Citation
Slade M, Bird V, Clarke E, Le Boutillier C, McCrone P, Macpherson R, Pesola F, Wallace G, Williams J, Leamy M (2015) *Supporting recovery in patients with psychosis using adult mental health teams (REFOCUS): a multi-site cluster randomised controlled trial*, Lancet Psychiatry, **2**, 503-514.

Supporting recovery in patients with psychosis using adult mental health teams (REFOCUS): a multi-site cluster randomised controlled trial

Mike Slade PhD*[1]
Victoria Bird BSc[1]
Eleanor Clarke MBBS[1]
Clair Le Boutillier MSc[1]
Paul McCrone PhD[1]
Rob Macpherson MD[2]
Francesca Pesola PhD[1]
Genevieve Wallace BSc[1]
Julie Williams MSc[1]
Mary Leamy PhD[1]

[1] King's College London, Health Service and Population Research Department, Institute of Psychiatry, Psychology & Neuroscience, Denmark Hill, London SE5 8AF, UK
[2] 2Gether NHS Foundation Trust, Rikenell, Montpellier, Gloucester GL1 1LY

* Corresponding author
Email: mike.slade@kcl.ac.uk
Tel: 020 7848 0795

Abstract

Background

Mental health policy in many countries is oriented around recovery. The evidence base for service-level pro-recovery interventions is lacking.

Methods

Two-site cluster randomised controlled trial in England (ISRCTN02507940). REFOCUS is a one-year team-level intervention targeting staff behaviour (increasing focus on patient values, preferences, strengths, goal-striving) and staff-patient relationships (coaching, partnership). 27 community-based adult mental health teams were randomly allocated to treatment-as-usual (n=13) or treatment-as-usual plus REFOCUS (n=14). Baseline (n=403) and one-year follow-up (n=297) outcomes were assessed for randomly selected patients with psychosis, representing 88% of target recruitment. Primary outcome was recovery, assessed using Questionnaire about Processes of Recovery (QPR).

Findings

Intention-to-treat analysis using multiple imputation found no difference in QPR Total (control 40·0 (s.d.10·2), intervention 40·6 (s.d.10·1), adjusted difference 0·68, 95%CI: -1·7 to 3·1, p=·58), or sub-scales. Secondary outcomes which improved in the intervention group were functioning (adjusted difference 6·96, 95%CI 2·8 to 9·2, p<·001) and staff-rated unmet need (adjusted difference 0·80, 95%CI 0·2 to 1·4, p=·01). This pattern remained after covariate adjustment and completer analysis (n=275). Higher-participating teams had higher staff-rated pro-recovery behaviour change (adjusted difference -0·4, 95%CI -0·7 to -0·2, p=·001) and patients had higher QPR Interpersonal scores (adjusted difference -1·6, 95%CI -2·7 to -0·5, p=·005) at follow-up. Intervention-group patients incurred £1,062 (95%CI -£1,103 to £3,017) lower adjusted costs.

Interpretation

Supporting recovery may, from the staff perspective, improve functioning and reduce needs. Overcoming implementation barriers may increase staff pro-recovery behaviours and interpersonal aspects of patient-rated recovery.

Funding

National Institute for Health Research.

Introduction

An orientation towards supporting personal recovery is national mental health policy in England and Wales[1] and throughout much of the English-speaking world. This focus on recovery has been re-iterated in the most recent Chief Medical Officer's report on public mental health.[2] In this context, personal recovery is defined as a way of living a satisfying, hopeful, and contributing life even with any limitations caused by illness.[3] This modern meaning of recovery can be contrasted with the traditional focus of clinical recovery on symptomatology and disability. Epidemiological evidence indicates that the majority of people experiencing mental illness will over the long term experience clinical recovery.[4]

Scientific knowledge about interventions to support personal recovery is emerging, including for example Cochrane reviews about vocational rehabilitation, peer support, and advance directives.[5] Programmes are underway internationally to support pro-recovery system transformation[6]. Despite this progress, policy is markedly in advance of research and practice. In addition to introducing new and evidence-based interventions, it is becoming clear that supporting personal recovery will also involve change in staff-patient relationships, treatments (e.g. with emerging evidence that psychosocial interventions for psychosis may be effective in the absence of pharmacotherapy),[7] and outcomes (with more diverse outcomes such as employment and relationships in addition to symptomatology and functioning).[8] Initiatives to support a recovery orientation are needed at higher levels within the system than the clinician-patient level, in order to achieve this organisational culture change within mental health systems.

In this report we describe an evaluation of the REFOCUS Intervention: a manualised team-level intervention to support personal recovery.[9] The evidence base for the intervention is summarised in the *Research in Context* Panel, and the understanding of practice change was informed by the theory of planned behaviour.[10] This theory proposes behavioural intent is influenced by attitudes and subjective norms, and by the perceived level of behavioural control. Meta-analysis of health research suggest the theory accounts for over 20% of actual behaviour.[11] The REFOCUS Intervention is intended to be trans-diagnostic and suitable for all types of adult community mental health teams. An international review found that staff can support recovery through what they do with patients (the Supporting Recovery practice domain), and how they work with patients (the Working Relationship practice domain).[12] The intervention therefore

targets care content (the 'what') by supporting the use of three working practices, and care processes (the 'how') through training staff in coaching and giving opportunities for other recovery-promoting relationships. The intervention and evaluation are based on the REFOCUS Model (contained in the manual),[9] which following the MRC Framework for Complex Health Interventions[13] specifies the intended causal pathway from intervention, through changes in practice and patient experience, to patient outcome of enhanced recovery. We report a multi-site cluster randomised controlled trial comparing outcomes for patients in community mental health teams receiving or not receiving the REFOCUS Intervention. Although the intervention is trans-diagnostic, our evaluation focussed on the impact on patients with psychosis, with the aim of providing evidence to inform disorder-specific clinical guidelines. We hypothesised that recovery would be improved for patients with psychosis, in comparison with usual care.

Methods

Study design and participants

We undertook a cluster randomised controlled trial across two mental health Trusts in England. The trial manual[9] and protocol (available at www.biomedcentral.com/1471-244X/11/185)[14] were published, ethical approval was obtained (East London Research Ethics Committee, 11/LO/0083), the trial was registered (ISRCTN02507940, controlled-trials.com), researchers were trained in administration of all standardised measures, and trial conduct was overseen by a Trial Steering Committee.

As the intervention is at the level of the team, we used a cluster design with a cluster being a community mental health team, to reduce contamination, because teams are the unit of service delivery in the NHS. Team inclusion criteria were adult, community-based mental health teams providing care co-ordination using the Care Programme Approach,[15] a national framework for care co-ordination and resource allocation in mental health care. Two sites were used: South London and Maudsley NHS Foundation Trust (SLaM) in south-east London and 2gether NHS Foundation Trust in Gloucestershire. SLaM is the largest mental health trust in the UK, has an annual income of £330m, spent across over 100 sites spanning urban and suburban settings. It employs 4,500 staff in 296 teams, works with 34,128 service users. 2gether is a rural / semi-rural Trust, employing 806 staff in 23 adult mental health teams, and working with 4,301 service users. In both sites, all potentially eligible teams were identified by service

managers, and then researchers discussed participation with the service and team managers and lead clinicians.

Patient participants were identified from each team's caseload. Inclusion criteria were aged 18-65 years, primary clinical diagnosis of psychosis, e.g. schizophrenia, schizo-affective disorder, bipolar disorder, no immediate plans for discharge or transfer, not currently receiving in-patient care or in prison, speaks and understands English, not participating in substantial other study, is sufficiently well to participate in opinion of clinician, and is in regular contact (as judged by the team) with at least one worker in the team. Exclusion criteria were being unable to give consent or being unknown to, or uncontactable by, the service. The caseload was screened for initial eligibility (age, diagnosis) based on clinical records, clinicians obtained assent from the patient to be approached by researchers, and then written informed consent and baseline data were obtained from participants by researchers before randomisation.

Staff inclusion criteria were providing clinical input to a participating team, not also providing clinical input to another participating team, and (for staff suggested as the key informant by the patient) being in regular clinical contact with the participating service user. All staff gave written informed consent and completed baseline assessments before randomisation.

Randomisation and masking

Teams were allocated on an equal basis to intervention (treatment as usual plus REFOCUS Intervention) or control (treatment as usual), stratified by wave (four SLaM Boroughs, two 2gether localities) to ensure balance. Block randomisation of teams was undertaken by the independent Mental Health and Neuroscience Clinical Trials Unit (MH&NCTU). For each team, the screened caseload of potentially eligible patient participants was randomly ordered using procedures set out by MH&NCTU, and participants were then recruited in list order. Participating staff, patients and researchers were aware of allocation status at follow-up.

Procedures

All teams were multidisciplinary and provided care co-ordination under the Care Programme Approach (CPA), whose key features include systematic arrangements for assessing health and social needs, formation of a care plan identifying the health and

social care required from a variety of providers, appointment of a key worker to monitor and co-ordinate care, and regular review of the care plan.

Teams allocated to the intervention arm additionally received the REFOCUS Intervention. The REFOCUS intervention is described in detail in a published manual,[9] but in brief comprises a one-year, whole-team intervention to increase community mental health team support for recovery. It aims to impact upon team and individual staff values (which can be conflicting)[16], recovery-related knowledge, skills and behaviour, and staff-patient relationships. The intervention has two components: behavioural and interpersonal. The behavioural component comprises three desired behaviours by staff, called Working Practices (WPs). WP1 is Understanding Values and Treatment Preferences, and involves focussing on the patient's values and identity beyond being a patient, and placing their preferences at the centre of care planning. WP2 is Assessing Strengths, and involves using a standardised assessment of personal and social strengths to identify existing and potential resources the patient can build on. WP3 is Supporting Goal-striving, and involves orienting clinical care around goals valued by the patient. These working practices are undertaken in the context of the interpersonal component, called Recovery-promoting Relationships, which included training staff to use coaching skills in interactions with patients,[17] and undertaking a Partnership Project, in which staff and patients from the same team take on a joint and non-clinical task, co-produced between staff and patients, with a small amount of resources (£500 per team). Approaches to supporting implementation were: intervention briefing meetings separately for staff and patients / informal carers about the study; 12 hours (three four-hour sessions) of staff training in personal recovery provided by two trainers (one with a professional background and one with a service use background); 16 hours (one eight-hour day, two four-hour sessions, telephone support, optional booster coaching sessions) of training in coaching for recovery from a coaching trainer; six externally facilitated team manager reflection groups to support culture change; six team reflection groups (three externally facilitated, three unfacilitated) to foster experiential learning; and use of a reflective practice tool in individual supervision.

