Clinical effectiveness of a staff training intervention in mental health inpatient rehabilitation units designed to increase patients' engagement in activities (the Rehabilitation Effectiveness for Activities for Life [REAL] study): single-blind, cluster-randomised controlled trial

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Summary

Background Mental health inpatient rehabilitation services focus on people with complex psychosis who have, for example, treatment-refractory symptoms, cognitive impairment, and severe negative symptoms, which impair functioning and require lengthy admission. Engagement in activities could lead to improvement in negative symptoms and function, but few trials have been done. We aimed to investigate the effectiveness of a staff training intervention to increase patients' engagement in activities.

Methods We did a single-blind, two-arm, cluster-randomised controlled trial in 40 mental health inpatient rehabilitation units across England. Units were randomly allocated to either a manual-based staff training programme delivered by a small intervention team (intervention group, n=20) or standard care (control group, n=20). The primary outcome was patients' engagement in activities 12 months after randomisation, measured with the time use diary. With this measure, both the degree of engagement in an activity and its complexity are recorded four times a day for a week, rated on a scale of 0–4 for every period (maximum score of 112). Analysis was by intention-to-treat. Random-effects models were used to compare outcomes between study groups. Cost-effectiveness was assessed by combining service costs with the primary outcome. This study is registered with Current Controlled Trials (ISRCTN25898179).

Findings Patients' engagement in activities did not differ between study groups (coefficient 1·44, 95% CI –1·35 to 4·24). An extra £101 was needed to achieve a 1% increase in patients' engagement in activities with the study intervention.

Interpretation Our training intervention did not increase patients' engagement in activities after 12 months of follow-up. This failure could be attributable to inadequate implementation of the intervention, a high turnover of patients in the intervention units, competing priorities on staff time, high levels of patients' morbidity, and ceiling effects because of the high quality of standard care delivered. Further studies are needed to identify interventions that can improve outcomes for people with severe and complex psychosis.

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Introduction

Mental health inpatient rehabilitation services in the UK focus on people with complex long-term health problems that prevent them being discharged home after an acute admission. Many patients have a diagnosis of schizophrenia[1] complicated by additional difficulties such as non-response to first-line drugs,[2] cognitive impairment (usually affecting executive function and verbal memory), pervasive negative symptoms (such as apathy, reduced motivation, and blunted affect),[3–5] and substance use.[1,6] These complex problems result in major impairments in social and everyday functioning.[6] However, the proportion of people with complex psychosis is fairly small. Around 10% of new referrals to secondary mental health services

need rehabilitation[7] and, at any time, only 1% of mental health inpatients occupy a rehabilitation bed. However, in addition to the substantial clinical challenges these individuals pose for professionals, care of patients constitutes a major resource pressure for the UK's National Health Service (NHS) and social services, amounting to 25–50% of the total mental health budget.[8] Interventions that can reduce the need for inpatient care, even by a small reduction in length of stay, will have a large effect on resources absorbed by this population of patients.

Although specific interventions can improve outcomes for people with a diagnosis of schizophrenia,[9] most people are referred for rehabilitation when these options

have either been exhausted or if difficulties arise with respect to engaging the person in treatment.[6] Despite high levels of need and costs of care for this group of patients, evidence for effective interventions to guide mental health rehabilitation practitioners is scant.

Occupational therapy, which aims to improve people's everyday living skills,[10] is central to mental health rehabilitation. Facilitating patients' activity reduces the negative symptoms of psychosis,[11,12] but evidence is less clear of its ability to improve social function. However, some studies suggest an association through promoting people's motivation and daytime structure.[13–15] The level of activity of users of inpatient services is alarmingly low: in a survey of an acute admission ward in London, UK, inpatients spent less than 17 min/day in an activity other than sleeping, eating, or watching television.[16] In 1992, Curson and colleagues[12] reported that 80% of long-term inpatients spent more than 5 h/day doing nothing. Findings of other studies confirm that people with schizophrenia spend a large amount of time engaged in passive activities such as sleeping and watching television.[17–20] Although the importance of staff facilitation of patients' activities has been highlighted,[21] as far as we know, no randomised controlled trials have been done to test the efficacy of interventions with this focus.

We designed a cluster-randomised controlled trial that comprised one phase of a national programme of research into mental health rehabilitation services in England (the Rehabilitation Effectiveness for Activities for Life [REAL] study). We aimed to investigate the effectiveness of a training intervention for staff at mental health inpatient rehabilitation units (the GetREAL intervention) to increase patients' engagement in activities.

Methods

Study design and setting

The study protocol has been described elsewhere.[22] Briefly, we designed a single-blind, two-arm, cluster-randomised controlled trial, with mental health inpatient rehabilitation units as the unit of randomisation. We did a survey of NHS mental health inpatient rehabilitation services across England during an earlier phase of the REAL research programme.[23] 52 (87%) of 60 NHS trusts participated, comprising 133 mental health inpatient rehabilitation units with a median of 12 (IQR 9–15) occupied beds. We assessed units with the Quality Indicator for Rehabilitative Care (QuIRC), an international, standardised, quality assessment method completed by the unit manager.[24,25] Units scoring below the median on the total QuIRC score were eligible for inclusion in the trial, with the rationale that poorer performing units might benefit from our intervention. All patients within participating units were invited to participate in the study.

The South East Essex research ethics committee approved the study (09/H1102/45). For patients unable to give informed consent because of impaired mental capacity, the research ethics committee gave permission for data and case notes to be gathered from a key staff member. The study is registered with Current Controlled Trials (ISRCTN25898179).

