RESEARCH ARTICLE

Embedding shared decision-making in the care of patients with severe and enduring mental health problems: The EQUIP pragmatic cluster randomised trial

Karina Lovell[1,11☯], Penny Bee[1☯], Helen Brooks[2☯], Patrick Cahoon[3☯], Patrick Callaghan[4☯], Lesley-Anne Carter[5☯], Lindsey Cree[1☯], Linda Davies[5☯], Richard Drake[6☯], Claire Fraser[1☯], Chris Gibbons[7☯], Andrew Grundy[8☯], Kathryn Hinsliff-Smith[8☯], Oonagh Meade[9☯], Chris Roberts[5☯], Anne Rogers[10☯], Kelly Rushton[1☯], Caroline Sanders[5☯], Gemma Shields[5☯], Lauren Walker[1☯], Peter Bower[5☯]*

1 Division of Nursing, Midwifery & Social Work, School of Health Sciences, University of Manchester, Manchester, United Kingdom, 2 Department of Psychological Sciences, Institute of Psychology, Health and Society, University of Liverpool, Liverpool, United Kingdom, 3 Greater Manchester Mental Health NHS Foundation Trust, Manchester, United Kingdom, 4 School of Applied Sciences, London South Bank University, London, United Kingdom, 5 Division of Population Health, Health Services Research & Primary Care, School of Health Sciences, University of Manchester, Manchester, United Kingdom, 6 Division of Psychology & Mental Health, School of Health Sciences, University of Manchester, Manchester, United Kingdom, 7 Healthcare Improvement Studies Institute, University of Cambridge, Cambridge, United Kingdom, 8 School of Health Sciences, University of Nottingham, Nottingham, United Kingdom, 9 School of Psychology, National University of Ireland Galway, Galway, Ireland, 10 Faculty of Health Sciences, University of Southampton, Southampton, United Kingdom, 11 Greater Manchester Mental Health NHS Foundation Trust, Manchester, United Kingdom

☯ These authors contributed equally to this work.
* peter.bower@manchester.ac.uk

Abstract

Background

Severe mental illness is a major driver of worldwide disease burden. Shared decision-making is critical for high quality care, and can enhance patient satisfaction and outcomes. However, it has not been translated into routine practice. This reflects a lack of evidence on the best way to implement shared decision-making, and the challenges of implementation in routine settings with limited resources. Our aim was to test whether we could deliver a practical and feasible intervention in routine community mental health services to embed shared decision-making for patients with severe mental illness, by improving patient and carer involvement in care planning.

Methods

We cluster randomised community mental health teams to the training intervention or usual care, to avoid contamination. Training was co-delivered to a total of 350 staff in 18 teams by clinical academics, working alongside patients and carers. The primary outcome was the Health Care Climate Questionnaire, a self-report measure of 'autonomy support'. Primary and secondary outcomes were collected by self-report, six months after allocation.

Findings

In total, 604 patients and 90 carers were recruited to main trial cohort. Retention at six months was 82% (n = 497). In the main analysis, results showed no statistically significant difference in the primary outcome between the intervention and usual care at 6 months (adjusted mean difference -0.064, 95% CI -0.343 to 0.215, p = 0.654). We found significant effects on only 1 secondary outcome.

Conclusions

An intervention to embed shared decision-making in routine practice by improving involvement in care planning was well attended and acceptable to staff, but had no significant effects on patient outcomes. Enhancing shared decision-making may require considerably greater investment of resources and effects may only be apparent over the longer term.

Introduction

Mental health conditions impact substantially on quality of life and productivity, and are a major driver of worldwide disease burden. The global cost of mental illness was estimated at 2.5 trillion US dollars (£1.9 trillion / 2.1 trillion Euros) in 2010, set to rise to 6 trillion US dollars (£4.6 trillion/5 trillion Euros) in two decades. Improving mental health care is an international priority [1].

Shared decision-making is an integral component of high quality care for both physical and mental health. Shared decision-making has been defined as 'an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences' [2]. Shared decision-making ensures that patients are active in decisions, that services focus on patient needs, and that professionals are better able to provide patient-centred care. Interventions in shared decision-making can increase the quality and safety of healthcare and enhance patient satisfaction, treatment adherence and outcomes [3].

Shared decision-making is recognised as a guiding principle of mental health policy and practice [4]. In the UK, mental health professionals providing care for patients with serious mental illnesses (such as psychosis) act as care co-ordinators under the Care Programme Approach which is mandated for patients with severe and enduring mental illness [5,6]. The Care Programme Approach involves an assessment of patient needs, choices about care and support, family and financial issues [7], followed by production of a care plan developed between professionals, the patient and (where relevant) their carer [5,6,8].