Outcomes

The primary outcome was recovery, assessed using the Questionnaire about the Process of Recovery (QPR).[18] This measure was identified as most appropriate in a systematic review of recovery measures.[19] QPR is a 22-item patient-rated assessment

of recovery, developed from a qualitative study led by service user-researchers.[20]. Example of items are 'I can actively engage with life' and 'I am able to develop positive relationships with other people'. Each item is rated on a five-point scale from 0 (Disagree Strongly) to 4 (Agree strongly). The initial version comprised two sub-scales: QPR Intrapersonal (17 items, range 0-68) and QPR Interpersonal (5 items, range 0-20), with higher scores indicating increased recovery. Adequate internal consistency (Intrapersonal 0·94, Interpersonal 0·77), construct validity, and test-retest reliability (Intrapersonal 0·87, Interpersonal 0·76) were demonstrated. A subsequent evaluation by the measure developers using a new dataset found a 15-item (range 0-60) one factor solution, with items all coming from the QPR Intrapersonal sub-scale and demonstrating adequate internal consistency (0·93) and test-retest reliability (0·70).[21] Their evaluation found a significant correlation between the 15-item QPR and standardised measures of symptomatology, hope and self-esteem. Three scores are produced based on means ratings: QPR Intrapersonal subscale (17 items), QPR Interpersonal subscale (5 items), and the extrapolated QPR Total score (15 items), all with range 0 (low recovery) to 4 (high recovery).

Scoring and references for remaining measures are given in Appendix Table 1. Secondary patient-rated outcome measures were hope (Herth Hope Index [HHI]), quality of life (Manchester Short Assessment of Quality of Life [MANSA]), empowerment (Mental Health Confidence Scale [MHCS]), well-being (Warwick-Edinburgh Mental Well-Being Scale [WEMWBS]), and met and unmet needs (Camberwell Assessment of Needs Short Appraisal Schedule-Patient [CANSAS-P]). Secondary patient-rated experience measures were satisfaction (Client Satisfaction Questionnaire [CSQ]) and recovery support (INSPIRE). Secondary staff-rated outcomes were met and unmet needs (CANSAS-Staff [CANSAS-S]), functioning (Global Assessment of Functioning [GAF]), and social disability (Health of the Nation Outcome Scale [HoNOS]). Researchers rated symptomatology (Brief Psychiatric Rating Scale [BPRS]) and service use in the previous six months (Client Service Receipt Inventory [CSRI]).

For the quantitative element of the process evaluation, staff completed measures of their recovery-related knowledge and attitudes (Recovery Knowledge Inventory [RKI]), attitudes towards mental illness (Mental Illness: Clinicians' Attitudes [MICA]), and two unstandardised measures. The Participation Scale [PS] rated participation (i.e. attendance and engagement) in the key intervention components of personal recovery

training, coaching training, and team reflection sessions. The Recovery Practice Scale [RPS] assessed self-rated skills, behavioural intent, and behaviour in relation to coaching, values, strengths, goal-striving, and partnership relationships.

Data collection was undertaken by researchers who were trained in all measures. Baseline data were collected prior to the allocation date. Teams were contacted four months before allocation, and most data were collected in the month before the allocation date. All staff were asked to complete RKI, MICA, and RPS. Researchers met with patients, who after giving informed consent completed all patient-rated measures (QPR [primary outcome], CANSAS-P, HHI, MANSA, MHCS, WEMWBS, CSQ, INSPIRE) and identified a paired member of staff from their team (either their care co-ordinator or other appropriate professional). Researchers completed BPRS and CSRI with the patient. The identified paired staff were then approached and asked to complete CANSAS-S, HoNOS, and GAF. Teams were then allocated to either intervention or control. One year after randomisation, all assessments were repeated, with intervention group staff also completing PS. Follow-up patient data were sought irrespective of any change in circumstances (e.g. team disbanded, discharged, move to new Trust, in prison, currently in-patient). Data collection began one year after allocation date, with most data collected by one month later. Patient participants were offered £10 for their time after both assessments, and entered into a £50 prize draw. Staff data were collected from the same member of staff where possible, otherwise from an appropriate alternate.

Paper data were transcribed to an electronic database. Researchers were trained in data entry and followed a data entry protocol to ensure consistency. Data validation rules were used in the database to reduce transcription errors. All ID numbers were then checked to ensure match between paper and electronic data, and all missing data were manually checked to ensure correct entry. A random 20% sample of service user-rated (QPR, CSQ and CANSAS-P) and staff-rated (CANSAS-S, GAF, HoNOS, MICA, RKI, RPS) follow-up data were manually checked against paper copies, with agreement of 99.75% (staff) and 99.66% (service users).

Statistical analysis

The primary outcome was QPR. Our target analysable sample published in the protocol was 336 patients, using a sample size calculation assuming 29 teams with 17% attrition

to 25 teams, an estimated team-level Intra Cluster Correlation of 0·05 (a conservative estimate of the similarities of teams),[22] 15 patients per team with 7% attrition to 14 per team, and parameter estimates of medium standardised effect size (0·4), alpha=0·05 and power 0·8. Analysis was done by FP and PM (who were masked to treatment allocation), using Stata 11. The proportion of missing data across primary and secondary outcomes is shown in Appendix Table 4. Missing data were estimated for the whole sample (other than the six participants who had died by follow-up) using multiple imputation by chained equation ('MICE' command) with 50 imputations. The imputation model reflected clustering at team level, and (as multiple imputation relies on the assumption that data are missing at random (MAR)) included the baseline outcome measures as well as covariates in the imputation model to increase the likelihood of the MAR assumption and improve the estimation of the missing values. Sensitivity analyses showed that the distributions of the imputed items and complete cases were comparable, produced equivalent result patterns (shown in Appendix Table 6), and analysis based on missing data imputed for outcome measures at baseline and follow-up (compared with baseline only) was not associated with increased biased estimates as indicated by Monte Carlo estimates.[23]

Our main analysis was conducted using intention-to-treat (ITT) principles (irrespective of whether they received the intervention or not) on the imputed data. Regression analysis was used to assess study arm differences on primary and secondary outcomes while adjusting for baseline scores.[24] We took team-level clustering into account by using random effects regression analyses with maximum likelihood estimation using the 'xtmixed' command. The model was also adjusted for wave, to reflect the stratification design. We used prospective alpha allocation to correct for Type I error inflation due to multiple testing.[25] We set the experiment-wise alpha (αe) at 0·10, with the significance level for testing the primary outcome set to 0·05 (αp) while the remaining 0·05 of alpha can be distributed equally among secondary outcomes (i.e. α=0·05/14=0·004). Scores screening was implemented prior to our analyses whilst model diagnostics were conducted following our regression analyses.

Sensitivity analyses were then conducted, involving adjustment for sociodemographic covariates which may be associated with our outcomes.[26] These covariates, collected at baseline and chosen due to association with primary and secondary outcomes, were gender, age, years using mental health services, ethnicity (white British vs. other),

accommodation type (privately owned and rented vs. other), marital status (single vs. relationship), and education (higher education vs. not). Covariates were entered simultaneously into the regression model to assess whether results were modified.

Finally, we conducted *post-hoc* analyses relating to participation. To assess whether staff participation at team level was associated with QPR follow-up scores, adjusted for baseline, we extrapolated a measure of team participation by pooling the ratings on PS for each team ($\alpha = \cdot 89$), using data only from staff who did not move teams and had both baseline and follow-up ratings. We used a median split to dichotomise intervention teams into High or Low participation, allowing a variable 'Team Participation' (Control, Low participation, High participation) to be extrapolated.

We were also interested in assessing the association between staff participation and follow-up staff process measures for non-moving staff with complete data. We used a median split on PS across all teams, to identify low and high participating staff within the intervention group, allowing extrapolation of a 'Staff Participation' variable (Control, Low participation, High participation).

We regressed patient outcome (missing data estimated following scale guidelines or pro-rated where less than 20% of items were missing) on Team Participation, and staff process measures (for non-moving staff with complete data) on Staff Participation, whilst taking into account clustering at the team level using the Stata 'xtmixed' command, adjusting the model for baseline scores and Trust centre.

The cost of the intervention was based on the staff time involved in delivering it combined with unit costs for those staff members (derived from unit costs[27] and NHS Reference Costs, and shown in Appendix Table 7). These costs were then divided by the current caseload numbers for each team to derive cost per service user. This is a conservative approach because it assumes that the training will only benefit current service users. If we instead assume that future services users may also benefit then the cost would be reduced. Other service use data included contacts with primary and secondary health care services (including days in hospital) and social care. No imputation was used for loss to follow-up, but we used the standard economic evaluation approach that when a service was used but number of contacts not recorded, imputation using median values from complete cases was used. This occurred for a small number

of cases and a wide range of services, and was required to allow total costs to be calculated. Costs were calculated by combining the service use data with appropriate unit cost information (NHS Reference costs 2012/13). Costs were compared between the two groups for participants with baseline and follow-up cost data, using a bootstrapped regression model to account for the likely skewed data and with baseline costs controlled for. Costs are reported in 2012/13 UK pounds.

Role of the funding source

The funder had no role in study design, data collection, data analysis, data interpretation, the writing of this report, or the decision to submit for publication.

Results

Between April 2011 and May 2012, 27 teams (18 SLaM, 9 2gether) and 403 patients were recruited (Figure 1).

