overall programme (the strengths and limitations of individual studies are discussed in the relevant sections) include completing all aspects of the programme to time and target. We recruited to time and target with each individual study, recruiting in excess of 2135 service users, carers and health professionals over the 5 years of the programme. Our service user and carer involvement was integral from conception, delivery and dissemination of the programme. A further strength of the programme was our extensive dissemination outputs produced by service users and carers and subsequent outputs (in total we published 14 academic papers and presented at > 50 conferences). We also developed a PROM and audit tool that can be used by researchers and in routine clinical practice.

The most important limitation of our programme was our failure to work further on implementation earlier in the programme; although our implementation workstream ran throughout the 5 years, more intense organisational buy-in earlier on may have yielded different results. This is justified from the promising results of our 'Willing Adopters' programme.

Discussion

Our programme set out to improve the involvement of service users and carers in care planning in mental health services. Through four inter-related workstreams, we successfully achieved all of our objectives on time, and reached or exceeded all of our recruitment targets. We have successfully co-developed, co-delivered and evaluated a 'best-evidence' training intervention for mental health professionals. We have developed and validated a 14-item PROM, providing the first unidimensional measure of service user and

carer involvement in mental health-care planning. We have developed a six-item audit tool to measure service user satisfaction with care planning involvement and assessed service user and carer preferences to weight its constituent items and help direct quality improvement in practice. In parallel to this work, we have co-produced patient-mediated materials, including animations and pocket-sized prompt cards for service-users and carers, and shared these extensively to reach a maximum audience.

Developing and evaluating our training intervention

Using evidence gathered from literature reviews and our own extensive work with stakeholders, we developed our training intervention in collaboration with service users, carers and NHS representatives. Our training embraced a bottom-up approach to professional behaviour change, and offered 18 hours of facilitated training to multidisciplinary teams (12 hours of direct learning, 6 hours of follow-up supervision), plus an additional 8 hours of optional self-directed learning. Our training was co-delivered, by service users and carers, to 350 mental health professionals (304 care co-ordinators) working in CMHTs in 10 NHS trusts in England. We evaluated the impact of the training on patient outcomes by recruiting 604 service users and 90 carers to a cluster trial, and 682 service users to a cross-sectional study. Our training was well attended and positively evaluated by staff but had no significant effect on our patient-rated primary outcome measure (the HCCQ-10) 6 months after training.

Our inability to demonstrate benefits from our training intervention demands exploration. We evaluated an intervention that was derived from published evidence and designed specifically to overcome known barriers to collaborative care planning. The recent Making Good Decisions in Collaboration (MAGIC) programme[79] has identified many front-line challenges to embedding shared decision-making into UK NHS secondary health-care settings, including the misplaced confidence of staff, a perceived lack of support for shared decision-making and inaccurate assumptions about patients' preferences. Importantly, the MAGIC study excludes mental health settings, but its findings resonate closely with those of our own systematic review, which has similarly identified barriers relating to the readiness, skills and confidence of mental health professionals to engage service users and carers in discussions about their care.[5] Extensive qualitative work undertaken in phase 1 of the EQUIP programme subsequently confirmed the need to train front-line staff in partnership working and identified this as a training priority upheld by all stakeholder groups.

Our training intervention was designed and delivered in line with stakeholder preferences and took account of current best evidence emphasising the importance of interprofessional learning, interactive group work and educational outreach. We set out to train whole teams and included exercises and role plays that challenged embedded attitudes, reviewed current practice, built a shared understanding of service user involvement and improved skills in sharing decision-making with patients. Training attendance was high, but there were important limits. We stipulated an attendance rate of 80% per team, and 10 out of 18 teams achieved this goal (range 48–100%). However, no psychiatrists attended, which may ultimately have limited the impact of our intervention.

Our training was evaluated extremely positively by attending professionals, with co-delivery by service users and carers being the most valued aspect of the intervention. The co-production and co-delivery of training in partnership with service users and carers is becoming increasingly common in mental health and presents a unique opportunity to promote the ethos of partnership working at all levels of a health-care system.

Although we sought qualitative feedback on the relevance and impact of our training from staff, we did not assess the ongoing enactment of enhanced beliefs and skills. Anecdotal feedback collected during supervisory sessions and data collected during the nested process evaluation suggested that pockets of practice improvement occurred, but direct observations and/or analysis of real-time care planning discussions are needed to independently verify this behaviour change. Professionals involved in the process evaluation also felt that such changes may be too subtle for services users to notice within the follow-up period. Without such data, we are unable to determine definitively whether our training failed to translate into practice change, or whether practice changes did occur but failed to demonstrably affect trial outcomes.

Identifying and quantifying outcomes

The notion that training may have instigated practice changes but did not have a significant impact on patient outcomes raises one of two possibilities: either the practice-based charges were not of sufficient depth or spread to enact an effect or the trial outcomes were not sufficiently sensitive to this change.

Previous programmes have identified a lack of suitable patient-reported measures for shared decision-making, and our team has successfully responded to this challenge by developing and validating a new patient-reported measure of mental health-care planning involvement. Importantly, however, the availability of this measure was not assured at the programme commencement and thus an alternative primary outcome measure was sought.

The primary outcome for our trial was the HCCQ-10, a self-report scale based on self-determination theory.[46] The HCCQ-10 measures 'autonomy support', defined as patient perceptions of the degree to which health professionals support patient choice and ensure that their behaviour (and behaviour change) is congruent with patient values. The HCCQ-10 has 10 items, an example of which is 'My mental health-care provider team has worked with me to develop a mental health-care plan', and is aligned with our aim to improve patient and carer involvement in the care planning process. Secondary outcomes assessing patient experience and benefit were chosen by a consensus exercise with our patient advisory group, and included our newly validated EQUIP PROM.

We used established tools and all outcome measures were validated for our patient population. Although concerns have been expressed about the suitability of some measures (e.g. the WEMWBS for people with psychosis), all measures retained acceptable levels of reliability and validity, raising confidence in our trial's findings.

Challenges in the timing and concept of outcome measurement cannot be underestimated. Although outcome assessments occurred at the 6-month follow-up, it is not untypical for people under the Care Programme Approach (CPA) to have their care plan reviewed on an annual basis. Although most, if not all, of our participants were under the CPA, we took the view that care planning is a continuous process rather than a single event of activity. Opportunities to use the training in routine contacts thus extended beyond the CPA. Data from patient self-report suggested that 79% of patients saw their CMHT during the 6-month follow-up, with a mean of 12.3 contacts per person. Although these data are reassuring, we cannot exclude the possibility that patients' appraisals of autonomy remained biased towards their experiences in more formal care planning meetings.

Longer follow-up has been possible in our 'Wiling Adopter' sites, and early evidence is emerging to suggest improvements in care planning assessed by Care Commission Quality (CQC) ratings. Whether these improvements can be directly attributed to our training intervention or to wider organisational strategy is unclear. Published literature on shared decision-making highlights a tension between the use of validated and reliable measures for research purposes, and the neglect of measures normally used to drive quality improvement.[80] Adopting recognised quality improvement measures can potentially strengthen team commitment to practice-based interventions and enhance the likelihood of positive behaviour change.

Locating training in the context of wider organisational change

Accepting that our trial measures were fit for purpose and sensitive to change places onus on philosophical and structural design of our intervention. Our decision to prioritise a bottom-up approach and deliver training to front-line staff was justified by the need to balance effective intervention with maximal reach. However, the lack of significant differences in outcomes between our trial arms suggests that short-term staff training is not an effective way to embed service involvement in care planning practice.

Significantly, our results concur with a growing body of evidence that highlights the challenges associated with embedding shared decision-making in routine services.[81–85] At present, evidence on how to encourage service user involvement in care planning decisions is limited[86] and there is no proven method of implementing

shared decision-making across routine mental health settings. A recent review of studies to enhance shared decision-making in psychosis has shown that the majority of trials have delivered and evaluated interventions to patients, with only one testing training for clinicians.[82] Our programme, and specifically our trial, thus provides some important learning.

Synthesis of findings across our workstreams suggests that it is unlikely, although not impossible, that our training intervention was suboptimally applied. A recent systematic review[87] suggests that the majority of training interventions can improve staff skills, and qualitative evaluation within our programme provides confirmatory evidence of individual impact. Direct communication with participating trusts has enabled us to estimate < 5% turnover of staff from baseline to the 6-month follow-up, adding weight to our expectation of a proximal training effect. Rather, we argue that our training intervention most probably encountered its biggest challenges in initiating and sustaining routine behaviour change and having an impact on distal patient-centred outcomes.