Randomisation

The study statistician (LM) used a random number generator to select 40 units from a pool of 64 mental health inpatient rehabilitation services that had a QuIRC score below the median. We approached the managers of these units to explain the aim of the trial, sent them a study information sheet, and gave them up to 4 weeks to decide if they wanted their unit to participate. If the unit manager did not want to take part in the study, another unit was selected at random from the remaining 24.

Randomisation was done independently of the REAL research team by the Aberdeen Randomisation Service. They randomly allocated units (in a 1:1 ratio) either to receive the GetREAL staff training intervention (intervention group) or to continue with standard care (control group). They staggered randomisation to allow sufficient time for the REAL research team to gather baseline data and for the staff training intervention to be delivered sequentially at every unit. The REAL researchers (IH and NG) and study statistician (LM) were unaware of group allocations.

Procedures

Units randomly allocated to standard care (control group) continued with their usual service and were able to use any resources at their disposal to provide maximum care for patients. We did not restrict the work of these teams.

Units allocated to the GetREAL intervention (intervention group) received staff training, which we developed initially then refined further through consultation events with experts in mental health rehabilitation from across England, including occupational therapists, and by doing a pilot study (at two units). The GetREAL intervention consisted of three stages: predisposing, enabling, and reinforcing.[22]

In brief, during the predisposing stage, we aimed to gain support for the GetREAL intervention from senior unit managers and clinicians through a consultation meeting at each of the participating sites facilitated by a senior psychiatrist who was a member of the research team (HK, FH, and TC).[26] During the enabling stage, we identified and addressed barriers to change through team-level action plans and training of staff in appropriate new skills.[27] This stage of the intervention was delivered by one of two GetREAL intervention teams (independent of the research team), consisting of a senior occupational therapist, an activity worker, and a patient expert. The occupational therapist and activity worker spent 5 weeks at every participating unit, during which time they reviewed the unit's resources and practices related to patients' activities. Along with the patient expert, they facilitated a 1-day training course for nurses and support

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(unregistered) staff at the unit, through which they presented occupational therapy and motivational techniques[28,29] to encourage patients' engagement in activities (eg, use of picture cards and activity wheels to guide discussion with patients about their interests). The occupational therapist and activity worker provided daily

	Units at which criteria were achieved (n=20)
Predisposing stage	
Predisposing meeting held with unit's senior team members, attended by at least one of the REAL research group's senior psychiatrists (HK, FH, TC), to explain the aim of the GetREAL intervention, answer queries, and recruit senior staff	16 (80%)
Dates for initial GetREAL training days for unit staff, and release of staff to attend, agreed with the unit manager before the GetREAL team arrive	17 (85%)
Unit manager agreed to provide unit keys and, if possible, access to computer and email accounts for the GetREAL team	18 (90%)
Enabling stage	
Initial training	
At least two members of the GetREAL team delivered the initial training	20 (100%)
At least 50% of staff at the unit attended	19 (95%)
Initial evaluation forms completed by all staff attending	18 (90%)
Action plans agreed for the next 4 weeks	19 (95%)
Modelling	
GetREAL team worked alongside unit staff for 5 weeks, including the training days	20 (100%)
At least one structural change or enhancement agreed to facilitate patients' activity levels	20 (100%)
Other changes needed secondary to the GetREAL team's suggestions that might not relate directly to patients' activities	18 (90%)
Individual goal-setting (with respect to activities) undertaken and recorded in care plans for at least 50% of patients on the unit	10 (50%)
Final training	
At least two members of the GetREAL team delivered the final training	20 (100%)
At least 50% of the unit's staff attended	11 (55%)
Certificate of attendance awarded to at least 50% of unit staff (staff had to attend both the initial and final training to receive the certificate)	14 (70%)
Reinforcing stage	
At the end of the 5-week enabling stage, written action plan for the unit to continue the GetREAL work for the next 12 months agreed with unit staff	20 (100%)
Action plan circulated to all unit staff by the GetREAL team	20 (100%)
At the end of the 5-week enabling stage, activity was included in at least 50% of patients' individual care plans	16 (80%)
A link person was identified to keep in email contact with the GetREAL team for up to 12 months	18 (90%)
GetREAL team members remained in email contact for 12 months after the enabling phase	20 (100%)
Link person made contact with the GetREAL team at least once during the 12-month period	9 (45%)
Supervision and support of the GetREAL team	
GetREAL patients' consultants supported by occupational therapists by email, telephone, or in person as needed	20 (100%)
GetREAL activity workers supervised by occupational therapists every week during each intervention cycle	20 (100%)
GetREAL occupational therapists supervised at least three times per intervention cycle by the REAL research occupational therapist or the REAL organisational change specialist (or both), by phone, Skype, email, or in person	15 (75%)
GetREAL occupational therapists had a line management meeting with the REAL senior occupational therapist once per intervention cycle	20 (100%)

Table 1: Fidelity assessment of the GetREAL staff training intervention

support for staff in the unit for the remainder of the 5-week period, to model the intervention and give hands-on support for staff so they could gain confidence in the implementation of these techniques. For example, help was given with respect to co-facilitating activity-based groups and working individually with staff and patients, both on the unit and in the community. Unit structures and routines that impeded activities were addressed (eg, ensuring staff in the unit had access to funds for activities, and altering routines such as fixed mealtimes). At staff meetings, the GetREAL team reinforced the importance of ensuring that planned activities were given the same priority as other aspects of treatment and care. The reinforcing stage entailed maintaining the changes made to practice.[30] In the fifth week, the GetREAL team facilitated a half day workshop to review the intervention with the unit manager and staff and to agree how best to incorporate the skills acquired into the unit's usual structures and processes. An action plan reflecting the outcomes of this workshop was drawn up by the GetREAL team's occupational therapist, and a member of staff from the unit was identified to oversee delivery of the action plan in the unit after the GetREAL team left (referred to as the link person). Email support to the unit was available from the GetREAL team for the next 10 months (12 months after randomisation). A prompt email was sent by the GetREAL team occupational therapist to the link person twice over this period to encourage contact. The GetREAL teams received regular supervision from senior members of the research team (SC and TM). The GetREAL intervention was endorsed by the UK College of Occupational Therapy; further details, including a copy of the GetREAL manual, are available on request.