There is broad consensus among stakeholders regarding the importance of shared decision-making in mental health, although debates continue [4,9]. Yet, despite a sustained policy emphasis, this has not been translated into practice [10]. A national survey of 7500 patients by the Care Quality Commission in the UK found that only 34% agreed that they were 'definitely' involved as much as they wanted to be in decisions [11,12]. The Government Five Year Forward View for Mental Health highlighted co-produced care planning as a key goal and a recommended Care Quality Commission quality standard by 2020 [13].

Although there is a large literature on patient decision aids, the evidence on how to encourage shared decision-making in mental health is far more limited [14]. A recent review of studies to enhance shared decision-making in psychosis found 11 trials of a variety of

interventions, with some evidence of effects on measures of 'subjective empowerment'. However, studies were generally small and of only modest quality. Furthermore, most delivered interventions to patients (an approach which may be more difficult to implement at scale), and only one study tested training for clinicians [15]. At present, there is no proven method of implementing shared decision-making across routine mental health settings.

The recent MAGIC study explored how shared decision-making could be embedded within the UK NHS, and identified many challenges. These include misplaced confidence amongst staff about their current practice, a perceived lack of tools to support shared decision-making and inaccurate assumptions about patients' preferences [16,17]. MAGIC examined a number of clinical contexts, but excluded mental health, where shared decision-making faces particular challenges, reflecting a unique history founded on concepts of containment and coercion [18]. Patients often present with long term and complex diagnoses, and experience significant stigma [19,20]. Our recent review of shared decision-making in mental health identified similar challenges to those found in MAGIC, including the readiness, skills and confidence of mental health professionals to engage [21]. Our review also highlighted different frames of reference for mental health professionals and patients, with patients' judgments of success heavily influenced by the consistency and quality of care planning relationships, whereas staff highlighted the quality of the end product of shared decision-making (the written care plan).

MAGIC concluded that 'implementing shared decision making is challenging but possible'[17]. Although some shared decision-making interventions have demonstrated effectiveness [15], these often involve selected settings with local enthusiasts around specific clinical decisions. We do not know how best to deliver change in a comprehensive way to embed shared decision-making across routine clinical services facing resource and time constraints. Our aim was to test whether we could deliver a practical and feasible intervention in routine community mental health services to embed shared decision-making by improving patient and carer involvement in the care planning process.

Methods

Design

The primary design was a pragmatic 'cluster cohort' randomised trial. The intervention was targeted at staff and we randomised teams to avoid contamination. Following cluster randomisation, we recruited patients cared for by teams of community mental health professionals in both arms (see Fig 1). We assessed those patients at 6 months, comparing outcomes in the teams trained to embed shared decision-making in their routine care planning, with control teams delivering routine care planning alone. Our trial protocol has been published [22, S1 Protocol] and the trial was registered (ISRCTN16488358). The full trial protocol is supplied as a supporting information file (S2 Protocol).

In terms of the PRECIS-2 criteria [23], we enhanced the pragmatic nature of our trial by adopting very broad patient inclusion criteria, delivering the intervention in routine care settings, limiting the resources required to deliver the intervention, allowing flexibility in delivery and adherence, using an outcome of direct relevance to patients, and adopting intention to treat analysis.