Our inability to show an effect of the training may in part be explained by data from our qualitative process evaluation, which suggested that, despite ideological buy-in from trained staff, our training failed to become embedded and normalised in local provision. Supervision sessions were offered to staff post training but demonstrated very low uptake. This widespread failure to engage in supervision may in part reflect the fact that professionals' work priorities, workload and availability were not conducive to incorporating new knowledge and skills from training into their existing role. Qualitative data collected at the 6- and 12-month follow-ups suggested that there was an absence of organisational readiness to accept change, and an underestimation and deficient investment in the amount of relational work required to make it successful. This combination of stretched staff and services, in the absence of organisational requirement and support to incorporate training into usual practice, most probably had an impact on the probability of eliciting measurable changes in service user and carer involvement.

Service users and professionals in the process evaluation identified alternative roles, such as recovery workers, support workers and occupational therapists, as being the most likely to have the time to undertake the required relational work to successfully enact user-centred care planning. A recent review supports the incorporation of such alternative forms of service provision within mental health care to improve outcomes for patients while reducing the pressure on the mental health system.[88]

Lessons in change management for mental health services

Effective change management demands accurate analysis of the causes of the presenting problem. A particular strength of our programme lies in our two substudies that were informed and underpinned by implementation science (studies 6 and 7). Baseline data from our nested process evaluation suggested that the current operationalisation and utilisation of care planning within mental health services was likely to be a significant barrier to involving patients and carers in the care planning process,[76] and pointed to a need to develop a successful strategy to optimise training implementation.

Our focus on developing and evaluating a relatively low-cost, bottom-up approach to behaviour change inevitably led to the prioritisation of our training intervention. In line with the change management literature, we designed a training intervention to enact developmental (skills-based) and transitional (cognitive-based) change. We included a director of nursing and the host trust's director of patient experience as co-applicants with costed time for programme input and involved these high-level managers in evidence synthesis and intervention design. In response to baseline data that identified a need for high-level buy-in to facilitate training attendance, we also leveraged higher managerial support to make our training mandatory to front-line staff. These strategies were effective in promoting meaningful engagement in our intervention but did not fully extend to securing the levels of organisational support necessary to support the translation of training into everyday practice. Future work should consider adopting evidence-based, phase-specific implementation strategies to enhance training impacts and effects.

A key learning point derived from the recent MAGIC programme was that professional attitudes and understanding of shared decision-making constitute a core focus for practice change.[83] Importantly, however, although MAGIC examined a number of clinical contexts, it excluded mental health. Mental health services have a unique service history founded on concepts of containment and coercion[89] and, as such, any initiative to enhance service user involvement and decision-making may face particular and additional challenges. Patients in mental health services often present with long-term and complex diagnoses, and can experience significant stigma.[90,91] These observations allude to potentially important differences between mental and physical health services that may require a somewhat different balance and mix of intervention components and evidence to effectively redress. Historically, the majority of patients and carers have felt marginalised in care planning decisions,[5] and the potential for short-term training interventions to have an impact on these entrenched attitudes may be disproportionately constrained.

Of particular interest in the current programme was the readiness of our 'Willing Adopter' sites to accept our training intervention without clear evidence of clinical effect or cost-effect. Arguably, equipping professionals with the skills to effectively involve service user and cares in their care may be conceived as a value-based initiative, with potential for continuous rather than immediate improvement in health-care culture and outcomes, which is supported by data from the process evaluation. Strong moral and ethical reasons for involving people in care planning persist and the historical marginalisation and neglect of mental health services may be fostering an urgent need for innovation. The most successful 'Willing Adopters' in our programme have benefited from substantial high-level managerial support, supportive 'middle managers' and excellent staff who appear open to change. Thus, at a time when NHS redesign techniques are advocating bottom-up commitments from patient and professional stakeholders, our work has demonstrated an explicit need to continue to ensure that these are located within active spheres of organisational accountability and systems-level transformation. For example, the process evaluation identified the need to reconsider the structure and content of existing care planning documentation. All of the stakeholders felt that the current formulation of care plans served organisational agendas rather than the needs of service users,[76] and this limited the relevance of including service users in such bureaucratic processes. Future work should consider ways to increase the relevance of care planning to the everyday lives of service users.

Macrolevel theories of health-care improvement have been previously criticised for their limited explanatory power and may not be appropriate for understanding fine-grained enablers of and barriers to the sustainability of change. Participation in our research trial required some institutional *agreement* from our host health organisations but did not require significant *commitment* beyond the promise of staff training time. It is therefore unclear if our training participants viewed our intervention as integral to service function, or merely as a research-based initiative competing with other demands. Effective interventions may ultimately require more comprehensive and enduring commitment, including explicit validation of time spent with patients, endorsement of partnership through clinical leadership and incentives, and fostering new ways to meet patient needs within the constraints of current resources. However, such comprehensive models raise significant challenges for implementation and assessment in a rigorous, controlled fashion. A further consideration is the extent to which a RCT was the correct vehicle to test our intervention. On reflection, it may have been more appropriate to focus on implementation outputs as demonstrated by our 'Willing Adopters'. Further work is indicated to explore the enablers and outcomes of our training implementation in the context of everyday implementation.

Identifying alternative strategies for evaluation

Outside our cluster trial, our programme took a whole-systems approach to service improvement. This approach acknowledged the multifactorial issues involved in health care and recognises that successful implementation relies on a combination of interventions supporting the organisation, the clinicians and the patients. Long-standing deficits in mental health policy and practice have led to feelings of exclusion and passivity for many patients, and, therefore, parallel efforts to increasing patient agency, activation and health literacy are likely to become important. We have co-produced with service users and carers animations and prompt cards to increase the likelihood of mutually useful conversations between patients

and clinicians and provide an alternative or additive strategy for evaluation. Our strategic use of social media to communicate our work has substantially enhanced the reach and impact of these outputs and set a precedent for future dissemination. The importance of accountability in care planning, and finding ways of eliciting needs from service users that are meaningful to them, which might fall outside conventional care planning practices, are essential to explore.

Recommendations for future research

- There remains an urgent need to develop ways of improving service user and carer involvement in their care plans. More complex, comprehensive and enduring interventions may be required, such as the use of incentives, linkage to routine outcome monitoring and better integration into routine clinical systems. However, such comprehensive models raise significant challenges for their implementation (and their assessment in a rigorous, controlled fashion).
- Research should focus on developing and evaluating new organisational initiatives to address contextual barriers to service and carer involvement in care planning. These initiatives should include the introduction of both 'bottom-up' and 'top-down' structural changes, such as accountability systems, as well as system-level strategies that encourage or facilitate shared access to care plans.

Implications for clinical practice

The evaluation of the training intervention was extremely positive. The co-production and co-delivery of training in partnership with service users and carers is increasingly common in mental health care. In this study, we have shown the possibilities and potential of this endeavour. When working with service users and carers in the development and delivery of training it is important that service users and carers are equipped to handle potential resistance from staff. The roles of service users and carers should be negotiated carefully and agreed at the outset. The involvement of service users and carers must be concomitant with ongoing support and supervision. In the end, mental health professionals' involvement of service users and carers will be enhanced and further potential for shared decision-making is apparent.

Services we have been working with have recognised that service user and carer involvement requires improvement, but they need to acknowledge that, in addition to the training, new organisational initiatives to address contextual barriers to service and carer involvement in care planning are required. Such initiatives may include the introduction of 'top-down' structural changes, such as accountability systems, as well as system-level strategies that encourage or facilitate shared access to care plans. Initiatives may examine ways of incorporating mandatory requirements for staff to actively involve service users and carers in care planning (e.g. as part of clinical supervision, job role specifications and continuing professional development). This approach might affect changes in service user satisfaction in care planning involvement more effectively.

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Service user and carer trainers received numeration for training delivery. This payment was solely for training course facilitation post trial, and was negotiated with 'Willing Adopter' sites after all the evaluative research was completed.

Contributions of authors

Professor Karina Lovell was the chief investigator for the programme and was co-lead of workstream 2.

Professor Penny Bee was a co-applicant and was the lead of workstream 1 and workstream 4.

Professor Peter Bower was a co-applicant and co-lead for workstream 2.

Dr Helen Brooks led workstream 3 and undertook participant recruitment and research interviews and assessments in workstream 3 and the trial.