At the end of the intervention period, for every unit allocated to the intervention group, the supervising occupational therapist (SC) completed a proforma with the GetREAL team's occupational therapist and a senior member of the research team who had attended all the predisposing meetings (HK). We recorded the delivery of 24 specific aspects of the GetREAL intervention, with every item completed achieving a score of one (table 1).

The researchers (NG and IH) collected baseline data for four randomised units at a time (two allocated to the GetREAL intervention and two to standard care) during the 4 weeks before the GetREAL teams starting their intervention. All patients within these units were eligible to participate in the study, and we approached them to explain the aim and process of the study. We gave every participant an information sheet, and they had the opportunity to ask questions about the study. We did not interview patients who we assessed had the capacity to give informed consent and declined to participate. We repeated this process for collection of follow-up data at 12 months.

We obtained descriptive data at baseline for patients from staff and case notes, including demographics (age,

sex, and ethnic origin), diagnosis, length of history, and length of current admission. We also gathered information on potential mediators of outcomes, including staffing of the unit (obtained from the unit manager), patients' overall functioning (assessed with the global assessment of functioning scale),[31] substance use (staff-rated with the clinician alcohol and drug use scales),[32] and challenging behaviours that can make community placement difficult (rated by staff using the special problems rating scale).[33]

To minimise unmasking of the REAL research team, we stressed to staff at all participating units that they should not reveal to researchers whether they had received the GetREAL training intervention. Any unmasking of researchers was reported to the programme management group. We assessed the effect of unmasking by asking researchers (after they obtained 12-month follow-up data) to record their view about which units received the intervention and which were standard care sites. If unmasking happened during baseline data gathering, the second researcher obtained 12-month follow-up data to minimise bias.

Outcomes

The primary outcome was the degree to which patients were engaged in activity over the previous week, assessed using the time use diary 12 months after baseline.[34] This measure rates patients' activities during four periods every day: morning, lunchtime, afternoon, and evening. The degree of engagement in activity, and the complexity of the activity, is rated on a scale of 0–4 for every period, with lower scores denoting engaging in fewer activities or less complex activities, or both, giving a maximum possible score of 112. The scale has shown good inter-rater reliability, has been validated,[35] and seems to be sensitive to change.[34] IH and NG completed the time use diary retrospectively, during a semistructured interview with the patient. If patients did not have the capacity to give informed consent to participate in a face-to-face interview, we gathered information about their activities in the preceding week from their case records and discussions with their primary nurse.

We analysed several secondary outcomes. First was patients' social functioning, which was rated by a key staff member using the life skills profile,[36] a measure that comprises 39 items, each rated on a four-point scale, with the most positive response scoring four and the least scoring one, giving an overall score ranging from 39 to 156. Second was the length of current admission, which we measured in days. The third secondary outcome was the proportion of patients per unit who were either discharged or ready for discharge during the 12-month follow-up period. Fourth, we assessed the proportion of patients per unit who were discharged to an out-of-area placement during the 12-month follow-up period; this secondary outcome identifies difficulties with the availability of suitable,
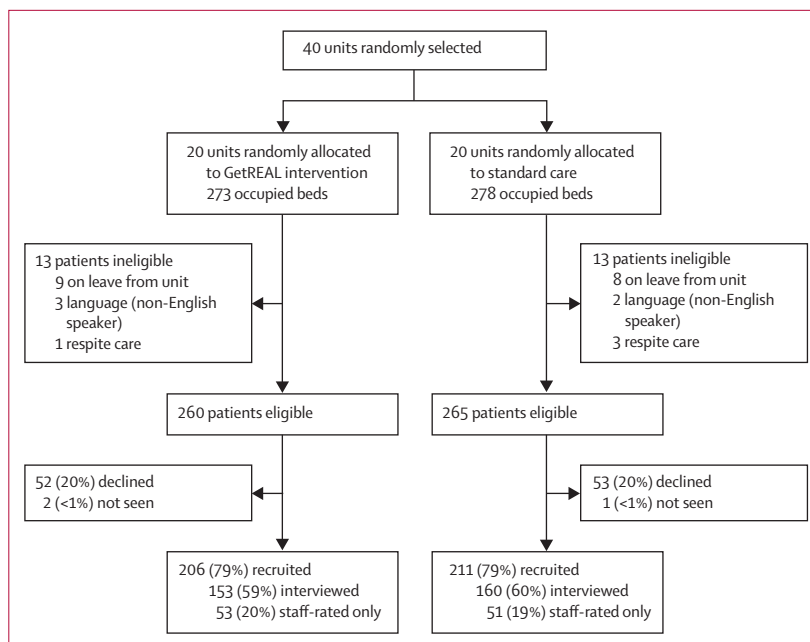

Figure 1: **Units and patients at baseline**

local, supported accommodation for patients to be discharged to. Fifth, we ascertained staff attitudes towards patients' progress with the question: "I expect this person to be able to move on to a more independent setting within the next 12 months". A key staff member (eg, the primary nurse) rated their view on a five-point Likert scale, with one being very unlikely and five being very likely. We converted this rating to a binary score for analysis—ie, very likely or likely versus neither likely nor unlikely, unlikely, or very unlikely). Our final secondary outcome was service quality, which we assessed with the QuIRC method.[24,25] The manager of every participating unit answered 145 questions on service quality and provision. The QuIRC score provides percentage ratings on seven domains of care: living environment; therapeutic environment; treatments and interventions; self-management and autonomy; social inclusion; human rights; and recovery-based practice.