Participants and recruitment

We recruited community mental health teams and patients between July 2014 and December 2015 from 10 NHS Trusts across England, UK. All teams within the participating NHS Trusts were eligible to take part, and eligible patients were aged 18+ with a severe and enduring mental illness (including psychosis, bipolar disorder, schizophrenia, personality disorder). We
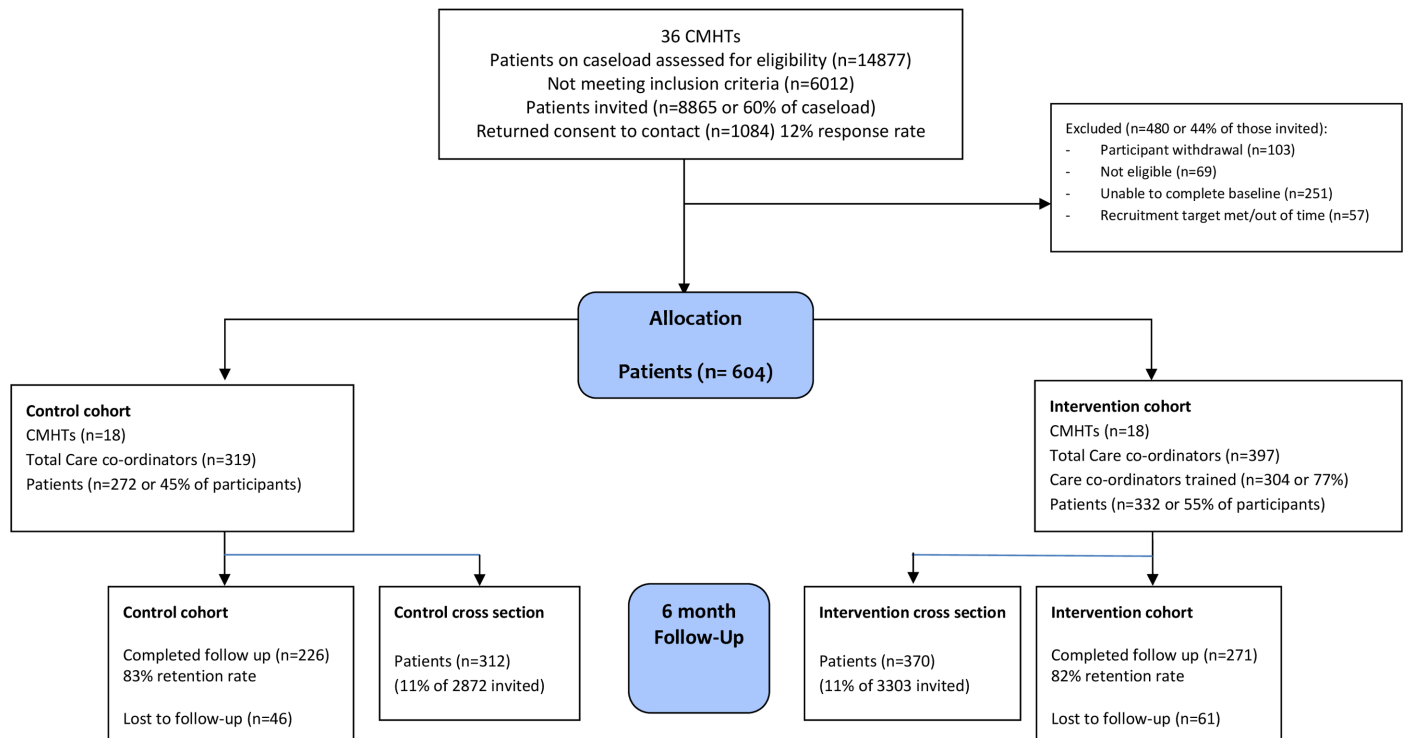
Fig 1. Consolidated standards of reporting trials (CONSORT) for cluster and cross sectional cohorts.

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excluded patients without capacity to provide fully informed consent, and those too unwell at recruitment, as judged by the teams. Patients were followed up six months after baseline measures were completed between January 2015 and July 2016.

During recruitment, we became aware that the number of patients 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. In total, 604 patients and 90 carers were recruited to the cluster cohort as detailed in the CONSORT (Fig 1). The mean number of patients recruited per team was 16.8 (SD 8.7, range 4–43). Retention at six months was 82% (n = 497).

We additionally included a 'cluster cross-section' sample to reduce the risk associated with loss to follow up in the patient sample in the cluster cohort design (see Fig 2). This involved recruiting patients under the care of teams in both arms at follow up only.

Patient flow in the cluster cross section is also shown in the CONSORT (Fig 1). In total, 682 patients were recruited with a mean number of patients per team of 18.9 (SD 14.1, range 2–62).

Intervention

Shared decision-making is a complex concept [24], and its interpretation in terms of the nature and degree of participation differs across and within lay and professional groups [25]. Much of the literature concerns 'patient decision aids', tools which focus on providing support for 'specific and deliberated choices among healthcare options' [3], often relating to specific conditions and management choices. Some aids are designed to be used by patients outside clinical consultations to support later discussions with professionals. Others (so-called *conversation aids*) are 'designed to encourage and directly support the conversations that patients and clinicians have when making decisions together' [26]. The intervention described here

In a standard 'cluster cohort' design, patients cared for by each cluster are recruited and undergo a baseline assessment (preferably before random allocation is completed). Each cluster is then randomised to either intervention or control. Follow up assessments are then conducted with the same patients, a set period after the baseline assessment.

In such a design, patients need to participate in two face-to-face assessments, which may be burdensome. The trial may thus be vulnerable to barriers to recruitment (i.e. only a small number of eligible patients may participate) and attrition (i.e. patients are lost to follow-up). This can reduce both sample size and external validity.

Our design included a 'cluster cross-section' to help ameliorate potential problems of recruitment and attrition within the cluster cohort. Six months after randomisation, assessments were posted to all patients under the care of the teams who are not part of the 'cluster cohort'.

Patients in the cross-section only had to agree to assessment once. Their assessment was less burdensome, including fewer measures, to further encourage participation.

However, the 'cluster cohort' design allows adjustment for a wider range of baseline characteristics at an individual level because of the greater range of measures included, giving potentially greater statistical power compared to analysis of the 'cluster cross-sectional' data.

Fig 2. Cluster design.

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was a type of conversation aid, to enhance the ability of staff to involve patients in decisions [27], and to embed shared decision-making into the existing care planning process in mental health services.