Mr Patrick Cahoon was a co-applicant and offered critical clinical and organisational insights with delivery and implementation.

Professor Patrick Callaghan was a co-applicant.

Dr Lesley-Anne Carter led the statistical analysis.

Mrs Lindsey Cree was a co-applicant.

Professor Linda Davies was a co-applicant.

Dr Richard Drake was a co-applicant.

Mrs Claire Fraser was the programme manager.

Dr Chris Gibbons undertook psychometric testing and development of the PROM.

Mr Andrew Grundy was a co-applicant.

Dr Kathryn Hinsliff-Smith undertook participant recruitment and research assessments for the trial.

Dr Oonagh Meade undertook participant recruitment and research interviews.

Professor Chris Roberts was a co-applicant.

Professor Anne Rogers was a co-applicant.

Dr Kelly Rushton undertook participant recruitment and research assessments for the trial.

Dr Caroline Sanders was a co-applicant for workstream 3.

Ms Gemma Shields conducted the health economics analysis.

Ms Lauren Walker was a co-applicant.

All authors contributed to delivering the programme and to the drafting, revision and approval of the final report. All applicants were involved in the programme conception, design, methods, analysis and interpretation.

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Gibbons CJ, Bee PE, Walker L, Price O, Lovell K. Service user- and carer-reported measures of involvement in mental health care planning: methodological quality and acceptability to users. *Front Psychiatry* 2014;**5**:178.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

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Appendix 1 The National Institute for Health Research Programme Development Grants final report form

NHS
National Institute for Health Research

Programme Development Grants are designed to allow strong collaborative teams to undertake development work to position themselves for successful applications for full NIHR Programme Grants; hence, it is anticipated that a final report will be an annex to any subsequent Stage 2 Programme Grant application.

Nevertheless, final reports are required for all work funded through the NIHR Programme Development Grants scheme, irrespective of whether or not they lead to an application for a full programme grant. The reasons are to:

- ensure accountability of the scheme
- demonstrate what has been achieved
- assess the impact of the work supported by the grants
- understand grant holders' plans beyond the award
- encourage quality assurance of research outputs
- aid in appropriate dissemination of research results

Please keep these aims in mind while completing your final report.

The report needs to offer:

a) a clear summary of the development work for practitioners and users of research
b) a record of challenges faced and modifications made as a consequence
c) plans for research that will follow the development work
d) a summary of any outputs, such as publications, from the research

A final statement of expenditure should be submitted at the same time as a final report. Please note that the final payment will only be released once the completed final report along with a final statement of expenditure has been received by the CCF

For further guidance or information on completion of your final report, please contact the Programme Grants for Applied Research Team at NIHR CCF, using the details below:

Programme Manager's Name
NIHR CCF help line: [redacted]

National Institute for Health Research

NIHR Programme Development Grants

Final Report Form

IMPORTANT

Note the maximum field sizes shown include both printing and non-printing characters such as spaces.

Reference Number RP-DG-1209-10020

Date submitted

For office use

1. Development Grant details	
Reference Number:	**RP-DG-1209-10020**
Title:	**Enhancing the quality and purpose of care planning in mental health services.**
Lead Applicant's Name:	**Professor Karina Lovell**
Contracting NHS Organisation:	**Manchester Mental Health and Social Care Trust**
Contract Start Date:	**01/10/2010**
Development work Start Date:	**01/10/2010**
Current Contract End Date:	**30/09/2011**
Original Duration:	**12 months**
Current Duration:	**12 months**
Total funding awarded (prior to any inflation uplifts):	**£95,431**

2. Grant holder's details

Title:	Professor
Surname:	Lovell
Forename:	Karina
Department:	School of Nursing, Midwifery and Social Work
Role in Research:	Principal Applicant
Institution:	University of Manchester
Street:	Oxford Road
Town/City:	Mancheste
County:	Manchester
Post Code:	M13 9PL
Telephone:	[redacted]
Extension:	
Email Address:	[redacted]

3. Summary (in Plain English)

Please provide a summary of the development work, including background, findings and conclusions. It is essential that you make the content of your summary and the implications of your work evident to the lay public. It should avoid technical terms and should be written in an accessible style and emphasise in particular the potential for patient benefit. **(Maximum 2,500 characters)**

Involving and allowing service users choice in their own care and hence recovery is at the centre of policy initiatives aimed at improving quality of care. This principle is enshrined and prioritised in healthcare. Despite this and the literature produced by user and carer groups which advocate that involving users and carers in care planning is fundamental to improving the quality of care, there is substantial evidence that many users and carers are marginalised and removed from the care planning process.

The aim of the programme grant is to improve user and carer involvement in care planning in mental health services. To prepare for a full application we conducted the following preparatory work:

i) to develop strong service user and carer collaboration in two mental health trusts and increase their capacity to engage in the Programme Grant,
ii) to undertake a review of the literature to better inform the Programme Grant,
iii) to enable the project team to form a consensual strong working group in order to deliver on the Programme Grant and
iv) to prepare, develop and confirm the design of individual work streams for the Programme Grant

We developed and delivered a successful research methods course for users and carers which equipped them with an understanding of research in order to improve their ability to engage with and understand research and researchers. Our user and carer consultation group has given us the time to develop close working relationships and to work in true partnership. Together we have reviewed outcome measures, defined the attributes of a suitable measure and agreed that we will develop and validate a suitable measure in our programme grant application.
The review of the literature achieved its objective, and has identified the key barriers and facilitators of sustained user and carer involvement in care planning processes. Its findings provide a solid foundation on which to base the programme grant. The team building workshops allowed us the time to work as a collaborative and effective group and to develop the programme application and to fully discuss the design in detail as well as the integration of all work streams.
In conclusion the preparatory work has allowed us to develop a full application for a programme grant with significant user and care involvement.

4. Research team

Describe any changes in the research team over the course of the development work. **(Maximum 1,500 characters)**

During the programme development grant a number of changes occurred. Professor Gask is retiring in 3 years and hence will not be available for the duration of the programme grant. She has requested that that she change her status from co applicant to collaborator. In consultation with Dr Gask we have engaged Dr Richard Drake (RD, psychiatrist) to be a co-applicant. RD has a clinical appointment with Manchester Mental Health and Social Care Trust and is actively involved in care planning. In addition he has a strong research track record in mental health.

Given the amount of qualitative work incorporated into the programme grant we have also engaged Dr Caroline Sanders (CS) as co-investigator. CS has a strong track record in medical sociology & qualitative methods and is experienced in devising peer-led training for care planning (in the context of end of life care).

Throughout the programme development grant we have worked with service users & carers and we have engaged 3 further co applicants from this group. Lauren Walker (LW) & Andrew Grundy (AG) have lived experience of mental health problems and Lindsay Cree (LC) a carer for her son who uses mental health services. Importantly LC is accredited to provide carer-led teaching to medical students.

Although Dr Quirk made a full contribution to the programme development grant he is unable to participate in the programme grant.

5. Keywords

Provide up to 8 keywords that relate to the work undertaken.

Care planning; mental health, User involvement, carer involvement, realist review, education, collaboration

6. Additional background information

Provide any background information that is essential to assessing the outcome of your Development Grant that is not in the original application. **(Maximum 3,000 characters)**

The new “No health without mental health” strategy (HM Government 2011) emphasises the importance of addressing poor outcomes in terms of employment and engagement of personal communities. This mental health outcomes strategy looks to communities, as well as the state, to promote independence and choice reflecting the recent vision for adult social care”. It is thus suggested that user centred care planning remains central to current and future policy direction in mental health.
The programme development grant has also benefitted from synergies with related work ongoing at the University of Manchester on care planning, including the Department of Health Policy Research Programme CAPITOL project on care planning in long-term conditions (Bower, Rogers), and the NIHR funded WISE trial on primary care based education for self management support and care planning (Rogers, Sanders, Bower). These projects have common core philosophies around shared decision making and patient involvement, which has enabled sharing of conceptual frameworks, empirical data and research designs which has made a substantive contribution to the current programme development grant and the resulting programme grant application titled Enhancing quality of user involvement in the planning of care (EQUIP).