To assess the cost-effectiveness of the GetREAL intervention, we measured the number of service use contacts using an adapted version of the client services receipt inventory.[37] We used unit cost data from Curtis[38] to obtain an estimate of the perceived cost of these contacts. When possible, we used information from a study on inpatient care in the UK to estimate the mean duration of service use.[39] Otherwise, we assumed that contacts lasted 30 min on average.

Statistical analysis

We entered data into the REAL study's database (Microsoft Access), which had range and logic checks
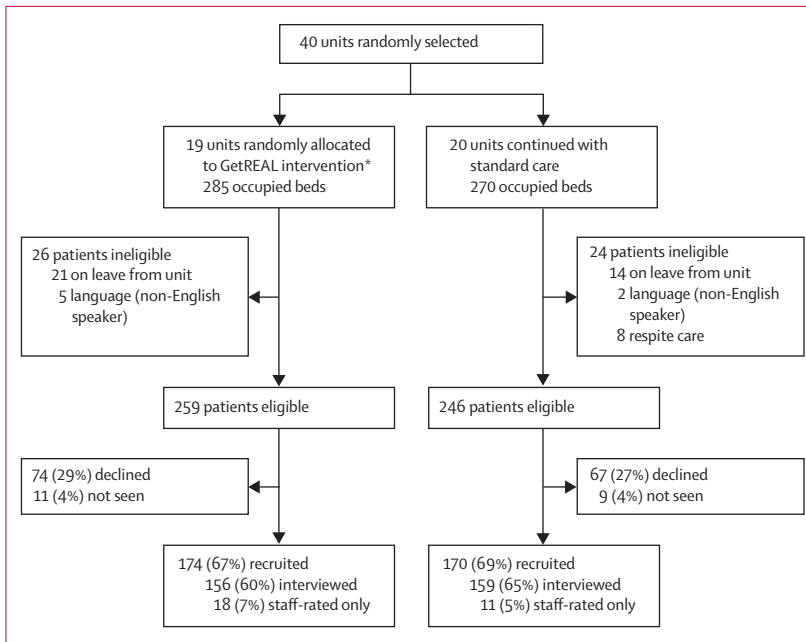
Figure 2: **Units and patients at 12-month follow-up**
*One unit closed during the study period.

built in to assist with data cleaning. 10% of data were double-entered to check for errors in data entry, with an error rate set at 5%, above which all data would be double-entered. The error rate was lower than 5% and, thus, no double data entry was needed.

Our primary analysis was based on a comparison of two means between study groups—ie, the mean unit score on the time use diary at 12-month follow-up. To detect an effect size of 0·35 SD between the intervention and standard care groups, with 80% power and assuming an intraclass correlation coefficient of 0·04 (based on data from our previous national survey),[23] and with an average cluster size of 12, we calculated that we needed 186 patients in each arm from a minimum of 31 clusters (rehabilitation units) in total.

We analysed data with Stata version 12 (College Station, TX, USA). We summarised descriptive characteristics of patients by study group, presented as either mean (SD), median (IQR), or numbers and proportions, as appropriate. Our main inference was at the level of the patient, because the aim of the intervention was to improve patients' engagement in activities; unit-level outcomes were of secondary interest. We used random-effects linear regression to analyse the primary outcome, adjusted for the baseline value of the patient-rated time use diary score, to evaluate the effect of the intervention. Some patients assessed at follow-up differed from those assessed at baseline, because some patients had been discharged and new patients admitted. Therefore, we used the mean baseline score for each unit (calculated for patients present in the unit during baseline data collection) in the model rather than scores for individual patients.

We investigated bias due to missing data and predictors of missingness. We then adjusted our analysis for predictors of missingness associated with the outcome, to preserve the missing-at-random mechanism. We investigated assumptions of normality of the residuals for the random-effects models. We also compared cluster summary means of the time use diary score, weighted by cluster size. We examined the agreement between staff and patients' time use diary scores by plotting the two scores against each other; if the plot was judged to show adequate agreement between the two scores then staff-rated data would be substituted for data missing from patients who did not have capacity to participate in the assessment (this process was akin to a sensitivity analysis). If we noted poor agreement between the two sets of ratings, missing time use diary scores would be imputed by multiple imputation, using ICE in Stata version 12. The variables we entered into the imputation model were: predictors of missing data; staff and patients' ratings of activity (time use diary scores) at 12-month follow-up; unit-level patients' ratings of activity at baseline; randomised allocation; whether the patient was detained involuntarily at 12-month follow-up; diagnosis; estimates of random effects to account for clustering; and QuIRC domain scores. We did a further sensitivity analysis, which was adjusted for the length of admission in the unit at 12-month follow-up and the GetREAL intervention fidelity score.

For the secondary outcomes, we used appropriate statistical models that allow for clustering (for outcomes measured at the level of the patient); we also used appropriate statistical tests based on cluster summary measures (for outcomes measured at the unit level). We did all analyses by intention-to-treat.