We designed an intervention to enhance shared decision-making in routine community mental health services, where there is limited time and resource for training and quality improvement. This required a compromise between effectiveness, acceptability to patients and professionals, and feasibility. Fig 3 describes our intervention according to the TIDIER guidelines.

Why: we aimed to co-develop, co-produce and co-deliver a best evidence, acceptable and feasible training programme to enhance involvement in care planning. Two reviews were conducted including: a narrative synthesis [21] which examined user-involved care planning within mental health services and to establish challenges to user involvement; and a scoping review of interventions to change professional behaviour. Focus groups and interviews with patients, carers and professionals [28-30] helped develop training content and delivery requirements and to determine the priorities for user and carer involvement in care planning.

What: a range of training materials have been developed for the training including PowerPoint slides, case scenarios, audio-recordings from health professionals, patients and carers and a trainer's manual.

Who: the synthesis suggested training should be multi-disciplinary, including all health professionals and psychiatrists. As far as possible, teams were trained together. The training was delivered by 2 academics with teaching experience and 3/4 service users and carers who 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 supervision. The consensus exercise indicated a minimum of 15 hours and maximum of 30. The course ran for 2 days (12 hours) plus 6 hours follow-up supervision and 8 hours self-directed learning (optional). Hence, each health professional received 18 hours of training and an 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.

Fig 3. Intervention components according to the TIDieR guidelines.

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To inform training content and format, we synthesised evidence from a systematic review of service user involvement in care-planning [21] and a scoping review of interventions to improve professional practice and change patient care. Focus groups and individual interviews with patients (n = 42), carers (n = 37) and health professionals (n = 51) were used to sensitise the training to the context of routine mental health services [28–31].

Training content was designed to counter negative attitudes to patient and carer involvement, enhance shared decision-making, and introduce these skills into time-limited interactions.

Training was co-delivered to teams by two clinical academics and patients and carers. We considered two days training feasible given current service pressures [31]. We involved patients in the design and delivery of the intervention, sought organisational 'buy-in' through engagement with Trust chief executives, senior managers and front line staff, and used role play to challenge entrenched attitudes and foster skills. Training materials included a trainer's manual, PowerPoint slides, case scenarios, and audio-recordings from health professionals and patients. Patient and carers delivering the training attended a four-day 'train the trainers' course [32]. We used the Training Acceptability Rating Scale [33,34] immediately after training to assess staff experience of the intervention [35].

Procedure

Teams were introduced to the trial by letters or meetings with senior managers. Meetings were held with team managers to facilitate study engagement.

To recruit patients into the cluster cohort, research officers from local clinical research networks sent patients an introductory letter, information sheet and 'consent to contact' form. Patients opted in by returning the 'consent to contact' form to the study team. Non-responders were contacted by telephone once to improve response rates. Where possible, consenting patients were asked to nominate a carer, who was provided with appropriate information, consent materials and carer measures.

To recruit to the cluster cross-section, we conducted a postal survey of all patients under the care of each team six months after randomisation (excluding those already in the cluster cohort).

Once patients and carers had been sent invitations, clusters were allocated randomly to either intervention or control. Allocation was determined by an external telephone randomisation service at the Clinical Trials Unit of the Manchester Academic Health Science Centre. Clusters from the same geographical area were submitted to the randomisation service in pairs. No further matching of these pairs on other characteristics prior to allocation was possible in practice [22].

Sites were recruited and trained in a rolling programme over 17 months. Although it is preferable to complete patient recruitment entirely before allocation, clusters needed advanced notice of training dates. We ensured that invitations were sent to patients prior to site knowledge of their allocation, reducing the risk of professionals influencing selective recruitment.

Researchers blind to allocation assisted participants in completing measures at baseline and six-months. Demographic data, primary, secondary and economic outcome measures were collected face-to-face for the cluster cohort and by post for the cluster cross-section and carer samples. Telephone and postal completion was also available (on request) for the cluster cohort during follow up data collection which took place between January 2015 and July 2016, with telephone completion involving reading out the scales to patients.

All teams allocated to the intervention received the shared decision-making intervention consisting of two days face-to-face training (12 hours total), an eight-hour optional self-

directed learning package and six hours supervision per team in the six months after training. We asked that at least 80% of staff designated as 'care co-ordinators' (i.e., those with a caseload) attended training. As far as possible, multi-disciplinary teams were trained together. Training was delivered within 6 weeks of patient recruitment. Usual care teams did not have access to the training.

Outcomes

All outcomes were collected by self-report, six months after allocation.