7. Development work undertaken

Taking each component of your Development Grant research plan in the order in your application form, describe the work that you have undertaken and whether or not it successfully addressed the questions or problems that it was aimed to address. Also mention any challenges faced and modifications made as a consequence. **(Maximum 25,000 characters)**

The programme development grant work plan had four stages:

i) to develop strong service user and carer collaboration in two mental health trusts and increase their capacity to engage in the Programme Grant,
ii) to undertake a review of the literature to better inform the Programme Grant,
iii) to enable the project team to form a consensual strong working group in order to deliver on the Programme Grant and
iv) to prepare, develop and confirm the design of individual work streams for the Programme Grant including the identification of key outcome measures and/or the need to develop new ones.

Stage 1: Engage with and develop strong service user collaboration, increasing the capacity and confidence in order to fully engage in the programme grant.

Aim

This stage of the programme development grant aimed to build the capacity of service users and carers by providing a tailored training course on research methods. The aim of the training was to ensure that users and carers informed the research process and fully engaged in the development of the programme grant.

Recruitment & selection

Advertisements were widely distributed via two NHS trusts (Manchester Mental Health and Social Care Trust & Nottingham NHS Trust) and local user & carer groups. A single page application form was devised to capture recent lived experience in mental health services and preferably of care planning. From 25 applications, 13 candidates were short listed and invited to interview (9 Manchester, 4 Nottingham). Candidates who were not shortlisted did not have lived experience of care planning in secondary care. Although we only intended to offer 8 places we were so impressed by the calibre of applicants at interview that we decided to offer them all a place on the course, resulting in 5 additional places being created.

Training development and content

A 6 day course delivered 1 day a month for 6 months was developed and delivered at the University of Manchester. Each day was divided into four 50 minutes session, two in the morning, and two in the afternoon. The course was pitched at Masters Level and delivered using a blended learning approach including lectures, large & small group formats and online resources. Masters level training was felt to be necessary to engage participants fully in the research process. A key challenge was locating educational materials which both met the requirements of this level yet remained accessible to lay readers. Ben Goldacre's Bad Science was adopted as the core text and provided free of charge to all participants via development grant funding

Sessions were delivered by applicants from the programme team, who taught research theory and methods within their specialist area. Homework exercises were internally developed for use between sessions and drew on key mental health and health services literature relevant to each research topic.

All students were enrolled on a non-credit bearing course, enabling full student access to University of Manchester facilities, IT systems and library resources (databases, e-journals and books). Students were enrolled on Blackboard 9.0, the university on-line learning facility, allowed participants access to electronic as well as hard copies of all handouts, academic articles and audio recordings of teaching sessions. Learning materials were circulated in advance, and enlarged for those with visual impairment. All sessions were digitally recorded and audio files were available on Blackboard.

Training content:

Day 1: Orientation to the grant & the University of Manchester, IT and study skills refresher;
Day 2: Understanding the research process & developing research questions;
Day 3: Literature searching & critical appraisal;
Day 4: Qualitative methods;
Day 5: Quantitative methods & health economics;
Day 6: Ethical conduct, training evaluation and grant development discussion.

Attrition
Of the 9 completing the course 5 had 100%, two 83.3%, and two 66% attendance. Two service users and two carers withdrew for personal reasons (including one service user who was offered employment). All of those who withdrew stated that they would attend the course again given the opportunity.

Evaluation
The qualitative evaluation is based on feedback from both trainers and trainees. The course and content was very well received by attendees. All participants reported a high level of satisfaction with the course in particular, learning about research and its governance including understanding of research design, qualitative and quantitative methods and cost effectiveness. The 'Bad Science' text was highly regarded by participants who felt that it provided the necessary depth of knowledge to understand core research concepts (e.g. effect sizes & confidence intervals). Research interest was also raised with a number of participants also reading Ben Goldacre's weekly 'Bad Science' column in the Guardian.

'I would just like to say thank you for giving me het opportunity to take part in the research program; it made me feel so good about myself as it really boosted my confidence. It made me realise just how much of a difference I can make with the right tools and training. I would also like to thank all the tutors who took time to help; I learned a lot especially from Ann Rogers. I also enjoyed doing team work and being part of a team. I learned so much by being able to take part in the research program. It has been a dream come true attending university: it just proves that no matter what disabilities someone may have – physical or mental – with help dreams can come true. I hope I can be part of future research programs and I look forward to finding out what the future holds for me.' (Service user)
Positive messages emerging from the feedback included the experience of being on a course which promoted learning, validated previous experiences, improved confidence and provided opportunities. Value was also afforded to the added extras (e.g. Food, support, recordings, printing), regularity of the breaks provided, engaging staff and the genuine involvement of service users/carers. One of the key messages that came through from the group was the view of being treated as an equal amongst health professionals (a new experience for many of the group).
For future courses a number of suggestions were made to improve the course including: overcoming IT delivery problems, providing more resources in advance, and increasing inclusion in the university.
Requests were also made for opportunities to discuss health/wellbeing in a contained manner so as to prevent tangents during training, and to discuss issues about the training endpoint and further opportunities for the group.
Key messages from the trainers
Most participants had days when their mental health influenced their learning, and this required some additional input. However the course was developed from a normalisation stance which aimed to make the application and process like any other university course. The maintenance of this principle was important to both participants and trainers.
Training was resource intensive, and required 2-3 trainers per session to facilitate small group learning. All trainers commented on the enthusiasm of the participants, and their course commitment, demonstrated through the completion of all homework activities and learning beyond the mandatory content, i.e. by visiting the library to find out more.
Trainers identified a number of value added components including the resolution of remuneration to enable cash payments, provision of lunches & refreshments, and the development of learning materials in a variety of formats.
One of the key messages that emerged from the trainers was that the training itself had enabled them to feel more confident working with users and carers. None of the trainers had taught research methods to user and carers before and we learnt some valuable lessons (perhaps most importantly the lack of user friendly material available). In addition valuable feedback was provided from users and carers about teaching styles and materials used.

Post course legacy
During the course participants began engaging in PPI activities to provide feedback on several grant applications. They expressed a desire to continue to undertake this role and engage in developing service user/carer-led research projects. A number of participants have been co-opted into the programme grant application, steering group, and/or potential researcher roles (identified as PhDs within the programme grant application).
In order to ensure the legacy of the group and to undertake future training sessions, applications for additional funding have been made to Manchester Academic Health Sciences Centre (MAHSC) and Manchester Mental Health Trust Flexibility & Sustainability Funding. An additional day has been organised in November 2011 to update the trainees on the outcome of these. The course has already been cited by the MHRN as an exemplar of good practice. Regardless of the outcome of the

programme grant application we are committed to continuing this group and involving them in further research opportunities.

Outcome
The training achieved its objective, to equip service users and carers with an understanding of research in order to improve their ability to engage with and understand research and researchers. Considerable learning has been achieved by service users, carers and trainers about how to devise educational course of this kind and improve future courses. Trainees have contributed to the programme grant design and some will be part of the research team.

Stage 2: A substantial (realist) review of the literature

A substantial review has been completed, the findings of which underpins the proposed Programme Grant The word limit preclude us from detailing the full report here. An extended abstract is presented below.

Background and aim
Recent policy initiatives (1-3), emphasise the importance of involving service users in the planning of their own care. The drive to include service users within this process is considered a necessary and potentially effective means of improving the responsiveness of services, and making them better tailored to people's needs and social circumstances. Despite this there is a wealth of evidence to suggest that, in mental health services, users are dissatisfied with their level of involvement in care planning (4). A previous review (5) identified a range of benefits to user involvement in care planning including: improved service development, information provision, service user feedback mechanisms, esteem of service users, and the attitudes and morale of staff. Included studies were limited to small-scale, uncontrolled studies however and failed to elucidate impact on service utilisation, quality of care, or health improvement. Recent studies in mental health have evaluated the impact of enhanced user involvement interventions on service level outcomes, but, by nature of their design, are limited in terms of their ability to reveal barriers to wider implementation. In order to improve outcomes across mental health populations, it is necessary to understand the various intra and inter-individual mechanisms and organisational systems by which user involvement in care planning can be optimised over time.
The primary aim of this review was to identify the key barriers and facilitators of sustained user & carer involvement in care planning. To this end, we set out to examine how user involvement is typically operationalised in a mental healthcare context and where, how and why user involvement may meet with resistance. A secondary aim of the review was to identify where further research synthesis may be warranted if the subtleties of these key challenges and catalysts to user involvement are to be better understood.