We estimated the cost of the GetREAL intervention by adding the cost of time spent by the GetREAL team to deliver the intervention to the cost of staff attending training sessions. We ascertained the cost-effectiveness of the GetREAL intervention using an incremental cost-effectiveness ratio. Specifically, we calculated the cost of achieving an extra 1% in the primary outcome measure (patient-rated time use diary score). To account for both clustering of data and correlation between costs and outcomes, we estimated a bivariate multilevel model using MLwiN version 2.29 (Centre for Multilevel Modelling, University of Bristol, Bristol, UK). We assessed uncertainty around this estimate with a cost-effectiveness plane and a cost-effectiveness acceptability curve.

Role of the funding source
The funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report. HK, LM, RZO, MK, LK, and PMcC had access to raw data. The corresponding author had full access to all data in the study and had final responsibility for the decision to submit for publication.

Results

Of the 133 services surveyed, two took part in a pilot of the study intervention and, of the remainder, 64 scored below the median value (69·6%) on the total QuIRC score and were eligible for the trial. From these 64 units, 40 were randomly selected for inclusion in the REAL study. 20 units were randomly assigned to the GetREAL intervention and 20 continued with standard care (figure 1).

Patients were recruited between March, 2011, and July, 2012. At baseline, of 260 eligible inpatients in 20 intervention units, 206 (79%) were recruited to the study; of 265 patients admitted to 20 standard care units, 211 (79%) were recruited (figure 1). 53 (20%) patients in intervention units and 51 (19%) who were receiving standard care did not have the capacity to complete research interviews and, thus, only staff-rated time use diary scores were gathered.

12-month follow-up was completed by August, 2013. One intervention unit closed during the study period (suburban, community-based). At 12-month follow-up, of 259 inpatients in the 19 intervention units, 174 (67%) were recruited; of 246 individuals admitted to the 20 standard-care units, 170 (69%) were recruited (figure 2). 18 (7%) inpatients in intervention units and 11 (4%) who were admitted for standard care did not have the capacity to complete research interviews.

Six episodes of unmasking (15% of units) took place, all of which happened at intervention units while baseline data were being gathered. At these units, the second researcher obtained follow-up data. At the end of the trial, the researchers identified correctly the study group allocation of 29 (74%) of 39 units (κ 0·49, suggesting moderate agreement).

Table 2 shows the main unit characteristics at baseline and 12-month follow-up. Most units in both study groups were based in the community in suburban areas. Fewer intervention units than standard care units had access to a clinical psychologist (69% vs 90%; table 2). No other differences between study groups in staffing levels were noteworthy, and staff turnover in the past 12 months was similar between groups. However, intervention units had a higher turnover of patients in the past 12 months than did standard-care units (69% and 44%, respectively). Intervention and standard-care units did not differ with respect to QuIRC domain scores. No further differences (other than those noted at baseline) were noted at 12 months (table 2).

Table 3 shows patients' characteristics at baseline and 12-month follow-up. Most patients were male (mean age 43 years) with a diagnosis of schizophrenia and a median 15-year history of contact with mental health services. A few patients in both study groups used alcohol or drugs. Slightly more patients admitted to intervention units had been treated previously in a secure unit (for mentally ill offenders) than had inpatients at a standard-care unit; also, more patients in intervention units were

currently detained on an associated forensic section than were inpatients at standard units, although this dissimilarity was not reflected by differences in the risk history of other patients in the two study groups. The most prevalent risk was self-neglect, which was reported for around two-thirds of patients (table 3).

	Baseline		12-month follow-up	
	Standard care units (n=20)	GetREAL units (n=19)*	Standard care units (n=20)	GetREAL units (n=19)
Unit location				
Inner city	7 (35%)	9 (47%)	7 (35%)	9 (47%)
Suburban	13 (65%)	10 (53%)	13 (65%)	10 (53%)
Unit type				
Hospital ward	1 (5%)	5 (26%)	1 (5%)	5 (26%)
Community-based	19 (95%)	14 (74%)	19 (95%)	14 (74%)
Beds				
Beds on the unit (n)	15 (12–18)	15 (10–20)	15 (12–18)	15 (11–18)
Beds occupied (%)	95% (92–100)	93% (82–100)	96% (86–100)	90% (78–100)
Staffing				
Psychiatrist works on the unit	18 (90%)	17 (89%)	20 (100%)	18 (95%)
Access to a psychiatrist	2 (10%)	2 (11%)	0 (0%)	1 (5%)
Clinical psychologist works on the unit	10 (50%)	10 (53%)	13 (65%)	12 (63%)
Access to a clinical psychologist	8 (40%)	3 (16%)	7 (35%)	4 (21%)
Occupational therapist works on the unit	18 (90%)	17 (89%)	16 (80%)	17 (89%)
Access to an occupational therapist	0 (0%)	2 (11%)	4 (20%)	1 (5%)
Nurse works on the unit	20 (100%)	19 (100%)	20 (100%)	19 (100%)
Support worker works on the unit	20 (100%)	19 (100%)	20 (100%)	19 (100%)
Access to a social worker	17 (85%)	15 (79%)	19 (95%)	15 (79%)
Access to a counsellor or psychotherapist	13 (65%)	13 (68%)	14 (70%)	13 (68%)
Turnover in past 12 months				
Staff (%)	15% (10–20)	11% (6–16)	12% (7–22)	10% (7–13)
Patients (%)	44% (23–80)	69% (25–120)	56% (31–89)	70% (24–90)
Proportion of patients discharged in the past 12 months, or proportion ready for discharge but no suitable placement (%)	65% (35–90)	80% (39–145)	77% (49–103)	85% (41–113)
Mean (SD) Quality Indicator for Rehabilitative Care score				
Living environment domain	74% (9)	72% (9)	73% (9)	73% (9)
Therapeutic environment domain	62% (6)	65% (5)	66% (6)	67% (5)
Treatments and interventions domain	58% (7)	61% (7)	62% (7)	65% (6)
Self-management and autonomy domain	69% (6)	68% (8)	70% (7)	71% (6)
Human rights domain	72% (9)	72% (7)	71% (7)	75% (6)
Recovery-based practice domain	65% (7)	66% (9)	68% (6)	69% (7)
Social inclusion domain	55% (10)	57% (9)	62% (13)	65% (10)