Insert Figure 1 here

Teams comprised 14 (9 SLaM, 5 2gether) in the intervention arm and 13 (9 SLaM, 4 2gether) in the control arm (Appendix Table 2). Teams comprised 13 Recovery Teams providing long-term support to patients with complex health and social needs (4 control, 9 intervention), four Psychosis Teams specialising in work with complex need patients with psychosis (2 control, 2 intervention), three High Support Forensic Teams for patients with complex needs and risk issues (1 control, 2 intervention), three Assertive Outreach Teams for hard-to-engage patients (3 control), two Supported Living Teams for patients in supported accommodation (2 control), one Low Support Team for patients with less complex needs (1 intervention), and one Early Intervention Team for patients in the first 3-5 years of psychosis (1 control).

Baseline characteristics of patients are shown in Table 1.

Insert Table 1 here

Patients in the intervention group were more likely to live in privately owned/rented accommodation ($chi^2(1)=8{\cdot}92$, $p={\cdot}003$), to be in a relationship ($chi^2(1)=5{\cdot}6$, $p={\cdot}02$) and to

be unemployed ($chi^2(1)=5{\cdot}7$, p =·003), although these differences are not significant after Bonferroni adjustment (adjusted p-value<0·001) to account for multiple testing. The control group had more social disability rated on HoNOS (t(364)=4·0, p<0·001), but did not differ significantly on any other primary or secondary outcome (p-values ranging from ·02 to ·91) or total costs or process evaluation measure. Overall we conclude that allocation was unbiased.

Implementation

A total of 28 intervention briefing sessions were run by researchers for patients / carers (14 teams) and staff (14 teams). Attendance ranged from 0 to 25 patients, and 50% to 80% staff per team attended. 41 of the planned 42 recovery training sessions were run, with 8 to 24 attenders (median 14.4) in session 1, 4 to 21 (median 13.1) in session 2 and 6 to 15 (median 10.4) in session 3. All 42 of the planned 42 coaching training sessions were run, with 12 to 21 attenders (median 14.7) in session 1, 7 to 19 (median 12.0) in session to and 5 to 24 (median 11.3) in session 3. The proportion of staff attending these training sessions cannot easily be quantified because (as discussed in the next section) the high staff turn-over rate complicates the denominator. However, the research team's impression was that the majority of staff attended.

12 of the intended 36 externally facilitated team reflection groups were run, with attendance ranging from 5 to 21 (median 10.0). No formal records were kept of the unfacilitated team reflection groups or the team manager reflection groups due to research team capacity limitations, but the research team's impression was that these did not in general happen. Reasons for reduced engagement were low team motivation and logistical challenges (e.g. difficulties in obtaining cover for whole-team sessions, staff being too busy). There was no evidence of the Supervision Reflection Form being used in supervision sessions. Partnership Projects were events or activities planned and run jointly by staff and patients, with a budget of £500. Overall, five of the intended 14 Partnership Projects were run, comprising building a web-site, Christmas party, and an information session for a service user group (SLaM), and Olympics sports day and three-day outward bound course (2Gether).

Towards the end of their time in the trial, two teams (one intervention, one control) disbanded but it was still possible to obtain follow-up data from patients and paired staff (but not unpaired staff).

Outcome

A total of 532 staff participated in baseline and follow-up. Of these, 336 were in the same team at baseline and follow-up, 105 left after baseline, 70 joined before follow-up, and 21 moved between teams (9 to a team in the same arm, 8 from intervention to control, and 4 from control to intervention). Six patient participants (3 intervention, 3 control) died during the study period, each for reasons identified by their clinician as un-related to the intervention, and were disregarded for analysis. No harms due to the intervention were reported.

At one-year follow-up, QPR (primary outcome) data were collected for 275 (69%) of the 397 participants (Appendix Table 3). Missingness across QPR scales was not associated with any sociodemographic covariate and only CANSAS-P Met needs among the clinical measure (t(388)=2·2, p=·02). Patients with complete information on QPR at follow-up had higher met needs scores at baseline than those with missing data, although the difference became non-significant after adjusting for multiple pairwise comparisons. Rates for secondary outcome data collection ranged from 60% for MANSA to 91% for GAF. Missing data are characterised in Appendix Table 4.

In relation to complete cases (n=255, 121 control, 134 intervention), QPR mean scores were stable between baseline and follow-up in both study arms for QPR Total (control mean(s.d.): baseline 38·6(9·5) vs. follow-up 40·2(10·3); intervention: 38·5(9·8) vs. 40·6(10·1)), QPR Intrapersonal (control: 43·6(10·6) vs. 45·5(10·3); intervention: 43·7(10·6) vs. 46·1(11·1)) and QPR Interpersonal (control: 13·1(2·8) vs. 13·4(2·7); intervention: 13·6(2·2) vs. 13·8(2·6)).

Intention-to-treat analysis

ITT analysis for all 397 participants from all 27 teams (average cluster size 15, range 13 to 17) indicated that intervention group patients did not differ on QPR Total (b=·63, p=·55, 95%CI: -1.41 to 2.67), QPR Intrapersonal (b=·49, p=·44, 95%CI: 1·71 to 2·70) or QPR Interpersonal (b=·13, p=·75, 95%CI: -·93 to ·67) subscales at follow-up. The only differences in secondary outcomes were improved scores on the staff-rated GAF and CANSAS-S Unmet Need measures (with the CANSAS-S effect being non-significant after alpha adjustment for multiple comparison) in the intervention group at follow-up (Table 2).

Insert Table 2 here

After adjusting for covariates, effect sizes were weakened for CANSAS-S Unmet needs (b=-0·68, p=·07, 95%CI -1·42 to -0·006) and GAF (b=5·32, p=·002, 95%CI 2·03 to 8·61) (Appendix Table 5). Patterns were not modified across the other scales. ITT analysis on complete cases is shown in Appendix Table 6, and produced an equivalent pattern of results to the ITT analysis with imputed data.

As indicated by the Intra Cluster Correlations in Table 2, there was an effect of team on QPR Interpersonal, HHI, MANSA, MHCS, BPRS, GAF and all CANSAS measures. Examination of residuals revealed some skewness on the CSQ scale but the results were confirmed using bootstrap standard errors (data not shown).

As part of our *post hoc* analysis, we explored the association between Team Participation and follow-up QPR (average cluster size 11, range 7 to 14). We found QPR Interpersonal scores adjusted for baseline varied across Team Participation ($chi^2(2)=8·23$, p=·016). Patients in high participation teams had significantly higher QPR Interpersonal scores at follow-up than patients in low participation intervention teams and control teams (Table 3). Intra Cluster Correlation coefficient was 0.0 for all QPR scales.

Insert Table 3 here

Table 3 also shows that high participation teams also had more improvements on two secondary outcomes – HoNOS (becoming non-significant after Bonferroni adjustment) and GAF. No other effect on secondary outcomes was found.

To understand why recovery-supporting relationships may have improved in teams whose staff participated more in the intervention, our process evaluation investigated staff changes in recovery knowledge (RKI; average cluster size 10, range 4 to 18), attitudes towards mental illness (MICA; average cluster size 10, range 5 to 17) and self-rated fidelity (average cluster size 9, range 4 to 16) (Table 4). Intra Cluster Correlation was 0·0 for all measures.

Insert Table 4 here

Participation level by staff was not associated with adjusted follow-up scores on MICA and RKI. High staff participation was however associated with self-rated pro-recovery behaviour ($chi^2(2)=10{\cdot}92$, $p={\cdot}004$). Specifically, intervention team staff with higher participation reported significantly higher scores for pro-recovery behaviours than low-participating staff.

Service use information was analysed for a subsample of 266 patients due to data availability. Service use in the six months prior to baseline and in the six months prior to one-year follow-up showed a high level of contact with GPs and care coordinators (Table 5). The intensity of the use of some services at baseline and follow-up showed large variation, for example number of contacts with occupational therapists rose from 8 to 50 in the intervention arm, but this was for a small number of participants. Around two-thirds had contacts with psychiatrists at baseline, but this fell slightly to 55% for the intervention group by follow-up. Around one-quarter of participants in both groups had contacts with support workers during each period. At baseline around a half had day care contacts, falling to 38% for both groups by follow-up.

Insert Table 5 here

The mean intervention cost was £120 (Appendix Table 8), but this varied from £22 to £357. The most expensive service was psychiatric inpatient care even though this was used by relatively few participants (6% control group, 4% intervention group). Total service use costs were lower for intervention group participants at both baseline (£2,997 vs. £3,754) and follow-up (£2,752 vs. £3,853). Adjusting for baseline, the cost difference between intervention and control groups was £1,062 (95% CI, -£1,103 to £3,017), i.e. receiving the intervention was associated with lower costs, but the difference was not statistically significant. Patients in the high participation intervention teams had services costs that were on average £657 less than patients in low participation intervention teams, but again this was not statistically significant (95% CI, -£1,555 to £4,783). As there was no significant difference in either cost or primary outcome, further cost-effectiveness analysis was not undertaken.

Discussion

In this two-site cluster randomised controlled trial we evaluated a team-level intervention in 27 community adult mental health teams. There was no effect on the primary outcome of recovery. Most secondary outcomes did not differ, with the exceptions of improvements in the intervention group for functioning (which remained after adjusting for multiple testing) and staff-rated unmet need (which was not significant after adjusting). Although there was no evidence of changes in staff knowledge, skills or attitudes, self-reported pro-recovery behaviours did increase in staff with high participation (compared to those with low participation). Consistent with this, patients in high-implementing teams had higher scores on QPR Interpersonal sub-scale than patients in low-implementing teams. Finally, the intervention was associated with lower costs, but the difference was not statistically significant.