Methods
Realist review as a method of evidence synthesis aims to delineate the core mechanisms through which complex programmes are deemed to work. The essential steps in a realist review comprise clarifying the scope of the review, articulating the underlying theoretical framework, and searching for and appraising evidence. The scope of the review was international and examined user involvement across both organisational and service settings. Following substantial reading and consultation, a theoretical framework conceptualised user involvement in care planning as a core component of three broader philosophies: patient-centred care, shared decision making and patient empowerment. The success of each philosophy was further hypothesised to depend on three intervening variables: i) the capacities & competencies of users, ii) their relations with health professionals and iii) the organisational context in which their care occurs. Cross-matching these three frames of reference with the three care philosophies identified the key pathways and mechanisms through which user involvement may be expected to succeed or fail. Subsequent synthesis of the primary evidence provided a means of identifying the specific routes and procedural points through which user-involved care planning has been facilitated or barred.
A comprehensive search strategy was applied to electronic databases and grey literature sources. Results were screened for eligibility and data indexed against our framework. Each primary data source was evaluated in terms of its reporting quality, the appropriateness of its methods, and its internal and external validity.

Results
Searching yielded a total of 4800 articles, 1730 of which were retained after initial abstract screening. We excluded papers that failed to present useable data on the potential barriers & facilitators of user involved care planning in mental health. 137 papers were used to interrogate the central assumptions of our conceptual model. Of these 116 were empirical academic studies, 15 grey literature studies and 6 national consultations.

The synthesis revealed effective user involvement in care planning to be a multi-stage intervention, dependent on a number of broad conditions:

- the motivation of the user
- the perceived adequacy of information provision and choice
- the quality of the care planning relationship
- the effective engagement of users in the care planning process

Each condition incorporates multiple, complex processes and potential confounding influences, with consistency of practice and communication being identified as key mediating factors.
Users' ability to sufficiently influence their care was found to extend beyond the level of the individual, to relational and organisational hierarchical constraints on care. At the relational level, barriers included a lack of congruence between user and staff priorities for care, and staff anxiety surrounding implications for user well-being and safety. There was a general underestimation of users' willingness and ability to be involved, and a suggested failure among professionals to communicate care planning processes in lay terms. Staff in turn reported a lack of resources & support, and there was evidence of deficits in the skills, knowledge, and confidence required to effectively engage users in the process. Both users and professionals noted that factors related to staff working conditions, particularly in acute inpatient settings, such as stress, burnout, and lack of time, challenged user involvement in care planning.
Most notably, synthesis suggests that failures in partnership working will most likely occur wherever the frames of reference adopted by service providers and consumers diverge. Whilst staff tend to focus their attention on enhancing the outcomes of care planning, users are much more concerned with the process. Users report perceiving care-planning as too hierarchical and exclusive and it may be that health professionals are misattributing a lack of user motivation, with disaffection with the process. The situation may only improve when health professionals engage users in prospective decision making processes.
Future research is necessary to more fully examine the relationships between intra and inter-individual competencies and organisational capacities, including the propensity for intervention at the inter-individual level to moderate effects elsewhere.

Outcome
The review achieved its objective, and has identified the key barriers and facilitators of sustained user and carer involvement in care planning processes. Its findings provide a solid foundation on which to base the programme grant. In particular there appears to be a need to reduce the perceived power differential between users and professionals, potentially through promoting user self-efficacy whilst concomitantly reducing professional self-importance. Findings indicate that services should broadly, adopt strength-based recovery oriented approaches to care and provide sufficient training and adequate working conditions for staff. Efficient administrative systems are essential to facilitating user involvement including the timely allocation of care coordinators and stakeholder invitations to review meetings. Such features will directly inform the development of interventions in the programme grant.

Stage 3: Enable the team to form a strong and consensual working group.

Our aim was to enable the project team to meet regularly during the project to finalise key aspects of the Programme Grant. We said that we would organise 3 structured away days for the team to form a strong and consensual working group. We achieved this and held 3 full day meetings, the first was focussed on team building (facilitated by an external trainer) and developed and refined our shared objectives for the programme development grant. The second & third day workshops consisted of presentations on the user/carer training and the realist review. A half day workshop was convened between our user/carer group and programme team to explain the nature of the programme grant and present the initial results of the realist review. Discussions focussed on developing the content and coherence of the future work streams. A fifth workshop was held with both groups to present the review of potential outcome measures (see stage 4).

Outcome
We achieved our objective and provided us the opportunity to achieve a well functioning team essential to developing and delivering a programme grant.

Stage 4: Preparation, development and confirmation required for the development of a cluster randomised trial.

This stage consisted of two key components. The aims of these two components were to:

- Identify the potential outcome measures which evaluate the level of user/carer involvement & satisfaction with care planning.
- To develop and finalise the work streams of the full programme grant.

Identifying potential outcome measures which evaluate the level of user and carer involvement and satisfaction with care planning

As part of our search strategy for our realist review (stage 2) we searched for potential outcome measures for a planned randomised controlled trial. Nine measures were identified. A workshop with our user/carer consultation group (n=10) and co-applicants (n=6) was held in July 2011. The key details of each of the 9 measures found in our review were tabulated and actual copies of measures (where available) were presented to the group.

Three small groups were formed to discuss each measure in turn and to either reject or accept its potential value to the trial. Results of this exercise were tabulated and used to prompt further discussion. Consensus was achieved on each measure. Two measures were viewed as potentially useful but despite the team writing to the authors we were unable to obtain copies. These measures therefore had to be rejected. Only 2 measures were developed for UK use and none were deemed suitable by the group. It was thus agreed that a new measure would be developed and validated in the programme grant.

To inform this development, the group divided into their small working groups to list the key concepts/attributes important in developing a user/carer measure. From these discussions a shared list of attributes was generated.

The final exercise consisted of determining the key domains which should be measured as secondary outcomes. To assist the group we provided each member with a copy of Crawford M et al 2011, 'selecting outcome measures in mental health: the views of service users. (J Ment Health. 20:336-346). This article details how expert panels of people with experience of mental health problems discussed and rated a range of commonly used questionnaires/measures used in mental health research studies. The group was asked to use this document as a platform for discussion rather than using the domains detailed in the article. The key domains identified were Quality of life, Alliance/engagement, Hope, Satisfaction, Mental health symptoms, Satisfaction, Recovery and Medication side effects.

To develop and finalise the work streams of the full programme grant.

We have developed and finalised all 4 work streams and have developed a coherent programme grant. The entire team (included additional applicants) and the user and carer consultation group have significantly contributed to the final application. One key example was the decision to develop and validate an outcome measure (as detailed above). A second example was to decide on the most appropriate design to evaluate the extent of user and care involvement in care planning. Following lengthy discussion our design depends in part on the outcome measure that will be developed for assessing quality in care planning. Where the outcome depends on data gathered directly from the patient, a cluster cohort design may be appropriate as this allows adjustment for baseline characteristics at an individual level thereby increasing power. It does nevertheless bring with it the possibility of selection bias and may be weakened by retention in the study, a key factor in this clinical group. The alternative is to use a cross-sectional design but this would tend to require a larger sample size due to the lack of baseline adjustment and reduced sensitivity of the measure. This would be more feasible where data can be gathered from clinical records using an audit tool. Given that we propose to use both patient responses and clinical records, the trial may combine features of both designs according to the outcome measure selected. In this event, we may nest a design cohort within two cross-sectional surveys taking place prior to and after the intervention.

Outcome

We achieved our aims and have been able to develop all aspects of the programme grant application.

Overall Conclusion

We successfully completed our aims of the programme development grant within a 12 month period and most importantly have submitted a fully developed programme (EQUIP). Our training programme for users and carers exceeded both applicants and training participant's expectations with regard to both the process and outcomes. Our user and carer consultation group and training has given us the time to develop close working relationships and to work in true partnership. Together we have reviewed the literature on suitable outcome measures, defined the attributes of a suitable measure and agreed that we will develop and validate a suitable measure in our programme grant application. In addition we

have identified those domains that will be used as secondary outcomes in the programme application.

Perhaps our biggest challenge has been the review which was much larger than originally anticipated. The size and complexity of this review necessitated more resource (supported by the University of Manchester) than we budgeted for. However, the output (which will be published) provides one of the most sophisticated critiques of barriers & facilitators to user and carer-involved care planning in the literature. The team building workshops allowed us the time to work as a collaborative and effective group and to develop the programme application into what we feel is a significantly better application than had we not been afforded this opportunity.