Data are number of units (%) or median (IQR), unless otherwise indicated. *20 units were enrolled at baseline but one closed down during the study.

Table 2: Unit characteristics

	Baseline		12-month follow-up	
	Standard care units	GetREAL units	Standard care units	GetREAL units
Sociodemographic factors				
Men	134/208 (65%)	127/193 (66%)	113/170 (66%)	121/174 (70%)
Mean (SD) age (years)	43 (12)	43 (14)	44 (12)	44 (13)
White	157/208 (75%)	141/193 (73%)	130/170 (76%)	129/174 (74%)
Diagnosis				
Schizophrenia	137/202 (68%)	141/185 (76%)	118/165 (72%)	126/165 (76%)
Bipolar affective disorder	15/202 (7%)	9/185 (5%)	14/165 (8%)	11/165 (7%)
Schizoaffective disorder	15/202 (7%)	14/185 (8%)	10/165 (6%)	13/165 (8%)
Psychiatric history				
Median (IQR) contact time with mental health services (years)	15 (9–25)	15 (8–26)	16 (8–27)	14 (8–24)
Median (IQR) number of previous admissions	4 (2–7)	5 (2–10)	4 (2–8)	4 (2–8)
Median (IQR) number of previous involuntary admissions	2 (1–4)	3 (1–5)	2 (0–4)	2 (1–5)
Median (IQR) length of current admission (months)	24 (11–48)	29 (13–86)	27 (13–59)	26 (11–80)
Median (IQR) length of current admission in rehab unit (months)	9 (4–23)	14 (5–28)	13 (5–25)	10 (5–29)
Current admission involuntary	142/194 (73%)	144/181 (80%)	116/152 (76%)	126/158 (80%)
Currently detained involuntary	92/198 (46%)	117/181 (65%)	74/155 (48%)	108/160 (68%)
Risk history				
Previous high security admission	9/193 (5%)	8/176 (5%)	4/148 (3%)	8/157 (5%)
Previous medium security admission	23/193 (12%)	26/176 (15%)	13/148 (9%)	22/157(14%)
Previous low security admission	41/193 (21%)	47/193(27%)	26/148 (18%)	55/156 (35%)
Ever detained on forensic section	26/193 (13%)	33/177 (19%)	20/148 (14%)	30/159 (19%)
Currently detained on forensic section	18/193 (9%)	28/177 (16%)	16/148 (11%)	27/159 (17%)
Ever been in prison	39/192 (21%)	37/177 (21%)	25/147 (17%)	46/155 (29%)
Prison in past 2 years	3/192 (2%)	1/177 (1%)	0/147 (0%)	3/155 (0%)
History of violence				
None	84/190 (44%)	65/177 (37%)	66/148 (45%)	59/154 (38%)
2 or more years ago	74/190 (39%)	78/177(44%)	53/148 (36%)	59/154 (38%)
Less than 2 years ago	32/190 (17%)	34/177 (19%)	29/148 (20%)	36/154 (23%)
Worst act of violence within past 2 years				
Threatened someone with weapon	10/190 (5%)	11/177 (6%)	14/147 (9%)	10/151 (6%)
Assault but victim did not need hospital treatment	27/190 (14%)	22 /177 (12%)	54/147 (36%)	64/151 (41%)
Assault and victim needed hospital treatment (admission)	2/190 (1%)	5/177 (3%)	4/147 (1%)	4/151 (3%)
Homicide	0/190 (0%)	0/177 (0%)	1/147 (1%)	2/151 (1%)
Sexual offence ever	19/191 (10%)	17/177 (9%)	13/148 (9%)	20/153 (13%)
Fire-setting ever	27/189 (14%)	27/176 (15%)	17/148 (12%)	26/154 (17%)
Self-harm ever	63/190 (32%)	76/177 (43%)	59/147 (40%)	63/154 (41%)
Recurrent self-harm in the past 2 years	6/192 (3%)	7/177 (4%)	8/147 (5%)	3/153 (2%)
Self-neglect in the past 2 years	129/191 (67%)	107/174 (61%)	92/147 (63%)	94/153 (61%)
Alcohol use	19/208 (9%)	12/192 (6%)	13/170 (7%)	16/173 (10%)
Substance use	11/208 (6%)	16/192 (8%)	13/170 (7%)	7/173 (4%)
Functioning, activity, and challenging behaviours				
Unlikely to be ready for discharge in next 12 months*	88/208 (42%)	78/192 (41%)	70/170 (41%)	77/173 (45%)
Mean (SD) score on the global assessment of functioning*	52 (7)	51 (7)	52 (8)	51 (9)
Mean (SD) score on the life skills profile*	125 (17)	123 (20)	127 (18)	127 (18)
Mean (SD) score on the time use diary	46 (11)	45 (11)	47 (12)	48 (11)
Median (IQR) score on the special problems rating scale*	1 (0–3)	1 (0–3)	1 (0–3)	1 (0–2)

Data are number of patients/total population (%), unless otherwise stated. *Staff-rated.