Why was no improvement shown in the primary outcome of recovery? Four explanations can be considered. First, and the explanation we favour, is that the intervention was inadequately implemented. Staff participation (i.e. both physical presence and full engagement in training) was self-rated by (unavoidably unblinded) staff who may therefore have been susceptible to social desirability bias, i.e. rating fuller engagement than was actually experienced. The bias may be modest, because there is no obvious reason why it would not have an equivalent impact across all intervention arm staff, thus introducing an inflation rather than a bias. Also, the outcome measure was patient-rated. Noting this possibility of bias, however, the study showed that where staff participated more, there was an increase in self-reported pro-recovery behaviours and patient-reported recovery in the relationships sub-scale of the QPR. A qualitative process evaluation nested in the trial investigated the experiences of staff,[28] and found evidence that implementation barriers occurred at the individual, team and organisation level. A recent Cochrane review has shown that implementation of treatment guidelines within specialist mental health services is often poor.[29] Implementation of evidence-based interventions in routine practice face three 'translational roadblocks': adoption in principle, early implementation and persistence of implementation.[30] Although policy supports the implementation of pro-recovery intervention (adoption in principle), this may not lead to early implementation. Broader implementation strategies are needed, including leadership and organisational culture.[31]

Second, the REFOCUS Intervention may be ineffective in its primary aim of improving personal recovery within the one-year time frame of the intervention. Indeed, the original REFOCUS Intervention was 18 months, and needed to be shortened due to trial recruitment issues. Participants had been using mental health services for an average of more than 15 years, suggesting settled staff-patient relationships. Other studies have showed that trusting relationships with staff can take longer to form than possible in a time-limited intervention.[32] Future research might evaluate the REFOCUS intervention with an inception cohort of new referrals to the team, to test the impact on staff-patient relationships which are less established. Similarly, comparison between different groups of workers (e.g. multidisciplinary versus unidisciplinary teams, teams with versus without peer support workers) would allow contamination at the level of staff and any interaction between worker profession and implementation to be investigated.

Third, existing practice of control group staff may have already been pro-recovery. Control group staff received no formal training through REFOCUS, and although the intervention manual was available to download, we found no evidence of difference in primary outcome in either arm, and little evidence of contamination due to staff movement. For example, many staff in SLaM teams in both arms would previously have received some recovery training,[33] so sustained changes in control group cannot be excluded. However, the recovery orientation of participating teams as measured by RKI (control mean 2·94, intervention mean 2·97) was lower than the mean RKI score of 3·94 found in an Australian study,[34] suggesting there was not a high recovery orientation at baseline.

Finally, although the choice of endpoint assessment was based on recommendations from a systematic review,[19] the QPR has not previously been used as a primary outcome in a trial and its sensitivity to change has not been fully established, raising the possibility of an insufficiently responsive measure failing to detect change. One perspective which has been advanced is that evaluation of the process of recovery using the outcome-oriented methods of evidence-based medicine is intrinsically problematic, and more sociological approaches are needed.[35] In an unpublished qualitative evaluation of the experience of patient participants in the trial, effective implementation was associated with positive changes in process (more open and collaborative relationships with staff), hope and empowerment, highlighting the challenges of

capturing the impact of complex interventions. As a minimum, further psychometric evaluation of QPR and other candidate recovery measures is indicated.

In relation to the protocol,[14] this report addresses Objective 1 (intervention effectiveness). Other objectives are addressed elsewhere: Objective 2 (Validation of the REFOCUS Model) in published[36] and submitted process evaluation papers; Objective 3 (Optimise trial parameters) through this trial report and a revised intervention manual;[37] and Objective 4 (the relationship between clinical and recovery outcomes) in a submitted paper. The main protocol deviation was that efforts to estimate researcher blinding at follow-up were abandoned, when it became clear that being blind to team (i.e. allocation status) was logistically not possible for the researchers.

We identify several strengths. The intervention is theory-based, and the mixed-methods evaluation in routine clinical settings across two sites included a range of quantitative and qualitative approaches to understanding fidelity, intermediate processes, and outcome. The clinical population is representative, although the inclusion criterion of clinical judgement about being well enough (to allow consideration of the full range of reasons why being approached to participate may not be appropriate) and the relatively good social functioning indicated by GAF and HoNOS scores indicate that the most disabled people on the caseload may not have participated. The full range of adult mental health teams typically provided in NHS Trusts was included, which maximises representativeness. One limitation is the absence of a pilot study to inform implementation, which might have identified in advance the practice change challenges found in this trial: high staff turnover within teams with low morale as a consequence of significant reorganisation taking place across both Trusts. Applying a structured assessment of feasibility,[36] indicates that the intervention involves several implementation barriers, including staff training, complexity, human resources and staff time. We identified organisational leadership and stability plus readiness to change at team level as predictors of implementation,[28] which could provide criteria for inclusion of high-implementing teams in future evaluations. A second limitation is the recruitment shortfall. The analysable sample comprised 297 against a target of 336, primarily due to a higher-than-anticipated 26% (106/403) patient attrition rate at follow-up. Achievement of an 88% target may mean the study was under-powered to detect difference. Third, the design did not stratify by team type, raising the possibility of differential implementation across different team types. The relationship between team type and outcome was not

analysed in this study because of the uneven allocation and because categories were derived from team name and may therefore be overlapping, but future trials might more formally establish team type and either use a homogenous sample or stratify by team type.

The study contributes to a wider context (Panel), and has a number of clinical implications. From the staff perspective, efforts to support recovery may lead to improved functioning and may also reduce unmet need for people with psychosis (though not from the patient perspective). It is plausible that conversations between staff and patients about values, treatment preferences, and strengths will translate over time into changes in functioning and assessed need. In this study the observed differences do not seem to have been mediated through changes in the recovery variables studied, indicating a complex relationship between these variables. If the positive impact in high-participating teams is not due to staff bias in rating implementation, then the REFOCUS Intervention has the potential to be an effective pro-recovery intervention, if implementation barriers can be addressed. At the societal level, anti-stigma campaigns have been found to make attainment of valued social roles more possible.[38] Within mental health services, the challenge may be to embed as an organisational culture an expectation of partnership-based staff-patient relationships and a focus on the values and treatment preferences, strengths and goals of patients. Fully supporting recovery may therefore require interventions across the whole mental health service, including the patient as an active partner and involving a combination of evidence-based patient-level interventions,[5] team-level interventions such as REFOCUS, and organisational transformation approaches.[39]

Insert Panel here

Acknowledgements

We thank the REFOCUS advisory committees for sharing their expertise and the REFOCUS research team at 2gether NHS Foundation Trust for help with data collection. We acknowledge the support of the NIHR Mental Health Research Network. This article presents independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research (PGfAR) Programme (Grant Reference Number RP-PG-0707-10040), and in relation to the NIHR Biomedical Research Centre for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London. The project will be published in full in the NIHR PGfAR journal. The views expressed in this publication are those of the authors, and the views and opinions expressed by interviewees are those of the interviewees, and do not necessarily reflect those of the NHS, the NIHR, MRC, CCF, NETSCC, the PGfAR programme or the Department of Health. Further information available at researchintorecovery.com/refocus.

Disclosure of interest

VB, CL, ML and JW are funded by a National Institute for Health Research (NIHR) Programme Grant for Applied Research. MS is supported by the NIHR Biomedical Research Centre for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London. VB does consultancy for the National Collaborating Centre for Mental Health. No author, within the past 3 years, and with a relevant company or competitor, has any stocks or shares, equity, a contract of employment, or a named position on a relevant company board or competitor. No author has been asked by any organisation other than The Lancet to write, be named on, or to submit this paper. No author directly benefits financially from this submission.

Author contributions

MS was Principal Investigator, ML Programme Co-ordinator and RM site lead. VB, EC, CLB, GW and JW contributed to design and data collection. FP and PM led data analysis. All authors made a substantial contribution to the drafting of the manuscript, revising it critically for important intellectual content, and gave final approval of the version to be published.

Ethics committee approval

Ethical approval was obtained (East London REC 3, 11/LO/0083).

References

1. HM Government. No health without mental health. Delivering better mental health outcomes for people of all ages. London: Department of Health; 2011.
2. Mehta N, Croudace, T., Davies, S. Public mental health: evidenced-based priorities. *Lancet* 2014; **doi:10.1016/S0140-6736(14)61400-8**.
3. Anthony WA. Recovery from mental illness: the guiding vision of the mental health system in the 1990s. *Psychosocial Rehabilitation Journal* 1993; **16**: 11-23.
4. Slade M, Williams J, Bird V, Leamy M, Le Boutillier C. Recovery grows up. *Journal of Mental Health* 2012; **21**(2): 99-103.
5. Slade M, Amering, M., Farkas, M., Hamilton, B., O'Hagan, M., Panther, G., Perkins, R., Shepherd, G., Tse, S., Whitley, R. . Uses and abuses of recovery: implementing recovery-oriented practices in mental health systems. *World Psychiatry* 2014; **13**: 12-20.
6. Australian Government. Partners In Recovery: Coordinated support and flexible funding for people with severe, persistent mental illness and complex needs initiative. Canberra: Department of Health and Ageing; 2012.
7. Morrison AP, Turkington, D., Pyle, M., Spencer, H., Brabban, A, Dunn, G., Christodoulides, T., Dudley, R., Chapman, N., Callcott, P., Grace, T., Lumley, V., Drage, L., Tully, S., Irving, K., Cummings, A., Byrne, R., Davies, L.M., Hutton, P. Cognitive therapy for people with schizophrenia spectrum disorders not taking antipsychotic drugs: a single-blind randomised controlled trial. *Lancet* 2014; **383**: 1395-403.
8. Shepherd G, Boardman, J., Rinaldi, M., Roberts, G. ImROC Briefing paper 8. Supporting recovery in mental health services: Quality and Outcomes. London: Implementing Recovery through Organisational Change; 2014.
9. Bird V, Leamy M, Le Boutillier C, Williams J, Slade M. REFOCUS: Promoting recovery in community mental health services. London: Rethink (researchintorecovery.com/refocus); 2011.
10. Ajzen I. The theory of planned behaviour: reactions and reflections. *Psychol Health* 2011; **26**(9): 1113-27.
11. McEachan RRC, Conner M, Taylor NJ, Lawton RJ. Prospective prediction of health-related behaviours with the Theory of Planned Behaviour: a meta-analysis. *Health Psychology Review* 2011; **5**(2): 97-144.
12. Le Boutillier C, Leamy M, Bird VJ, Davidson L, Williams J, Slade M. What does recovery mean in practice? A qualitative analysis of international recovery-oriented practice guidance. *Psychiatr Serv* 2011; **62**: 1470-6.
13. Medical Research Council. A framework for development and evaluations of RCTs for complex interventions to improve health. London MRC; 2000.
14. Slade M, Bird V, Le Boutillier C, Williams J, McCrone P, Leamy M. REFOCUS Trial: protocol for a cluster randomised controlled trial of a pro-recovery intervention within community based mental health teams. *BMC Psychiatry* 2011; **11**: 185.
15. Department of Health. Effective care co-ordination in mental health services. London: HMSO; 1999.