Our aim was to embed shared decision-making by improving patient and carer involvement in the care planning process. The primary outcome was the Health Care Climate Questionnaire (HCCQ-10), a self-report scale based on self-determination theory [36]. The HCCQ-10 measures 'autonomy support', defined as patient perceptions of the degree to which they experience their health professionals as supporting choice, and ensuring their behaviour (and behaviour change) is congruent with their values. According to self-determination theory, autonomy support is more likely to lead to behaviour change and improved health outcomes [37]. The scale has ten 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 7 point scale from 'strongly disagree' to 'strongly agree'. An overall score is calculated as the mean of the items, with a higher score indicating greater 'autonomy support'.

Secondary outcomes were chosen by experts and a consensus exercise with our patient advisory group. Patient perceptions of involvement in care planning decisions were assessed via a newly developed and validated 61 item self-report measure (EQUIP PROM). The measure provides a unidimensional measure of service user and carer involvement in mental health care planning and has since been further revised to produce a short-form 14-item scale [38]. We also measured patient satisfaction with mental health services (Verona Service Satisfaction Scale—VSSS-EU-54) [39,40]; patient-reported side-effects of antipsychotic medication (Glasgow Antipsychotic Side-effect Scale—GASS) [41]; mental well-being (Warwick-Edinburgh Mental Well-being Scale -WEMWBS) [42]; recovery and hope (Developing Recovery Enhancing Environments Measure—DREEM) [43]; anxiety and depression (Hospital Anxiety and Depression Scale—HADS) [44]; alliance and engagement (California Psychotherapy Alliance Scale -CALPAS) [45]; a single item measure of global quality of life from a scale (World Health Organisation Quality of Life—WHOQOL-BREF) [46]. Carer satisfaction was measured via the Carers and Users' Expectations of Services—carer version (CUES-C) [47]: carers also completed the short form of the EQUIP PROM and the WHOQOL-BREF. The EQ-5D-5L [48] was used to estimate Quality-Adjusted Life Years (QALYs), alongside a questionnaire on frequency of use of health and social care services. Economic outcomes will be reported separately.

The UK National Research Ethics Service (NRES Committee North West Lancaster) approved this study (REC Reference 14/NW/0297). All participants gave informed consent before taking part.

Sample size and statistical methods

The primary outcome was the HCCQ-10, prioritised by our patient advisory group. Data on the HCCQ-10 in this patient population was limited, so we used a standardised effect to calculate sample size. A trial with 12 clusters per arm, a mean of 20 patients per cluster (total n = 480) would have power greater than 80% to detect a standardised effect size of 0.4, assuming an intra-cluster correlation coefficient of 0.05 and 80% follow up (n = 384 patients with

complete data). We felt that this effect size was plausible when assessing an outcome such as patient perceptions of autonomy support, which would be more amenable to change than clinical outcomes. Power is increased by the inclusion of baseline covariates. For the cross-sectional component, we aimed to recruit at least the same number of patients per cluster, to provide the same power.

Analysis was completed using Stata 13 [49] and followed a statistical analysis plan prepared prior to analysis and approved by the independent programme steering group. The plan identified the cluster cohort as the primary analysis, with the cluster cross section and combined analyses to be presented as secondary analyses. For the cluster cohort, 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 trial. We adopted a 5% level for statistical significance.

Results

As there were no substantial differences in results between cluster cohort and cluster cross section samples, we present detailed results only for the former in the text. Full data on the cluster cross section and carers are found in the S1 Table.

Baseline characteristics

Table 1 shows baseline characteristics of the teams and patients included in the cluster cohort, and Table 2 shows baseline scores on study measures. Characteristics were similar between intervention and usual care. Characteristics of patients in the cluster cross section and carers are presented in the S1 Table. The sample included a range of self-reported mental health disorders, including, depression (47%), anxiety (32%), bipolar (25%), schizophrenia (23%), personality disorder (17%), panic disorders (9%), eating disorder (6%) and phobia (5%).

Intervention delivery

We delivered the intervention to staff in 18 teams drawn from 10 NHS trust sites. The training cohort comprised 350 professionals of whom 304 were care coordinators (nurses, occupational therapists and social workers), along with pre-registration students, support workers and clinical managers (n = 46). Ten of 18 teams met our request to send 80% of care coordinators at the training, with an overall mean of 77% of care co-ordinators attending (range in teams from 48–100%). Using the Training Acceptability Rating Scale post-training, we found relatively high levels of satisfaction (median overall TARS scores = 56/63; median TARS acceptability scores = 34/36) and perceived effect (median TARS perceived impact score = 22/27).

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 community mental health team during the six month follow up, with a mean of 12.3 contacts.

Outcome data—Primary analysis

107 patients were lost to follow up (see CONSORT Fig 1), resulting in 497 patients available for analysis. 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

Table 1. Baseline characteristics of patients in the cluster cohort.