Table 3: Patients' characteristics

Items from the fidelity assessment (table 1) that were achieved by all units were removed from the analysis. Of the remaining items, the mean score was 13 (SD 2).

For statistical analysis, units in the standard-care group were scored 0 on the fidelity measure. The areas of weakest fidelity were in individual goal-setting,

	Coefficient* (95% CI)
Patient's time use diary score (complete case), adjusted for mean baseline time use diary score only	1·44 (–1·35 to 4·24)
Patient's time use diary score (complete case), adjusted for mean baseline time use diary score and predictors of missingness	0·68 (–2·41 to 3·76)
Patient's time use diary score to unit level ANCOVA, weighted by cluster (unit) size	1·23 (–1·75 to 4·20)
Staff-rated time use diary score, adjusted for mean staff-rated baseline time use diary score and predictors of missingness	0·55 (–2·39 to 3·49)
Patient's time use diary score (complete case), adjusted for mean baseline time use diary score, predictors of missingness, and staff turnover in the past 12 months	0·91 (–2·64 to 4·47)
Patient's time use diary score (complete case), adjusted for mean baseline time use diary score, predictors of missingness, staff turnover in the past 12 months, access to a psychologist in the unit, and service user turnover in the past 12 months	1·90 (–1·10 to 4·89)
Patient time use diary score (complete case), adjusted for mean baseline time use diary score, predictors of missingness, length of admission, and GetREAL treatment intervention fidelity	–0·13 (–15·96 to 15·71)
Patient time use diary score after multiple imputation, adjusted for mean baseline time use diary score only	1·43 (–1·37 to 4·23)

*Reference category: standard-care units.

***Table 4*: Primary outcome analyses**

	Coefficient* (95% CI)
Life skills profile score	–0·91 (–6·53 to 4·72)
Length of current admission in rehabilitation unit (days)	–7·27 (–18·23 to 3·69)
Length of current admission (days)	–12·53 (–44·80 to 19·74)
Staff expectations of patients moving on in next 12 months	1·05† (0·47 to 2·33)
Patient turnover per unit (%)	1·06 (–30·46 to 32·58)
Staff turnover per unit (%)	–4·39 (–14·86 to 6·08)
Discharged or ready to be discharged per unit (%)‡	0·11 (–1·75 to 1·96)
Cost of perceived service use (£)	195 (–49 to 440)
Unit Quality Indicator of Rehabilitative Care domain score (%)	
Living environment	–0·10 (–5·52 to 5·31)
Therapeutic environment	0·87 (–2·58 to 4·33)
Treatments and interventions	2·57 (–1·68 to 6·82)
Self-management and autonomy	1·31 (–2·90 to 5·52)
Human rights	3·11 (–1·29 to 7·51)
Social inclusion	0·59 (–3·61 to 4·79)
Recovery-based practice	2·85 (–4·71 to 10·41)

*Reference category: standard care units. †Odds ratio: logistic regression was used (binary outcome). ‡Square root used rather than raw %.

***Table 5*: Secondary outcome analyses**

attendance at the final training session, and contacts between the link person and GetREAL team during the reinforcing stage (table 1).

Agreement between time use diary ratings completed by patients and staff was not judged adequate for staff scores to be substituted for those of patients who did not have capacity to answer for themselves. In 58% of cases, the difference between scores was less than five points, but for 23% of cases the patient's rating was at least five points higher than the staff rating, and in 20% of cases the staff rating was at least five points higher than the patient's rating.

Multivariable analysis identified three predictors of missingness: white ethnic origin (odds ratio 0·13, 95% CI 0·03–0·56); years since first contact with mental health services (1·07, 1·01–1·13); and score on the global assessment of functioning (0·81, 0·72–0·90). Patients' engagement in activities 12 months after randomisation (primary outcome) did not differ between study groups (coefficient 1·44, 95% CI –1·35 to 4·24; table 4), even after adjustment for predictors of missingness, length of admission, staff turnover, and GetREAL fidelity score. Furthermore, no difference was noted when only staff-rated time use diary scores were used or when the patients' time use diary scores were analysed at the unit level (unit means) rather than as individual scores. Multiple imputation using patients' characteristics and

patient-rated and staff-rated time use diary scores did not alter findings.

Very few units reported discharging patients to an out-of-area placement in the previous 12 months at baseline (four standard-care units, two intervention units) or at 12-month follow-up (four standard-care units, three intervention units). Therefore, this secondary outcome was not investigated further. Intervention and standard care units did not differ with respect to any other secondary outcomes (table 5).

The cost of the GetREAL intervention was estimated at £102 per month per patient (appendix p 1). The number of contacts with specific staff differed between intervention groups (appendix p 2); with the exception of the cost of contacts with nurses, costs between the two study groups were similar. The incremental cost of an extra 1% increase in the primary outcome measure was £101. The cost-effectiveness plane suggested that most replications were situated in the north-east or the north-west quadrant (appendix p 3); it is unclear what value decision makers would place on increasing the level of activity in mental health rehabilitation units. However, the cost-effectiveness analysis suggested that a willingness-to-pay of more than £100 per percentage point increase in time spent on an activity would be necessary for the intervention to have a probability greater than 50% of being cost effective (appendix p 4).