16. Le Boutillier C, Slade, M., Lawrence, V., Bird, V., Chandler, R., Farkas, M., Harding, C., Larsen, J., Oades, L., Roberts, G., Shepherd, G., Thornicroft, G., Williams, J., Leamy, M.,. Competing priorities: staff perspectives on supporting recovery. *Administration and Policy in Mental Health and Mental Health Services Research* in press.
17. Grey B, Bailey, S., Leamy, M., Slade, M. REFOCUS Coaching Conversations for Recovery. Participant Manual. London: Slam Partners; 2014.
18. Neil S, Kilbride M, Pitt L, et al. The questionnaire about the process of recovery (QPR): A measurement tool developed in collaboration with service users. *Psychosis* 2009; **1**: 145-55.
19. Shanks V, Williams J, Leamy M, Bird VJ, Le Boutillier C, Slade M. Measures of Personal Recovery: A Systematic Review. *Psychiatr Serv* 2013; **64**: 974-80.
20. Pitt L, Kilbride M., Nothard, S., Welford, M., Morrison, A. Researching recovery from psychosis: a user-led project. *Psychiatric Bulletin* 2007; **31**: 55-60.
21. Law H, Neil, S., Dunn, G., Morrison, A. Psychometric properties of the Questionnaire about the Process of Recovery (QPR). *Schizophrenia Reseach* 2014: http://dx.doi.org/10.1016/j.schres.2014.04.011.
22. Machin D, Campbell, M., Tan, S., Tan, S. Sample size tables for clinical studies, 3rd edition. Chichester: Wiley-Blackwell; 2008.
23. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. *Stat Med* 2011; **30**(4): 377-99.
24. Egbewale BE, Lewis M, Sim J. Bias, precision and statistical power of analysis of covariance in the analysis of randomized trials with baseline imbalance: a simulation study. *BMC medical research methodology* 2014; **14**: 49.
25. Moye LA. Alpha calculus in clinical trials: considerations and commentary for the new millennium. *Stat Med* 2000; **19**(6): 767-79.
26. Slade M. Personal Recovery and Mental Illness. Cambridge;: Cambridge University Press.; 2009.
27. Curtis L. Unit costs of health and social care. Canterbury: PSSRU; 2013.
28. Leamy M, Clarke, E., Le Boutillier, C., Bird, V., Janosik, M., Sabas, K., Riley, G., Williams, J., Slade, M. Implementing a complex intervention to support personal recovery: A qualitative study nested within a cluster randomised controlled trial. *PLoS One* 2014; **9**: e97091.
29. Barbui C, Girlanda F, Ay E, Cipriani A, Becker T, Koesters M. Implementation of treatment guidelines for specialist mental health care. *Cochrane Database Syst Rev* 2014; **1**: CD009780.
30. Tansella M, Thornicroft G. Implementation science: understanding the translation of evidence into practice. *British Journal of Psychiatry* 2009; **195**: 283-5.
31. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science* 2009; **4**.
32. Tondora J, O'Connell M, Miller R, et al. A clinical trial of peer-based culturally responsive person-centered care for psychosis for African Americans and Latinos. *Clinical Trials* 2010; **7**(4): 368-79.

33. Gilburt H, Slade M, Bird V, Oduola S, Craig TK. Promoting recovery-oriented practice in mental health services: a quasi-experimental mixed-methods study. *BMC Psychiatry* 2013; **13**: 167.
34. Meehan T, Glover H. Using the Recovery Knowledge Inventory (RKI) to Assess the Effectiveness of a Consumer-Led Recovery Training Program for Service Providers. *Psychiatric Rehabilitation Journal* 2009; **32**(3): 223-6.
35. Watson DP. The Evolving Understanding of Recovery: What the Sociology of Mental Health has to Offer. *Humanity & society* 2012; **36**(4): 290-308.
36. Bird V, Le Boutillier, C., Leamy, M., Williams, J., Bradstreet, S., Slade, M. . Evaluating the feasibility of complex interventions in mental health services: standardised measure and reporting guidelines. *Br J Psychiatry* 2014; **204**: 316-21.
37. Bird V, Leamy, M., Le Boutillier, C., Williams, J., Slade, M. REFOCUS (2nd edition): Promoting recovery in mental health services. London: Rethink Mental Illness; 2014.
38. Evans-Lacko S, Corker, E., Williams, P., Henderson, C., Thornicroft, G. Effect of the Time to Change anti-stigma campaign on trends in mental-illness-related public stigma among the English population in 2003—13: an analysis of survey data. *Lancet Psychiatry* 2014; **1**(2): 121-8.
39. Shepherd G, Boardman J, Burns M. Implementing Recovery. A methodology for organisation change. London: Sainsbury Centre for Mental Health; 2010.
40. Leamy M, Bird V, Le Boutillier C, Williams J, Slade M. A conceptual framework for personal recovery in mental health: systematic review and narrative synthesis. *Br J Psychiatry* 2011; **199**: 445-52.
41. Bird V, Leamy, M., Tew, J., Le Boutillier, C., Williams, J., Slade, M. . Fit for purpose? Validation of the conceptual framework of personal recovery with current mental health service users. *Aust N Z J Psychiatry* 2014; **48**: 644-53.
42. Slade M, Leamy M, Bacon F, et al. International differences in understanding recovery: systematic review. *Epidemiology and Psychiatric Sciences* 2012; **21**: 353-64.
43. Bird V, Le Boutillier C, Leamy M, et al. Assessing the strengths of mental health service users - systematic review. *Psychological Assessment* 2012; **24**: 1024-33.
44. Williams J, Leamy, M., Bird, V., Le Boutillier, C., Norton, S., Pesola, F., Slade, M. Development and evaluation of a measure to identify mental health service support for recovery (INSPIRE). *Soc Psychiatry Psychiatr Epidemiol* in press.
45. Williams J, Leamy M, Bird V, et al. Measures of the recovery orientation of mental health services: systematic review. *Soc Psychiatry Psychiatr Epidemiol* 2012; **47**: 1827-35.
46. Tew J, Ramon S, Slade M, Bird V, Melton J, Le Boutillier C. Social factors and recovery from mental health difficulties: a review of the evidence. *British Journal of Social Work* 2012; **42**: 443-60.

		Control	Intervention
SOCIODEMOGRAPHICS		*n (%)*	*n (%)*
Gender	Male	127 (66%)	131 (63%)
	Female	66 (34%)	78 (37%)
Ethnicity	White	95 (49%)	115 (56%)
	Non-white	98 (51%)	92 (44%)
Accommodation	Owned/rented	22 (12%)	48 (23%)
	Supported	168 (88%)	161 (73%)
Relationship	Single	158 (82%)	151 (72%)
	In a relationship	35 (18%)	59 (28%)
Education	Secondary	95 (50%)	111 (54%)
	Higher education	96 (50%)	96 (46%)
		mean (s.d.)	*mean (s.d.)*
Age (years)		42·99 (11.56)	44·87 (10.22)
Use of mental health services (years)		15.52 (10.89)	16·13 (11·49)
PATIENT-RATED OUTCOME MEASURES			
QPR (n=365)	Total	38·97 (9·10)	38·53 (9·31)
	Intrapersonal	43·95 (10·10)	43·77 (10·18)
	Interpersonal	12·94 (2·67)	13·55 (2·43)
CANSAS-P Met (n=390)		3·66 (2·82)	3·98 (3·33)
CANSAS-P Unmet (n=390)		3·58 (2·79)	3·54 (3·01)
HHI (n=362)		35·92 (4·94)	35·25 (4·81)
MANSA (n=275)		4·60 (0·88)	4·75 (0·97)
MHCS (n=335)		66·38 (14·63)	65·23 (14·40)
WEMWBS (n=373)		46·68 (10·36)	47·39 (9·51)
PATIENT-RATED EXPERIENCE MEASURES			
CSQ (n=380)		25·51 (5·08)	25·24 (5·25)
INSPIRE Relationship (n=377)		76·76 (14·95)	77·77 (17·55)
INSPIRE Support (n=396)		59·39 (20·68)	65·41 (21·48)
STAFF-RATED OUTCOME MEASURES			
BPRS (n=349)		31·90 (9·17)	33·63 (10·13)
CANSAS-S met (n=387)		5·74 (3·52)	5·80 (3·67)
CANSAS-S unmet (n=387)		3·50 (2·79)	3·19 (2·82)
GAF (n=379)		64·15 (14·84)	64·66 (13·88)
HoNOS (n=366)		10·45 (6·44)	8·05 (5·08)
PROCESS EVALUATION MEASURES			
RKI		2·94 (0·40)	2·97 (0·38)
MICA		31·37 (6·96)	30·47 (6·96)
RPS			
Skills		2·73 (0·66)	2·79 (0·64)
Behavioural Intent		1·68 (0·37)	1·66 (0·34)
Behaviour		1·74 (0·77)	1·78 (0·78)

Table 1. Baseline sociodemographic and clinical characteristics (n=403)

	Regression		ICC
	b, p-value	(95%C.I.)	
PATIENT-RATED OUTCOME MEASURES			
QPR Total	0·63, p=·55	(-1·41 to 2·67)	0
QPR Interpersonal	0·13, p=·75	(-0·93 to 0·67)	·05
QPR Intrapersonal	0·49, p=·44	(-1·71 to 2·70)	0
CANSAS-P Met	0·43, p=·43	(-0·63 to 1·49)	·10
CANSAS-P Unmet	-0·31, p=·41	(-1·04 to 0·42)	·03
HHI	0·65, p=·30	(-0·59 to 1·88)	·03
MANSA	-0·04, p=·73	(-0·27 to 0·19)	·01
MHCS	2·00, p=·23	(-1·23 to 5·22)	·03
WEMWBS	0·76, p=·51	(-1·50 to 3·01)	·01
PATIENT-RATED EXPERIENCE MEASURES			
CSQ	0·71, p=·20	(-0·38 to 1·79)	0
INSPIRE Support	-2·43, p=·41	(-8·22 to 3·36)	·01
INSPIRE Relationship	-0·39, p=·86	(-4·66 to 3·88)	0
STAFF-RATED OUTCOME MEASURES			
BPRS	-1·85, p=·15	(-4·37 to 0·66)	·12
CANSAS-S Met	0·07, p=·91	(-1·29 to 1·16)	·13
CANSAS-S Unmet	**-0·80, p=·03**	(-1·52 to -0·65)	·10
GAF	**5.90, p<·001**	(2.61 to 9·18)	·01
HONOS	-1·21, p=·07	(-2·53 to 0·10)	·04