		Control (n = 272)		Intervention (n = 332)	
		n	**%**	**n**	**%**
Age	18–24	17	6.25	21	6.33
	25–44	99	36.40	114	34.34
	45–64	134	49.26	177	53.31
	65+	16	5.88	11	3.31
	Missing	6	2.21	9	2.71
Gender	Female	157	57.72	198	59.64
	Male	106	38.97	128	38.55
	Other	1	0.37		
	Missing	8	2.94	6	1.81
Ethnic Group	White	233	85.66	294	88.55
	Non-White	33	12.13	32	9.64
	Missing	6	2.21	6	1.81
Education	Secondary school	108	39.71	129	38.86
	Higher education	154	56.62	181	54.52
	Missing	10	3.68	22	6.63
Accommodation	Owner occupier	85	31.25	97	29.22
	Other	177	65.07	225	67.77
	Missing	10	3.68	10	3.01
Living Arrangements	Alone or with a pet	175	64.34	207	62.35
	With someone else	92	33.82	119	35.84
	Missing	5	1.84	6	1.81
Employment	Employed	37	13.60	45	13.55
	Other	231	84.93	280	84.64
	Missing	4	1.47	7	2.11
		Median	**IQR (n)**	**Median**	**IQR (n)**
Time experiencing mental health problems (months)		228	84–360 (265)	204	120–313 (320)
Time using NHS services (months)		109.5	42–252 (262)	121.5	52–240 (318)

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used in estimating linear mixed models. Missing baseline data for the cohort sample were cluster mean imputed [50].

Table 2. Baseline measures in cluster cohort.

	Control					Intervention					ICC
	Mean	**SD**	**Min**	**Max**	**n**	**Mean**	**SD**	**Min**	**Max**	**n**	
HCCQ-10	5.06	1.65	1	7	272	5.27	1.49	1	7	329	0.001
EQUIP PROM	22.58	9.68	0	44	214	21.99	9.73	0	44	250	0.011
HADS Anxiety	11.37	5.63	0	21	243	12.32	5.52	0	21	288	0.035
HADS Depression	9.18	5.57	0	21	243	10.04	5.51	0	21	288	0.061
VSSS-54	3.56	0.70	1.45	4.85	203	3.54	0.68	1.54	4.89	259	0.029
CALAPS-12	4.96	1.43	1.33	7	209	5.06	1.36	1	7	252	0.000
GASS	17.78	11.70	0	54	191	18.09	10.71	0	49.42	226	0.000
WHOQOL	3.02	1.14	1	5	209	3.03	1.18	1	5	255	0.020
DREEM	41.30	12.34	24	89	150	42.11	12.15	24	77	170	0.008
WEMWBS	39.12	13.55	14	70	221	38.65	13.04	14	70	264	0.045

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Baseline and follow up data on outcome measures for the cluster cohort for the primary outcome (HCCQ-10) using intention to treat analyses are reported in Table 3 (adjusted mean difference and 95% confidence interval). Results show no statistically significant difference in HCCQ scores between the intervention and usual care at 6 months. The intra cluster correlation coefficient describes the proporiton of variation in outcome due to differences between teams. The ICC for the primary analysis indicates that only 2% of the variation of HCCQ at 6 months was between teams. This ICC is smaller than the study was powered for (ICC = 0.05).

Model fit was assessed using diagnostic plots of the model residuals. A histogram of the residuals suggested normality, while plots of the standardised residuals against covariates indicated no correlations.

Outcome data—Secondary analysis

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 six months (Table 3).

Analyses of secondary outcomes in the cluster cohort are presented in Table 4, which found a significant effect on a single outcome of service satisfaction. All other analyses are presented in the S1 Table.

Discussion

Statement of principal findings

An intervention to embed shared decision-making in routine practice by improving patient and carer involvement in 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.

Strengths and weaknesses of the study

Our study achieved the required sample size in both the cluster cohort and cluster cross section. Our adoption of cohort and cross-sectional samples provided protection from potential

Table 3. Primary outcome measure (intention to treat analysis).

	Usual care			Intervention			Adjusted* mean difference	95% CI	P value	ICC	
Cluster cohort (primary analysis)*	Mean	SD	n	Mean	SD	n					
Baseline HCCQ10 (range 1–7)	5.06	1.66	272	5.27	1.48	332					
6 months HCCQ10	4.93	1.78	227	5.01	1.70	269	-0.064	(-0.343, 0.215)	0.654	0.02	
Cluster cross section (secondary analysis) #											
Baseline HCCQ10	N/A	N/A	N/A	N/A	N/A	N/A					
6 months HCCQ10	5.08	1.72	287	5.09	1.71	341	-0.080	(-0.462, 0.303)	0.683	0.05	
Combined (secondary analysis) †										Cohort	Cross section
Baseline HCCQ10	5.06	1.66	272	5.27	1.48	332					
6 months HCCQ10	5.02	1.75	514	5.06	1.71	610	-0.085	(-0.398, 0.228)	0.595	0.05	0.06

* Controlling for baseline HCCQ10, age, ethnicity, gender, time using NHS services and time experiencing mental health problems

Controlling for age, ethnicity, gender and time using NHS services

† Controlling for baseline HCCQ10 (using the missing indicator method), age, ethnicity, gender, time using NHS services, variables unbalanced between the cohort and cross-sectional samples: living arrangements and employment status.