References

1. Department of Health, The NHS Plan: A plan for investment, a plan for reform. 2000, London: DH.
2. Royal College of Physicians, Advance care planning. Concise guidance to good practice, ed. L. Turner-Stokes and B. Higgins. 2009, London: Royal College of Physicians.
3. Care Services Improvement Partnership and National Institute for Mental Health in England, Our Choices in Mental Health: A Framework for Improving Choice for People Who Use Mental Health Services and Their Carers. 2005: DH, London.
4. Healthcare Commission, The pathway to recover: a review of NHS acute inpatient mental health services. 2008, London: Healthcare commission.
5. Department of Health, Effective care co-ordination in mental health services: modernising the care programme approach - A policy booklet, London, Editor. 1999, DH.

8. Future plans for this programme of work
Do you still intend to submit a Stage 2 application for a Programme Grant? Yes
If Yes, briefly tell us when you plan to do this, and also how the development work has been useful in consolidating or modifying your original programme plans as described in the Development Grant application. **(Maximum 2,500 characters)**
The development work has been invaluable to us as a team; most significantly we have achieved what we believe to be truly meaningful user and carer involvement in the application. The user and carer consultation group (derived from all the participants on the programme group) has expressed its desire to continue its involvement in the application. 3 members are co applicants, 2 have expressed a desire to study further for a PhD. Both candidates have first degrees but had lost confidence in their academic abilities due to their mental health problems. Their fees have been costed into the full application. Three further members have agreed to be members of our steering group if successful in our application and 2 have stated a desire to be researchers. The workshop with users/carers and applicants has led to an open discussion and consensus on the attributes from a service user and carer point of view and the decision to develop and validate an outcome measure. Secondary outcomes (domains) have been identified by users and carers and this gives us a basis to decide on measure that fit these domains. The realist review has provided us with evidence based and conceptually rigorous underpinning to the application. The integration of all our development work has allowed us to discuss the design in considerable detail as well as the integration of all work streams. The process helped to identify developments to the economic components of the programme grant, including the addition of stated preference surveys, to ensure the quantitative assessment of the value and cost effectiveness of user led training is fully integrated into the research.
If No, please explain why, and explore if and how you might take research on the topic forward in another way in light of your development work. **(Maximum 2,500 characters)**
O

9. Dissemination of findings

Describe your plans for disseminating the findings of your development work. **(Maximum 2,500 characters)**

Our training course has been cited by the MHRN as an exemplar of good practice. We are seeking funding from a range of sources to run further courses.
An abridged version of the research training programme will be run at Nottinghamshire Healthcare NHS Trust's Recovery Education Centre in the form of a two-day workshop in March 2012. This workshop will be run by the four service users and Professor Callaghan.

We are presenting our work with users and carers to both Trusts and we are encouraging the group to publish their experience of the course. The realist review is now complete and we are currently in the process of preparing this for publication.

Please list any reports of the research funded via the Programme Development Grant award which have already been published or submitted for publication. Please also list any other outputs such as conference presentations, media interviews *etc*. achieved during the award.

Author (s)	Title	Reference/Further Details

Please note that all publications must acknowledge the funding from the NIHR Programme Development Grants scheme and must also contain a disclaimer indicating that the views and opinions expressed within it do not necessarily reflect those of DH/NIHR. Please also note that all publications and other outputs (whether in oral, written or other form) should be submitted to the NIHR CCF at the same time as submission for publication, or at least 28 days before the date intended for publication/presentation, whichever is earlier.

Grant-holders are also reminded of NIHR's support for the principle of Open Access to research as set out in its statement supporting UKPubMed Central:

http://www.nihr.ac.uk/files/pdfs/OpenAccessPolicyStatement.pdf.

10. Any other comments
Please tell us about any other aspect of the award that would help us to assess its success. **(Maximum 2,500 characters)**

11. Feedback
Please let us have any other comments, including ways in which the system for reporting might be improved.

Appendix 2 Workstream 1

Published manuscripts

See Bee *et al.*,[5,24,40] Cree *et al.*,[17] Fraser *et al.*,[36] Gibbons *et al.*,[37] and Grundy *et al.*[16]

The EQUIP synthesis day

EQUIP - Abstracts Booklet

CONTENTS:

Study 1: Realist Review

Research Aims: To examine how user involvement is operationalised within secondary mental health services compared to the theoretical principles upheld by contemporary mental health policy and to establish where, how and why challenges to user involvement occur.

Research Methods: Realist synthesis of evidence obtained from 14 electronic health and social science databases, grey literature sources (conference abstracts, policy documents and user-led enquiry) and hand searches of key psychiatry, medical and nursing journals.

Searches were limited to articles published in English from database inception to December 2012. Care planning was defined as any interaction between a user and health professional for the purposes of discussing or addressing that client's needs or treatment decisions. The scope of the review was international, examining user involvement in care planning across different secondary care settings. Study eligibility decisions and data extraction were carried out independently by two reviewers.

Data Summary: One hundred and twenty primary research studies were included in the review, with data derived predominantly from the UK (n=53) and US (n=28). Eighty one studies focused on community mental health teams and 49 on inpatient services. Eighty five reported on service user views, 22 on carers/family relatives and 29 on mental health professionals. Thirty provided 'rich' qualitative data descriptions.

Key Findings: Failures in partnership working occur at points where the frames of reference of users and providers diverge. Compared to professionals, users and carers attribute much higher value to the relational aspects of care planning. There is a marked mismatch between users' motivation for care planning involvement and information exchange, such that users and carers knowledge is often insufficient for shared need assessments and care negotiation to occur.

Limitations: Available data is biased towards service user views. The majority of data was deemed to be 'thin' i.e. lacking detail or failing to fully discuss the reasons for successful or failed user involvement. In depth data from carers and professionals remains sparse.

What the study adds: Synthesis shows that user involved care-planning has typically been reduced to a series of practice-based activities seeking to comply with auditors standards, rather than enhancing the quality of the user experience that these standards were originally designed to achieve. Organisations need to recognise and validate the time that professionals spend with service users, and display more tangible commitments to addressing their needs. Individuals need to demonstrate greater and more flexible engagement and communication skills.

Study 2: Professional Data

Research Aims: i) To develop a feasible and acceptable user/carer-led training package for mental health professionals to enhance user/carer involvement in care planning and ii) To develop a patient-reported outcome measure (PROM) that better meets user/carer requirements for quantifying the extent of their care planning involvement in UK mental health services.

Research Methods: Five focus groups (comprising four professional and one mixed user/carer/professional group) and 17 semi-structured individual interviews. All interviews and focus groups were audio-recorded, transcribed verbatim, anonymised, and analysed using Framework Analysis.

Participant Summary: The total number of professional participants providing data across study one (focus groups) and/or study two (interviews) was 35. Twenty-three (66%) were female, and sixteen male (34%). Thirty four (97%) were white. A good range of professional roles were represented. Eight (23%) were in management roles, the remaining (77%) were working directly with service users/carers. Host services included crisis teams; community mental health teams; later life/dementia teams; inpatient services; psychiatry; dual diagnosis and specialist drug/alcohol services; recovery services; mental health advocacy and occupational therapy.

Key Findings: A clear training need was identified and strong support for user/carer involvement in this training was evident. Consistent messages were apparent across a range of professionals. Whole team training was advocated to achieve greater impact. Individual barriers to user involvement included skill deficits and staff understanding of user-involved care planning. Organisational barriers include workload/resource pressures, the current KPI/target culture of the NHS and difficulties in balancing involvement with risk management procedures. Professional buy-in to effective, user involved care planning is likely to require greater standardisation of care planning models across services and a greater validation of the need and time required to achieve a more individualised, user-led approach.

Limitations: It is likely that the professional participants in this study were those who were motivated to achieve 'good' care planning and/or open to organisational and individual change. The data presented reflects the views of professionals within one Health and Social Care Trust and may not be generalisable to other individuals, settings and localities.

What the study adds: This study shows that a combination of individual and organisational factors currently hinder successful user/carer involvement in care planning. It highlights a clear need to deliver training to increase the quality and consistency of care planning procedures. Suggestions for the content and delivery of training are noted along with specific recommendations to ensure that training is aligned with implementation feasibility.

Study 3: User and Carer Data

Research Aims: i) To develop a feasible and acceptable user/carer-led training package for mental health professionals to enhance user/carer involvement in care planning and ii) To develop a patient-reported outcome measure (PROM)

Research Methods: Five focus groups involving 38 service users and carers and 28 semi-structured individual interviews. All interviews and focus groups were audio-recorded, transcribed verbatim, anonymised, and analysed using Framework Analysis. The analysis team comprised two service user/carer researchers and two additional researchers.