Table 2: ITT comparison between full imputed arms at follow-up, adjusted for baseline scores and wave (n= 397; 190 control, 207 intervention)

	Control	Intervention		Overall Wald test	Control vs. Low	Control vs. High	Low vs. High
		Low participation	High participation				
	n=144	n=67	n=74		b, p-value (95%CI)		
QPR Total mean (s.e)	40·01 (0·59)	40·74 (1·08)	41·30 (0·96)	$chi^2(2)=1·6$, p=·46	0·74, p=·55 (-1·70 to 3·18)	1·29, p=·26 (-0·94 to 3·53)	-0·56, p=·73 (-3·77 to 2·66)
QPR Interpersonal mean (s.e)	13·54 (0·20)	12·82 (0·37)	14·39 (0·33)	$chi^2(2)=8·2$, p=·02	-0·72, p=·09 (-1·54 to 0·11)	**0·85, p=·03 (0·09 to 1·62)**	**-1·57, p=·005 (-2·66 to -0·48)**
QPR Intrapersonal mean (s.e)	45·36, (0·65)	46·18 (1·18)	46·58 (1·06)	$chi^2(2)=1·2$, p=·54	0·82, p=·60 (-1·87 to 3·50)	1·21, p=·33 (-1·24 to 3·67)	-0·40, p=·83 (-3·93 to 3·14)
HoNOS	*n=168* 10·1, 0·41	*n=59* 7·8, 0·79)	*n=78* 10·1, 0·67)	$chi^2(2)=6·71$ p=·03	**-2·32, p=·01 (-4·08 to ·56)**	-·04, p=·96 (-1·60 to 1·51)	**-2·36, p=·041 (-4·62 to -·10)**
GAF	*n=169* 62·3, 1·07	*n=53* 67·1, 2·17)	*n=82* 69·3, 1·76)	$chi^2(2)=14·6$ p<·001	4.8, p=.051 (-·01 to 9·58)	**-7·0 p=·001 (-11·07 to 2·98)**	-2·24, p=·47 (-8·31 to 3·82)

Table 3: Association between team-level participation and patient-rated recovery, adjusted for baseline (n=285)

	Control	Intervention		Overall	Control vs. Low	Control vs. High	Low vs. High
		Low participation	High participation	Wald test			
	n mean (s.e.)	n mean (s.e.)	n mean (s.e.)		b, p-value (95%CI)		
RKI	129 2·92 (·03)	72 2·89 (·04)	56 2·99 (·04)	$chi^2(2)=3·0$ p=·23	-0·03, p=·49 (-0·12 to 0·06)	0·06, p=·22 (-0·04 to 0·16)	-0·09, p=·09 (-0·20 to 0·01)
MICA	131 30·12 (·55)	72 30·78 (·73)	58 30·65 (·82)	$chi^2(2)=0·6$ p=·75	0·66, p=·48 (-1·16 to 2·49)	0·53, p=·60 (-1·46 to 2·52)	0·13, p=·90 (-2·02 to 2·29)
RPS							
Skills	114 2·87 (·06)	66 2·74 (·08)	50 2·95 (·09)	$chi^2(2)=3·5$ p=·17	-0·14, p=·16 (-0·33 to 0·05)	0·07, p=·33 (-0·14 to 0·29)	-0·21, p=·08 (-0·45 to 0·02)
Behavioural intent	114 1·67 (·03)	66 1·60 (·04)	50 1·68 (·05)	$chi^2(2)=2·2$ p=·33	-0·07, p=·18 (-0·18 to 0·03)	0·01, p=·87 (-0·11 to 0·13)	-0·08, p=·21 (-0·21 to 0·05)
Behaviour	114 1·80 (·07)	66 1·54 (·09)	50 1·97 (·10)	$chi^2(2)=10·9$ p=·004	**-0·26, p=·02** **(-0·48 to -0·05)**	0·16, p=·18 (-0·08 to 0·40)	**-0·43, p=·001** **(-0·69 to -0·16)**

Table 4: Adjusted follow-up scores for staff-rated knowledge, attitudes and behaviour compared between levels of staff participation

	n (%) using service				Mean (SD) contacts of those using the service			
	Baseline		Follow-up		Baseline		Follow-up	
Service	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**
GP	98 (77)	116 (84)	104 (82)	115 (83)	3·7 (4·0)	3·5 (3·3)	3·3 (5·0)	3·2 (3·1)
Care coordinator	125 (98)	129 (93)	113 (89)	113 (81)	14·9 (13·0)	10·4 (7·7)	12·1 (12·9)	8·2 (7·1)
Psychiatrist	77 (61)	92 (66)	82 (65)	76 (55)	2·6 (2·8)	2·9 (3·1)	2·4 (2·1)	2·3 (2·5)
Other doctor	27 (21)	29 (21)	18 (14)	23 (17)	5·6 (17·0)	2·3 (1·4)	2·1 (1·1)	2·6 (2·2)
Psychologist	21 (17)	15 (11)	17 (13)	12 (9)	8·6 (10·0)	8·1 (8·8)	10·4 (9·7)	6·0 (7·0)
Social worker	13 (10)	14 (10)	3 (2)	9 (7)	3·9 (3·8)	8·1 (8·5)	13·3 (9·5)	6·9 (7·4)
Nurse	16 (13)	13 (9)	21 (17)	20 (14)	19·9 (44·0)	6·6 (6·9)	18·0 (37·8)	14·2 (39·1)
Occupational therapist	13 (10)	10 (7)	10 (8)	4 (3)	8·5 (10·5)	7·8 (10·2)	5·4 (7·5)	49·5 (87·3)
Support worker	32 (25)	30 (22)	32 (25)	29 (21)	24·4 (21·6)	29·3 (47·1)	57·6 (64·2)	45·2 (60·1)
Vocational worker	8 (6)	18 (13)	9 (7)	11 (8)	4·8 (7·5)	5·4 (6·1)	29·3 (58·5)	4·1 (4·8)
Drug and alcohol advisor	5 (4)	6 (4)	4 (3)	5 (4)	15·0 (18·9)	4·7 (4·3)	18·5 (20·4)	14·0 (12·5)
Other therapist	11 (9)	8 (6)	5 (4)	7 (5)	27·5 (53·4)	13·0 (11·9)	16·4 (13·1)	9·7 (8·2)
Psychiatric inpatient	10 (8)	13 (9)	7 (6)	6 (4)	44·0 (50·8)	30·6 (20·8)	67·3 (65·3)	59·7 (75·1)
Physical inpatient	6 (5)	6 (4)	13 (10)	7 (5)	3·4 (4·0)	3·5 (2·3)	7·7 (16·3)	6·0 (7·1)
Specialist team	16 (13)	12 (9)	10 (8)	7 (5)	20·9 (34·3)	14·3 (19·3)	13·0 (10·6)	9·6 (9·5)
Day care	57 (45)	72 (52)	48 (38)	53 (38)	28·9 (31·3)	36·0 (61·4)	35·7 (42·9)	36·3 (45·1)

Table 5. Service use in the six months prior to baseline and the six months prior to one-year follow-up (n=266)