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Table 4. Secondary outcomes in the cluster cohort (intention to treat analysis).

		Control			Intervention			Adjusted mean difference (Int–Control)	95% CI	P value	ICC
		Mean	SD	n	Mean	SD	n				
EQUIP PROM*	Baseline	22.82	8.76	272	22.08	8.60	332				
(range 0–44)	6 months	21.62	11.15	153	21.34	9.64	192	0.416	(-1.817, 2.648)	0.715	0.05
HADS-A	Baseline	11.35	5.36	272	12.25	5.19	332				
(Anxiety)+ (range 0–21)	6 months	10.86	5.85	172	12.10	5.38	208	0.373	(-0.391, 1.136)	0.339	0.00
HADS-D	Baseline	9.18	5.30	272	10.05	5.19	332				
(Depression)+ (range 0–21)	6 months	8.90	5.81	172	9.82	5.50	208	-0.020	(-0.880, 0.839)	0.963	0.00
VSSS-54+ (range 1–5)	Baseline	3.58	0.62	272	3.53	0.61	332				
	6 months	3.53	0.80	156	3.52	0.72	191	0.121	(0.002, 0.240)	0.045	0.01
CALPAS+ (range 12–84)	Baseline	4.98	1.27	272	5.06	1.19	332				
	6 months	4.86	1.45	152	4.82	1.38	191	-0.008	(-0.245, 0.262)	0.949	0.01
GASS# (range 0–66)	Baseline	17.75	10.36	272	18.30	8.94	332				
	6 months	17.81	11.52	115	19.81	10.32	143	1.297	(-1.071, 3.666)	0.283	0.05
WHOQOL* (range 1–5)	Baseline	3.03	1.01	272	3.05	1.05	332				
	6 months	3.20	1.18	158	3.16	1.11	200	0.027	(-0.167, 0.221)	0.784	0.00
DREEM* (range 24–120)	Baseline	41.71	9.59	272	42.11	9.27	332				
	6 months	42.63	12.45	118	43.54	13.26	142	-0.017	(-2.701, 2.666)	0.990	0.01
WEMWBS+ (range 14–70)	Baseline	39.22	12.30	272	38.80	11.89	332				
	6 months	41.09	13.74	162	38.80	13.31	203	-0.671	(-2.599, 1.256)	0.495	0.00

*Controlling for baseline outcome, ethnicity, gender, time using NHS services and accommodation type

+Controlling for baseline outcome, ethnicity, gender, time using NHS services, accommodation type and age

#Controlling for baseline outcome, ethnicity, gender and time using NHS services

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attrition bias, although in practice we achieved high follow up in both groups. Our comprehensive outcome assessment increases confidence that the lack of effect is robust.

Our pragmatic study was designed to maximise uptake among routine community mental health services. We intervened in 18 sites with over 300 care coordinators. However, our volunteer sites may not be fully representative of the 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 (e.g., if they considered the service user to be too unwell to participate), although this involved only a small proportion of patients (n = 6 or 1.25% of the 480 excluded after receiving consent to contact, 4 control and 2 intervention). 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. We offered patients the option of completing follow up assessments face-to-face or by telephone, as this potentially reduces bias if it leads to less attrition. It is possible that telephone adminstration might impact on patient responses, although this would be balanced over the arms of the trial.

Comparison with other studies

Significantly, our results concur with a growing body of evidence that highlights the challenges associated with embedding shared decision-making in routine services [2,15, 51]. Although some individual interventions and decision aids have shown an impact, these are often in selected clinical situations,[3] involving decisions about discrete treatments, and it is not clear whether their effects can be replicated outside the trial context. To make shared decision-making a routine part of mental health care, the challenge is to achieve effectiveness while simultaneously maximising reach.

Meaning of the study: possible mechanisms and implications for clinicians and policy makers Our failure to demonstrate benefit requires explanation. We evaluated an intervention derived from published evidence, specifically designed to overcome known barriers to shared decision-making. MAGIC identified a lack of suitable patient reported measures for shared decision-making. Our measure was validated, but the challenges of measurement should not be underestimated, especially among patients with limited previous experience of shared decision-making.

Understanding causal pathways in cluster trials requires an assessment of fidelity, which in the context of a training intervention means exploring processes involving the clusters (i.e., the delivery of training and supervision to the teams) and patients (which patients received the intervention, and what behaviour change occurred in those consultations?) [52]. At the cluster level, we achieved good staff attendance, but there were important limits. We stipulated an attendance rate of 80% of care co-coordinators per team, ten of which demonstrated 80% or greater attendance (range 48–100%). However, no psychiatrists attended, which may have limited the impact of our intervention.