Participant Summary: The total number of users/carers providing data across study one (focus groups) and/or study two (interviews) was 47. Twenty-six (55%) participants were female, and twenty-one (45%) male. Forty-two (89%) were white, and 4 (8.5%) were from black/minority ethnic groups. Ethnicity was not recorded for one participant. Thirty participants (64%) described themselves as service users, 14 (30%) as carers and 3 (6%) as both service users and carers.

Key Findings: Care plans were described negatively as meaningless, not tailored to the individual and not taking account of service users'/carers' wishes, experiences or needs. Good service user/carer involvement is facilitated by good relationships with and between staff, effective communication, partnership working and allowing sufficient time for explanations to be given and understood. Barriers to involvement include frequent staff changes, staff workload, lack of knowledge about services (by both staff and users/carers), unhelpful staff attitudes, and periods of more severe illness. Data suggested that training should target all staff although it was felt that senior clinicians would particularly benefit. Training should prioritise skills in active listening and communication, multicultural issues, assertiveness and time for reflection. Training should be mandatory, accredited and updated regularly. Co-delivery of training was advocated to convey the reality of care planning and to value the expertise of service user and carers. Service users/carers want to make varied and flexible contributions to training whilst simultaneously being supported and having their own concerns acknowledged. Potential barriers to effective training include staff workload, staff attitudes, lack of accountability and a reluctance among service users/carers to be involved as trainers.

Limitations: We interviewed a self-selected sample of service users and carers, many of whom had particularly strong views on the short-comings of the care planning process. A minority of participants were from BME groups.

What the study adds: Service users/carers have concerns about the way care plans are drawn up and implemented. There is a shared perception that staff are reluctant to involve service users and carers. Recommendation for the content and delivery of training are provided.

STUDY 4: TRAINING INTERVENTIONS LITERATURE

Research Aims:

To identify relevant reviews which could inform the development, delivery and/or implementation of the training the trainers course or the health professional training.

Research Methods:

A scoping review of the literature for relevant reviews about the effectiveness of training development, delivery and implementation.

Data Summary:

Three key reviews identified:

- Robertson, R. & Jochleson, K. (2007) *Interventions that change clinician behaviour: Mapping the literature*. London, NICE
- Reeves, S., Zwarenstein, M., Goldman. J., Barr, H., Freeth, D., Hammick, M., Koppel, I. Interprofessional education: Effects on professional practice and health care out comes. Cochrane Database of Systematic Reviews 2008, Issue 1. Art. No.: CD002213. DOI: 10.1002/14651858.CD002213.pub2
- Grol Grol, R. & Grimshaw, J. (2003) From best evidence to best practice: Effective implementation of change in patients' care. *The Lancet*, 362(9391):1225-30 (included in Reeves review)
-

Key Findings:

α) Small interactive groups more effective than large didactic groups

β) Educational outreach is effective

χ) Improving collaboration between health professionals might be helpful

δ) Multi-faceted interventions likely to be better than single strand

ε) Providing patient materials may help implementation

Limitations:

No systematic search – significant work will be completed in work stream 3 (implementation).

What the study adds:

The key implication for training (which we had not taken into account) is the potential of outreach work – in most other intervention studies we have conducted we have incorporated supervision.

EQUIP Synthesis – (All responses)

Synthesis Matrix

Component	*Realist Review*	*Users and carers (Focus groups and interviews)*	*Professionals (Focus groups and interviews)*	*Training interventions literature*	*Incorporated into the intervention*
Training					
What content needs to be incorporated in the intervention	Skills – not clear – goal setting problem solving smart goal setting. Process / ideal Care plan Flexibility of UI Opportunities. Engagement. Communication Skills Reversing stigma/perceived SU/C dis-interest. Thinking outside the box. Alternative methods of UI e.g. Skype. Pacing & Jargon – for understanding. Overcoming distance	Skills Listening Purpose – example. Active listening skills – Practical exercises. Factual information about confidentiality. Modules ID by user/carer quotes. Experiences of being over ruled/dismissed.	Skills – Purpose of CP – example model Standardisation/shared model (m/d working) Time management; Engagement & Listening skills; communication skills Evidence-Based Needs assessment Attitudes & values Balancing –Involvement alongside organisational needs/workload pressures. Shared CP Understanding. Shared decision making. Involving inpatients in CPs & managing crises. Focus on organisational implementation. Skills that staff feel they are missing. Balancing with Risk Responsibilities.	Multi-component patient materials. Collaborative working – working with wide range of networks. Multi-faceted interventions	
Who should attend the training	Whole Teams. Users, Professionals, Managers, Carers	GPS; A&E staff; Police; Courts. Professionals and SUs Carers (CP received). ALL 1, 2, 3 sector staff. Whole teams. Psychiatrists.	All Staff – Managers to frontline; GPs; H/SC profs in 3rd sector; pre-registration nurse/sw/medic. Whole Team. Pre-reg students.		
Where should the training take place?	**Workplace**		**Multi-disciplinary** **Organisation based** **Whole Team**		

Component	*Realist Review*	*Users and carers (Focus groups and interviews)*	*Professionals (Focus groups and interviews)*	*Training interventions literature*	*Incorporated into the intervention*
Training cont.					
What format should training take? (face to face/web based)			**Pre-session 'E' learning; Face to face; graduated format (start with basics); practical skills (role plays); Case studies/digital stories**		
How long and over what time period should the training be?			**Mandatory; Not one off - Refresher Course**		
What resources need to be developed?- e.g. user/carer podcasts (and for dissemination strand)			**Case Studies / digital stories**		
What are the systems training needs			**Standardisation**		

Component	*Realist Review*	*Users and carers (Focus groups and interviews)*	*Professionals (Focus groups and interviews)*	*Training interventions literature*	*Incorporated into the intervention*
Training the trainers					
Who should attend the training?		**SU's / Carers and professionals (co-delivered). Multiple trainers = sufficient capacity for flexible cover. Service users for co-production/ delivery. Not just the activists.**	**Need to have right skills as well as lived experience – don't select those with an axe to grind. Maybe have range of involvement roles – not all will want to 'teach'**	**Multi-disciplinary for staff trainers.**	
What should the training focus on?	**Teaching Care Planning Skills. Awareness of stigma. Assertiveness. Confidence. Value of course – hope/evidence for impact.**	**Assertiveness training. Listening skills & how to develop them. Ensuring capacity / responsibilities for delivery. Teamwork.**	**Teaching Care Planning Skills Challenging negative attitudes. Managing Classroom conflict. Presentation skills. Attitudes – positive impact of CP. Engagement Processes with senior / hard to reach Professionals**	**Small Group Teaching Don't just have opinion leaders Using patient-mediated interventions. Developing and delivering patient materials. Consensus Methods. Multi-faceted involvement**	
How long and over what time period should the training be delivered?	**Those with capacity to clearly express articulate range of needs**	**Updated not one-off. Ongoing support. Manageable chunks eg, 45 mins at a time.**	**Updated – not one-off. Short half day.**		

Component	*Realist Review*	*Users and carers (Focus groups and interviews)*	*Professionals (Focus groups and interviews)*	*Training interventions literature*	*Incorporated into the intervention*
Training the trainers *cont.*					
How do we select user and carer participants to deliver the training?		**People lived experience and interpersonal skill training; Diverse cultural grps. Be aware of SUs/Carers who have training experience and have offered to help further.**	**Good sized team – so small number of trainers are not over-burdened. Diversity of experience/skills. Recruited from different Trust areas. Teaching skills and good interpersonal skills. Prioritising 'teaching' / presentation skills. Transparent /formal recruitment process.**		
What resources need to be developed?		**Facilities should be very good. Respite care for people being cared for. Support sheets**	**Appropriate payment & recognition of time. Cover costs for respite care (to allow carers to attend) Support & debriefing process for trainees – MH issues could be triggered by involvement; could be hard dealing with cynical/ challenging staff. E-learning off line & online**		
Other					
Anything else that is important not covered by the above?		**Non-clinical training setting.**	**Considering cultural needs of trainee trainers – e.g., don't schedule training on Fridays**		

Appendix 3 Workstream 2

Published manuscripts

See Bower *et al.*,[55] Grundy *et al.*[23] and Lovell *et al.*[60]

Enhancing the Quality of User and Carer Involvement in Care Planning in mental health services: clinical cluster randomised controlled trial and process evaluation

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.