Systematic review

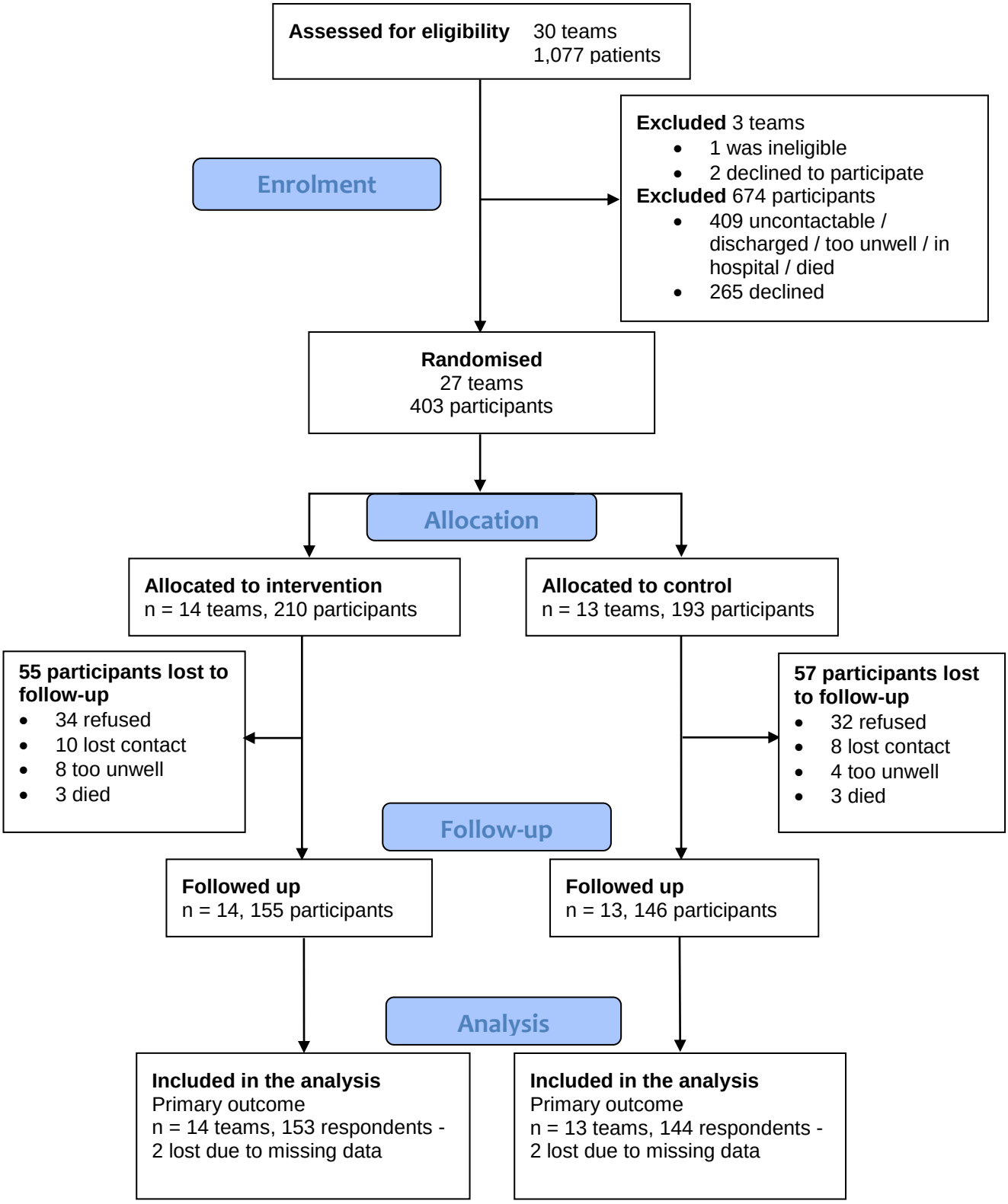
The REFOCUS Intervention is a manualised team-level intervention to improve mental health service support for recovery.[9] The development of the REFOCUS Intervention was informed by primary research and secondary systematic reviews addressing knowledge gaps. To undersand how recovery is supported, we completed an inductive, semantic-level thematic analysis of 30 international documents describing best pro-recovery practice which identified four practice domains.[12] The REFOCUS Intervention targets the Supporting Recovery and Working Relationships practice domains, and does not target the Promoting Citizenship and Organisational Commitment practice domains. To identify recovery processes to target through the intervention, we published a systematic review involving database searching (AMED, BNI, EMBASE, MEDLINE, PsycINFO, SSP, CINAHL, IBSS, ASSIA, BHI, sociological abstracts, SSA, all searched inception-2009), hand-searching of 3 journals web-based searching.[40] After rating using established quality assessment tools, narrative synthesis identified the recovery processes of Connectedness, Hope, Identity, Meaning and Empowerment: the CHIME Framework. The framework was subsequently validated with current service users[41] and cross-culturally.[42] To identify the best measure to use in WP2 (Strengths assessment) we systematically reviewed measures of strengths.[43] To identify the optimal primary outcome we systematically reviewed measures of recovery.[19] To inform the development of the new INSPIRE measure[44] we systematically reviewed measures of recovery support.[45] To understand staff perspectives, we developed a grounded theory of staff experiences of supporting recovery.[16] To maximise the feasibility of the intervention, we developed a new measure of feasibility based on implementation science research.[36] Based on this empirical work, and an understanding of social influences on recovery,[46] we used expert consultation with patients, carers, staff and researchers (n=56) to develop the REFOCUS Intervention, the REFOCUS Model[9] and the choice of secondary outcomes in the REFOCUS Trial.[14]

Interpretation

The REFOCUS Trial evaluated REFOCUS, a team-level intervention with an empirically-supported theory base for patients with psychosis in routine mental health services. The most likely explanation for the negative finding in relation to improving recovery is inadequate implementation, because higher level staff participation led to more staff-rated pro-recovery behaviour and improved interpersonal aspects of patient-rated recovery. The trial findings indicate that attention needs additionally to be paid to the Organisational Commitment practice domain, to maximise the extent to which supporting recovery is organisationally viewed as ‘core business’ rather than an additional task for mental health services.

Panel: Research in context

Figure 1: Flow Diagram for REFOCUS trial



Supplementary materials

Study Team and Collaborators

Applicants
Mike Slade (PI), Tom Craig, Gyles Glover, Morven Leese, Paul McCrone, Vanessa Pinfold, Shula Ramon, Zoe Reed, Geoff Shepherd, Jerry Tew, Graham Thornicroft, John Weinman

2Gether site lead
Rob Macpherson

Programme Co-ordinator
Mary Leamy

SLaM Research workers
Victoria Bird, Agnès Chevalier, Eleanor Clarke, Harriet Jordan, Clair Le Boutillier, Genevieve Williams, Julie Williams

SLaM University placement students
Faye Bacon, Ben Fortune, Monika Janosik, Matt Long, Kai Sabas.

2Gether Research workers
Sophie Brett, Kevanne Sanger, Clare Whitehead, Katie Yearsley.

2Gether Mental Health Research Network Clinical Studies Officers
Alison Harding, Emma Page, Genevieve Riley.

2Gether Steering Group
Jason Bloodworth, Raj Choudhury, Lyn Crooks, Faisal Khan, Irene Philpott, Andrew Telford, Les Trewin.

Statistician
Fran Pesola.

Administrative support
Deborah Kenny, Becks Leslie, Elaine Webb.

Trial Steering Committee
Sonia Johnson (Chair), Nora Donaldson (statistician), Pauline Edwards, Caroline Cuppitt.

ADVISORY COMMITTEES
1. REFOCUS Steering group
Rachel Churchill, Tony Coggins, Joanna Fox, John Larsen, Rachel Perera, Rachel Perkins, Gabrielle Richards, Guy Saward, Lynne Turner-Stokes.

2. International Advisory Board
Glenn Roberts, Mark Hayward, Michael Clark, Simon Bradstreet, Tom O'Brien, Larry Davidson, Lindsay Oades, Marianne Farkas, Courtenay Harding.

3. Lived Experience Advisory Panel (LEAP)
8 people who have experience of either using mental health services or caring for someone who has used services.

4. Black and Minority Ethnic Virtual Consultation Panel
12 members including researchers, clinicians and service users either from black backgrounds or with extensive experience of working with individuals from black backgrounds.

Link to study protocol
http://www.biomedcentral.com/1471-244X/11/185

Link to study protocol published on the authors' institutional website

https://kclpure.kcl.ac.uk/portal/en/publications/refocus-trial-protocol-for-a-cluster-randomised-controlled-trial-of-a-prorecovery-intervention-within-community-based-mental-health-teams%28a9b855a2-6a38-49c0-b268-94dd9d781e9b%29.html

Measure	Name and reference	Items	Range	Desirable score
PATIENT-RATED OUTCOME MEASURES				
QPR	Questionnaire about the Process of Recovery[18,21]			
	QPR Interpersonal	17	0 to 4	High
	QPR Intrapersonal	5	0 to 4	High
	QPR Total	15	0 to 4	High
CANSAS-P	Camberwell Assessment of Needs Short Appraisal Schedule – Patient[47]	22	0 to 22	Low
HHI	Herth Hope Index[48]	12	12 to 48	High
MANSA	Manchester Short Assessment of Quality of Life[49]	16	12 to 84	High
MHCS	Mental Health Confidence Scale[50]	16	16 to 96	High
WEMWBS	Warwick-Edinburgh Mental Well-Being Scale[51]	14	14 to 70	High
PATIENT-RATED EXPERIENCE MEASURES				
CSQ	Client Satisfaction Questionnaire[52]	8	8 to 32	High
INSPIRE	INSPIRE[44]	27	0 to 100	High
STAFF-RATED OUTCOME MEASURES				
BPRS	Brief Psychiatric Rating Scale[53]	18	0 to 126	Low
CANSAS-S	Camberwell Assessment of Needs Short Appraisal Schedule - Staff[47]	22	0 to 22	Low
CSRI	Client Service Receipt Inventory[54]			
GAF	Global Assessment of Functioning[55]	2	0 to 100	High
HoNOS	Health of the Nation Outcome Scale[56]	12	0 to 48	Low
PROCESS EVALUATION MEASURES				
RKI	Recovery Knowledge Inventory[57]	20	20 to 100	High
MICA	Mental Illness: Clinicians' Attitudes[58]	16	16 to 96	Low
PS[1]	Participation Scale	3	Very low to Very high	High
RPS[2]	Recovery Practice Scale	15	0 to 310	High

[1] Called 'REFOCUS Implementation Scale (RIS) in protocol. [2] Called Recovery Fidelity Scale (RFS) in protocol.