Discussion

In this cluster-randomised controlled trial, we investigated the effectiveness of the GetREAL intervention—a specific training plan for staff working in mental health

rehabilitation units aimed at increasing patients' engage-ment in activities—compared with standard care. We did not detect any clinical advantage of the GetREAL intervention over standard care at 12-month follow-up. The economic analyses suggested that the GetREAL intervention was more likely to increase costs, but these results were not significant. Furthermore, it is noteworthy that the estimated costs might not represent a real escalation in the costs of care but, instead, an increase in the proportion of time that staff spent in direct contact with patients rather than engaged in other tasks.

Our study has several strengths. First, we selected participating units at random from a pool of those that were assessed by us as performing below average in a previous national survey of these services.[23] Second, we minimised the amount of missing data by gathering information for the primary outcome through face-to-face interviews with patients and by using ratings obtained from staff and case notes for individuals who did not have the capacity to participate. Moreover, data for secondary outcome analyses were gathered from case notes and staff. Third, we only excluded from our study patients who had capacity, who declined consent, or who were on leave from the unit and, thus, unavailable for interview. Fourth, we adjusted our analyses for predictors of missingness and used an intention-to-treat approach. Fifth, although researchers were unmasked in 15% of units, the second researcher was able to obtain 12-month follow-up data to minimise observer bias. Finally, although more hospital-based units than community units were allocated to the GetREAL intervention, no differences were recorded between intervention and standard-care units with respect to access to public transport and community resources, both of which are assessed by the social inclusion domain of the QuIRC.

In our study, we assessed all inpatients in every participating unit 12 months after randomisation; therefore, loss to follow-up of individual patients assessed at baseline was not relevant. However, in view of the potential for changes (and closures) to services, particularly at a time of economic downturn in the NHS, we increased the number of units from 31 to 40 to ensure we had enough units in the study at 12-month follow-up. This adjustment was appropriate because one intervention unit closed down during the 12-month follow-up period. The median size of units (15 beds) was slightly larger than we expected from our previous national survey (12 beds); yet, we were unable to gather 12-month follow-up data for our target 372 patients (186 per study group). This shortfall seems to be attributable to fewer patients being assessed as not having capacity (such that data could be gathered from staff) at follow-up, and more patients who had capacity refusing consent. Therefore, although our study was slightly underpowered, supporting analyses concurred with the results of the primary patient-level analysis. Thus, our findings seem robust. However, we did not

investigate whether the intervention produced behavioural changes in staff who received training from the GetREAL teams, because our outcome was directed at the patient rather than staff.

Several possible explanations could account for the scant effectiveness of the intervention. First, although fidelity scores for units that received the intervention were fairly high, very few units made spontaneous contact with the GetREAL teams once they had left the unit after the 5-week enabling stage. This finding suggests that unit staff might not have continued to use the techniques they had practiced while the GetREAL teams were with them. Perhaps we might have noted a difference in patients' activity if we had assessed the effectiveness of the intervention at the end of the enabling stage; however, the aim of the intervention was to augment staff skills and embed changes in practice into the unit. Thus, we chose to assess outcomes 12 months after the GetREAL team had left. Underlying cultures in health-care settings are difficult to change,[40] and findings of an accompanying qualitative study suggest that reversion to previous practice could account for why our intervention failed to show effectiveness at 12 months (unpublished data [ML]). A more intensive reinforcement process might have sustained the intervention, by regular supervision of the link person to oversee the action plan in every participating unit.[41]

Second, the study was done during a time of turbulence in the NHS. The economic recession that began in 2008 and continued throughout the study period meant most units faced pressure to increase productivity and reduce costs. Unit managers and staff might, therefore, have found that continuing to implement the GetREAL practices was impossible in the context of competing priorities.

Third, patients might have been too severely impaired in functioning to benefit from the intervention. Mean time use diary scores among our study participants were lower than those of patients in another study who had a shorter duration of psychosis.[42] The severity of our study participants' health problems is also reflected in their lengthy contact with mental health services and

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Panel: **Research in context**

Systematic review

We did not do a systematic review because only a small amount of published work is relevant to mental health rehabilitation services in the UK. The members of our research team who had expertise in occupational therapy and organisational therapy supplied relevant scientific literature about the theoretical and practical basis for the intervention.

Interpretation

Our study findings highlight the need for further research that can inform evidence-based practice in specialist services for people with complex psychosis.

low mean scores on the global assessment of functioning. Thus, our study might have been too ambitious in expecting a specific intervention to improve engagement in activity. A more complex intervention that incorporates several evidence-based approaches for the treatment of psychosis, in addition to the GetREAL intervention, might be effective. However, the units that took part in our study generally had the appropriate range of staff to deliver evidence-based interventions recommended for people with psychosis,[9] and units scored fairly highly on the treatments and interventions domain of the QuIRC, which incorporates these routine interventions. More-over, our analyses included adjustment for the fact that fewer intervention units than standard-care units had access to a clinical psychologist, yet this difference did not alter our findings.

Fourth, because intervention units had a higher patient turnover than did standard-care units, staff would have had to modify their care approach repeatedly to be appropriate for a higher level of morbidity among new admissions. Therefore, perhaps staff were unable to adjust their approach to engaging patients in activities, thus preventing the intervention from having an effect. However, again, adjustment for this factor in our analyses did not alter our findings.

Finally, quality of care in English mental health rehabilitation units is higher than in other countries. Although we included units that scored below the median for quality across England, the lack of effectiveness could represent a ceiling effect in terms of how much quality of care can be improved, in view of current resources.

Our study highlights the need for specialist rehabilitation services for individuals with especially complex mental health problems. However, further work is needed to understand why bringing about change in this setting is so challenging.

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