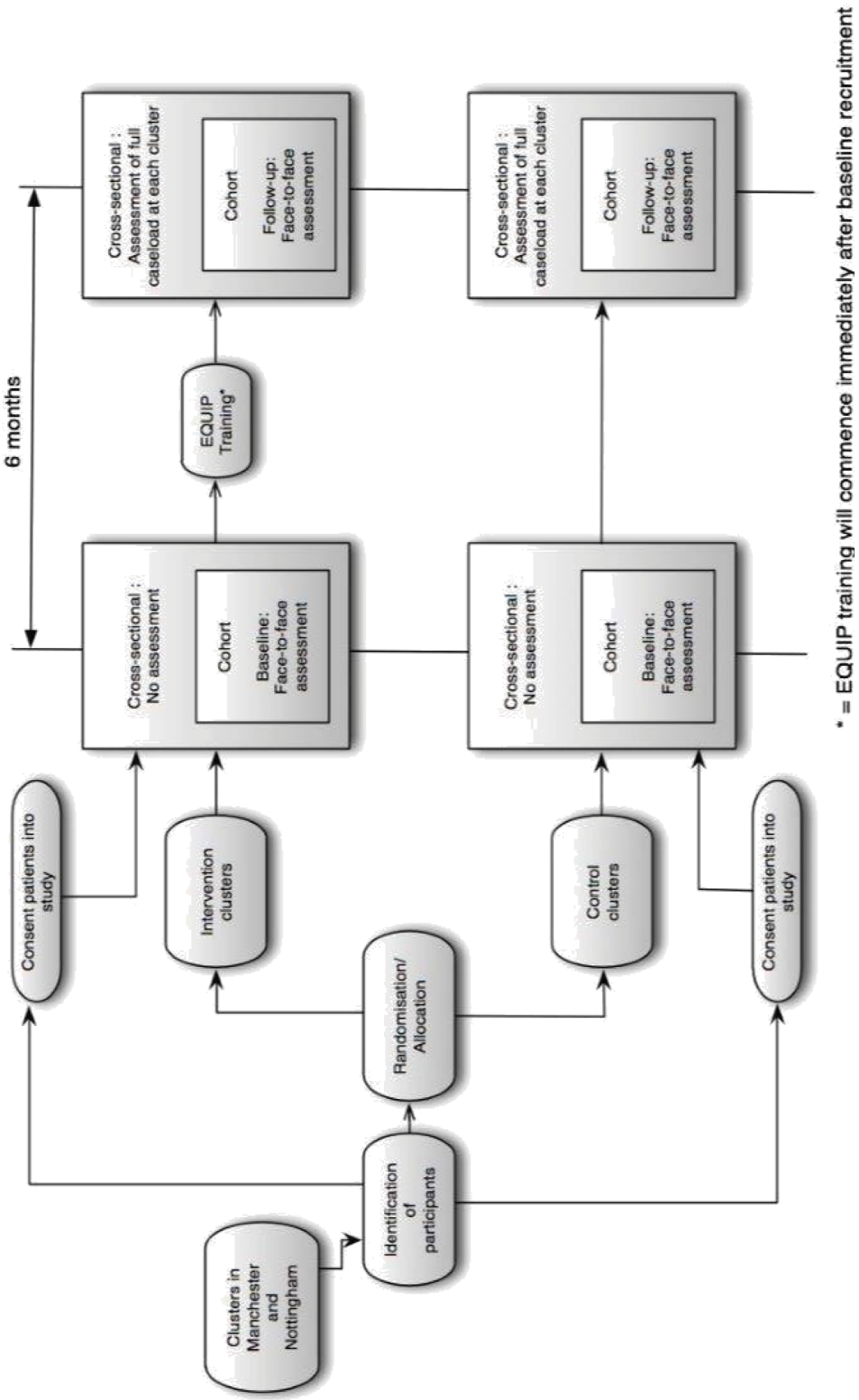
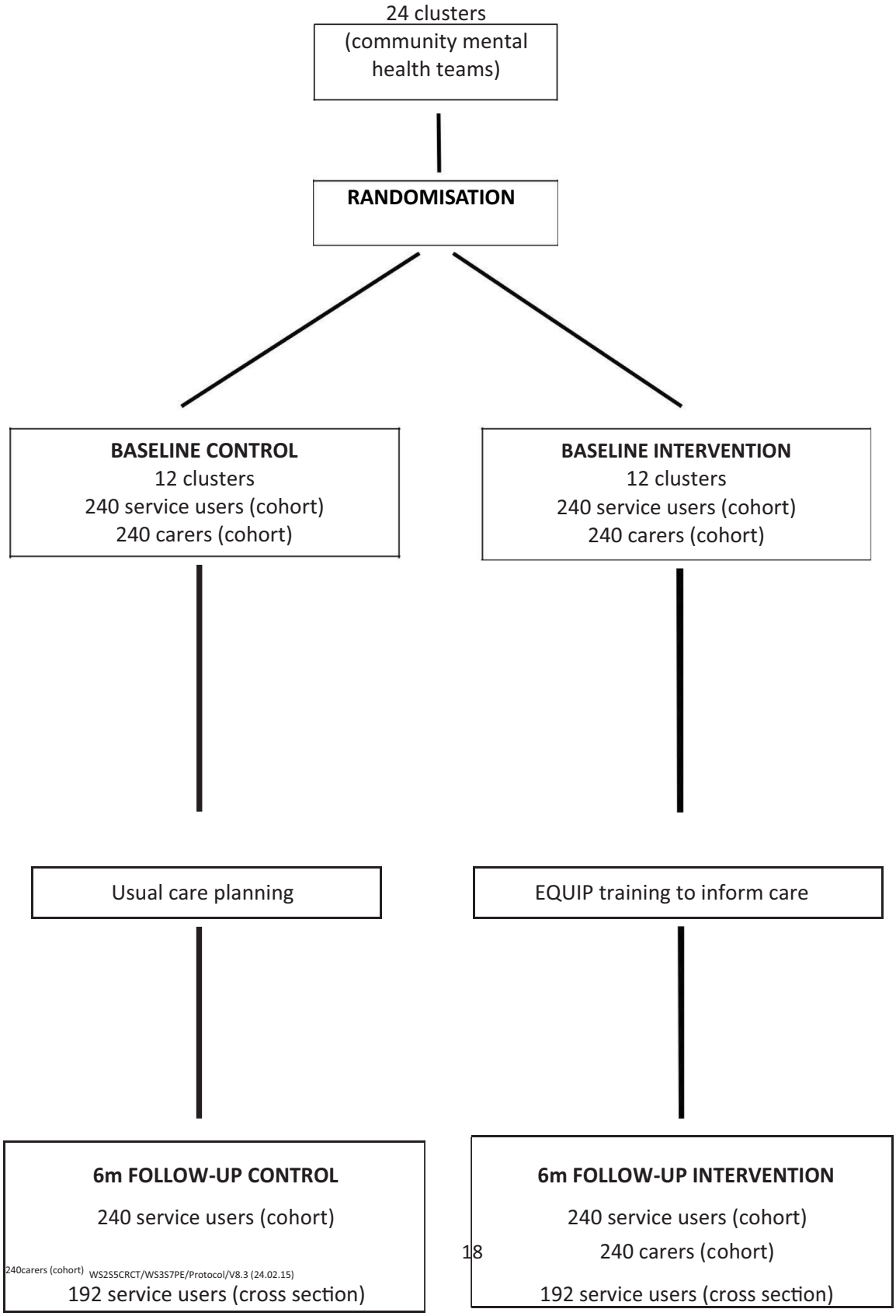


Figure 1 EQUIP cluster randomised trial design

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:

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

39

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

Appendix 4 Workstream 3

Published manuscripts

See Brooks *et al.*[66,75,76,123]

Appendix 5 Workstream 4

Enhancing the Quality of User and Carer Involvement in Care Planning card

Summary Training Acceptability Rating Scale analysis

Variable	Trial	Control group	'Willing Adopters'
Training participants	350	102	192
TARS completed	310	98	154
Overall TARS score (possible range: 6–63)	Mean 4.48, median 6	Mean 53.97, median 56	Mean 52.18, median 54
Acceptability score (possible range: 6–36)	Mean 32.99, median 34	Mean 32.09, median 2	Mean 1.27, median 32
Perceived impact score (possible range: 0–27)	Mean 21.48, median 22	Mean 21.64, median 23	Mean 20.88, median 21

EME
HS&DR
HTA
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