We did not have data on actual delivery of the skills taught in the training (for example, from observations or recordings of care planning discussions after the training). Data from the nested process evaluation incorporating semi-structured interviews with 54 patients, carers and professionals (conducted at baseline, 6 and 12 month post intervention) demonstrated that professionals may not have had sufficient opportunity to use skills derived from the intervention. This data demonstrated that the current operationalisation and utilisation of care planning within mental health services was a significant barrier to involving patients and carers in the care planning process [53]. Such organisational constraints and a lack of consideration of the relational work required to undertake shared decision-making in mental health services meant that despite ideological buy-in from professionals they were not able to routinely embed practices into local service provision.

MAGIC emphasised the importance of senior management demonstrating visible support for shared decision-making. Taking part in our trial required some institutional *agreement* from our host health organisations, although we did not require significant institutional *commitment* (such as investment of resources) beyond staff time. Effective interventions may require more comprehensive commitment, including explicit validation of time spent with patients, endorsement of shared decision-making through clinical leadership and incentives, and fostering new ways to meet patient needs within the constraints of available resources. Such comprehensive change will necessarily increase costs and limit delivery at scale. Historically, the majority of patients and carers have felt marginalised in care planning decisions [21]. The potential for short-term interventions such as the one tested here to impact on entrenched attitudes may be limited.

Unanswered questions and future research

There remains an urgent need to develop ways of improving shared decision-making at scale. More complex, comprehensive and enduring interventions may be required, such as the use of

incentives, adoption of formal decision aids, linkage to routine outcome monitoring, and better integration into routine clinical systems [27]. However, such comprehensive models raise significant challenges for their implementation (and their assessment in a rigorous, controlled fashion).

Conclusions

Our trial suggests that embedding shared decision-making into mental health care planning cannot be achieved within routine services, at least not to a level which generates demonstrable changes for patients. Enhancing shared decision-making may require considerably greater investment of resources and effects may only be apparent over the longer term.

Data sharing statement

Copies of the training materials, statistical code, and anonymised data are available from the corresponding author on reasonable request.

Supporting information

S1 CONSORT checklist.
(PDF)

S1 Table.
(DOCX)

S1 Protocol.
(PDF)

S2 Protocol.
(PDF)

Acknowledgments

Author Contributions

Conceptualization: Karina Lovell, Penny Bee, Patrick Cahoon, Patrick Callaghan, Lesley-Anne Carter, Linda Davies, Richard Drake, Chris Roberts, Anne Rogers, Caroline Sanders, Peter Bower.

Formal analysis: Karina Lovell, Penny Bee, Helen Brooks, Lesley-Anne Carter, Linda Davies, Chris Roberts, Anne Rogers, Caroline Sanders, Peter Bower.

Funding acquisition: Karina Lovell, Penny Bee, Patrick Cahoon, Patrick Callaghan, Linda Davies, Richard Drake, Chris Roberts, Anne Rogers, Caroline Sanders, Peter Bower.

Investigation: Helen Brooks, Claire Fraser, Andrew Grundy, Kathryn Hinsliff-Smith, Oonagh Meade, Chris Roberts, Kelly Rushton, Gemma Shields, Lauren Walker.

Methodology: Karina Lovell, Penny Bee, Helen Brooks, Patrick Callaghan, Lesley-Anne Carter, Lindsey Cree, Linda Davies, Richard Drake, Claire Fraser, Chris Gibbons, Andrew

Grundy, Oonagh Meade, Chris Roberts, Anne Rogers, Caroline Sanders, Lauren Walker, Peter Bower.

Project administration: Karina Lovell, Penny Bee, Helen Brooks, Patrick Callaghan, Claire Fraser, Oonagh Meade, Anne Rogers, Peter Bower.

Writing – original draft: Karina Lovell, Penny Bee, Helen Brooks, Patrick Cahoon, Patrick Callaghan, Lesley-Anne Carter, Lindsey Cree, Linda Davies, Richard Drake, Claire Fraser, Chris Gibbons, Andrew Grundy, Kathryn Hinsliff-Smith, Oonagh Meade, Chris Roberts, Anne Rogers, Kelly Rushton, Caroline Sanders, Gemma Shields, Lauren Walker, Peter Bower.

Writing – review & editing: Karina Lovell, Penny Bee, Helen Brooks, Patrick Cahoon, Patrick Callaghan, Lesley-Anne Carter, Lindsey Cree, Linda Davies, Richard Drake, Claire Fraser, Chris Gibbons, Andrew Grundy, Kathryn Hinsliff-Smith, Oonagh Meade, Chris Roberts, Anne Rogers, Kelly Rushton, Caroline Sanders, Gemma Shields, Lauren Walker, Peter Bower.

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