Appendix Table 1: Description of measures

Reference for measures

1. HM Government. No health without mental health. Delivering better mental health outcomes for people of all ages. London: Department of Health; 2011.
2. Mehta N, Croudace, T., Davies, S. Public mental health: evidenced-based priorities. *Lancet* 2014; **doi:10.1016/S0140-6736(14)61400-8**.
3. Anthony WA. Recovery from mental illness: the guiding vision of the mental health system in the 1990s. *Psychosocial Rehabilitation Journal* 1993; **16**: 11-23.
4. Slade M, Williams J, Bird V, Leamy M, Le Boutillier C. Recovery grows up. *Journal of Mental Health* 2012; **21**(2): 99-103.
5. Slade M, Amering, M., Farkas, M., Hamilton, B., O'Hagan, M., Panther, G., Perkins, R., Shepherd, G., Tse, S., Whitley, R. . Uses and abuses of recovery: implementing recovery-oriented practices in mental health systems. *World Psychiatry* 2014; **13**: 12-20.
6. Australian Government. Partners In Recovery: Coordinated support and flexible funding for people with severe, persistent mental illness and complex needs initiative. Canberra: Department of Health and Ageing; 2012.
7. Morrison AP, Turkington, D., Pyle, M., Spencer, H., Brabban, A, Dunn, G., Christodoulides, T., Dudley, R., Chapman, N., Callcott, P., Grace, T., Lumley, V., Drage, L., Tully, S., Irving, K., Cummings, A., Byrne, R., Davies, L.M., Hutton, P. Cognitive therapy for people with schizophrenia spectrum disorders not taking antipsychotic drugs: a single-blind randomised controlled trial. *Lancet* 2014; **383**: 1395-403.
8. Shepherd G, Boardman, J., Rinaldi, M., Roberts, G. ImROC Briefing paper 8. Supporting recovery in mental health services: Quality and Outcomes. London: Implementing Recovery through Organisational Change; 2014.
9. Bird V, Leamy M, Le Boutillier C, Williams J, Slade M. REFOCUS: Promoting recovery in community mental health services. London: Rethink (researchintorecovery.com/refocus); 2011.
10. Ajzen I. The theory of planned behaviour: reactions and reflections. *Psychol Health* 2011; **26**(9): 1113-27.
11. McEachan RRC, Conner M, Taylor NJ, Lawton RJ. Prospective prediction of health-related behaviours with the Theory of Planned Behaviour: a meta-analysis. *Health Psychology Review* 2011; **5**(2): 97-144.
12. Le Boutillier C, Leamy M, Bird VJ, Davidson L, Williams J, Slade M. What does recovery mean in practice? A qualitative analysis of international recovery-oriented practice guidance. *Psychiatr Serv* 2011; **62**: 1470-6.
13. Medical Research Council. A framework for development and evaluations of RCTs for complex interventions to improve health. London MRC; 2000.
14. Slade M, Bird V, Le Boutillier C, Williams J, McCrone P, Leamy M. REFOCUS Trial: protocol for a cluster randomised controlled trial of a pro-recovery intervention within community based mental health teams. *BMC Psychiatry* 2011; **11**: 185.
15. Department of Health. Effective care co-ordination in mental health services. London: HMSO; 1999.
16. Le Boutillier C, Slade, M., Lawrence, V., Bird, V., Chandler, R., Farkas, M., Harding, C., Larsen, J., Oades, L., Roberts, G., Shepherd, G., Thornicroft, G., Williams, J., Leamy, M.,. Competing priorities: staff perspectives on supporting recovery. *Administration and Policy in Mental Health and Mental Health Services Research* in press.
17. Grey B, Bailey, S., Leamy, M., Slade, M. REFOCUS Coaching Conversations for Recovery. Participant Manual. London: Slam Partners; 2014.

18. Neil S, Kilbride M, Pitt L, et al. The questionnaire about the process of recovery (QPR): A measurement tool developed in collaboration with service users. *Psychosis* 2009; **1**: 145-55.
19. Shanks V, Williams J, Leamy M, Bird VJ, Le Boutillier C, Slade M. Measures of Personal Recovery: A Systematic Review. *Psychiatr Serv* 2013; **64**: 974-80.
20. Pitt L, Kilbride M., Nothard, S., Welford, M., Morrison, A. Researching recovery from psychosis: a user-led project. *Psychiatric Bulletin* 2007; **31**: 55-60.
21. Law H, Neil, S., Dunn, G., Morrison, A. Psychometric properties of the Questionnaire about the Process of Recovery (QPR). *Schizophrenia Reseach* 2014: http://dx.doi.org/10.1016/j.schres.2014.04.011.
22. Machin D, Campbell, M., Tan, S., Tan, S. Sample size tables for clinical studies, 3rd edition. Chichester: Wiley-Blackwell; 2008.
23. White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. *Stat Med* 2011; **30**(4): 377-99.
24. Egbewale BE, Lewis M, Sim J. Bias, precision and statistical power of analysis of covariance in the analysis of randomized trials with baseline imbalance: a simulation study. *BMC medical research methodology* 2014; **14**: 49.
25. Moye LA. Alpha calculus in clinical trials: considerations and commentary for the new millennium. *Stat Med* 2000; **19**(6): 767-79.
26. Slade M. Personal Recovery and Mental Illness. Cambridge;: Cambridge University Press.; 2009.
27. Curtis L. Unit costs of health and social care. Canterbury: PSSRU; 2013.
28. Leamy M, Clarke, E., Le Boutillier, C., Bird, V., Janosik, M., Sabas, K., Riley, G., Williams, J., Slade, M. Implementing a complex intervention to support personal recovery: A qualitative study nested within a cluster randomised controlled trial. *PLoS One* 2014; **9**: e97091.
29. Barbui C, Girlanda F, Ay E, Cipriani A, Becker T, Koesters M. Implementation of treatment guidelines for specialist mental health care. *Cochrane Database Syst Rev* 2014; **1**: CD009780.
30. Tansella M, Thornicroft G. Implementation science: understanding the translation of evidence into practice. *British Journal of Psychiatry* 2009; **195**: 283-5.
31. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science* 2009; **4**.
32. Tondora J, O'Connell M, Miller R, et al. A clinical trial of peer-based culturally responsive person-centered care for psychosis for African Americans and Latinos. *Clinical Trials* 2010; **7**(4): 368-79.
33. Gilburt H, Slade M, Bird V, Oduola S, Craig TK. Promoting recovery-oriented practice in mental health services: a quasi-experimental mixed-methods study. *BMC Psychiatry* 2013; **13**: 167.
34. Meehan T, Glover H. Using the Recovery Knowledge Inventory (RKI) to Assess the Effectiveness of a Consumer-Led Recovery Training Program for Service Providers. *Psychiatric Rehabilitation Journal* 2009; **32**(3): 223-6.
35. Watson DP. The Evolving Understanding of Recovery: What the Sociology of Mental Health has to Offer. *Humanity & society* 2012; **36**(4): 290-308.
36. Bird V, Le Boutillier, C., Leamy, M., Williams, J., Bradstreet, S., Slade, M. . Evaluating the feasibility of complex interventions in mental health services: standardised measure and reporting guidelines. *Br J Psychiatry* 2014; **204**: 316-21.

37. Bird V, Leamy, M., Le Boutillier, C., Williams, J., Slade, M. REFOCUS (2nd edition): Promoting recovery in mental health services. London: Rethink Mental Illness; 2014.
38. Evans-Lacko S, Corker, E., Williams, P., Henderson, C., Thornicroft, G. Effect of the Time to Change anti-stigma campaign on trends in mental-illness-related public stigma among the English population in 2003—13: an analysis of survey data. *Lancet Psychiatry* 2014; **1**(2): 121-8.
39. Shepherd G, Boardman J, Burns M. Implementing Recovery. A methodology for organisation change. London: Sainsbury Centre for Mental Health; 2010.
40. Leamy M, Bird V, Le Boutillier C, Williams J, Slade M. A conceptual framework for personal recovery in mental health: systematic review and narrative synthesis. *Br J Psychiatry* 2011; **199**: 445-52.
41. Bird V, Leamy, M., Tew, J., Le Boutillier, C., Williams, J., Slade, M. . Fit for purpose? Validation of the conceptual framework of personal recovery with current mental health service users. *Aust N Z J Psychiatry* 2014; **48**: 644-53.
42. Slade M, Leamy M, Bacon F, et al. International differences in understanding recovery: systematic review. *Epidemiology and Psychiatric Sciences* 2012; **21**: 353-64.
43. Bird V, Le Boutillier C, Leamy M, et al. Assessing the strengths of mental health service users - systematic review. *Psychological Assessment* 2012; **24**: 1024-33.
44. Williams J, Leamy, M., Bird, V., Le Boutillier, C., Norton, S., Pesola, F., Slade, M. Development and evaluation of a measure to identify mental health service support for recovery (INSPIRE). *Soc Psychiatry Psychiatr Epidemiol* in press.
45. Williams J, Leamy M, Bird V, et al. Measures of the recovery orientation of mental health services: systematic review. *Soc Psychiatry Psychiatr Epidemiol* 2012; **47**: 1827-35.
46. Tew J, Ramon S, Slade M, Bird V, Melton J, Le Boutillier C. Social factors and recovery from mental health difficulties: a review of the evidence. *British Journal of Social Work* 2012; **42**: 443-60.
47. Slade M, Loftus L, Phelan M, Thornicroft G, Wykes T. The Camberwell Assessment of Need. London Gaskell; 1999.
48. Herth K. Abbreviated instrument to measure hope: development and psychometric evaluation. *J Adv Nurs* 1992; **17**: 1251-9.
49. Priebe S, Huxley P, Knight S, Evans S. Application and results of the Manchester Short Assessment of quality of life. *Int J Soc Psychiatry* 1999; **45** 7-12.
50. Carpinello S, Knight E, Markowitz F, Pease E. The development of the mental health confidence scale: A measure of self-efficacy in individuals diagnosed with mental disorders. *Psychiatric Rehabilitation Journal* 2000; **23**: 236-43.
51. Tennant R, Hiller L, Fishwick R, et al. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. *Health and Quality of Life Outcomes* 2007; **5**: 63.
52. Attkisson CC, Zwick R. The Client Satisfaction Questionnaire. *Eval Program Plann* 1982; **5**: 233-7.
53. Overall JE, Gorham DR. The Brief Psychiatric Rating Scale (BPRS): Recent Developments in Ascertainment and Scaling. *Psychopharmacol Bull* 1988; **24** 97-9.
54. Beecham J, Knapp M. Costing psychiatric interventions. In: Thornicroft G, ed. Measuring mental health needs. London: Gaskell; 2001: 200-24.
55. American Psychiatric Association. Diagnostic and statistical manual of mental disorders (4th edn.). Washington DC American Psychiatric Association 1994.

56. Wing JK, Beevor AS, Curtis RH, Park SB, Hadden S, Burns A. Health of the Nation Outcome Scales (HoNOS). Research and Development. *Br J Psychiatry* 1998; **172** 11-8.
57. Bedregal L, O'Connell M, Davidson L. The Recovery knowledge inventory: Assessment of mental health staff knowledge and attitudes about recovery. *Psychiatric Rehabilitation Journal* 2006; **30**: 96-103.
58. Kassam A, Glozier N, Leese M, Thornicroft G. Development and responsiveness of a scale to measure clinicians' attitudes to people with mental illness (medical student version). *Acta Psychiatr Scand* 2010; **122**: 153-61.

Team name	Caseload	Screening list	Patients contacted by researchers	Recruited	Allocation wave	Allocation	Follow-up QPR
SLaM teams	*n*	*n*	*n*	*n*			*n*
Support and Recovery Service (Southbrook Road, Lewisham)	223	147	65	14	SLaM 1	Intervention	12
Support and Recovery Service (Northover, Lewisham)	223	118	35	15	SLaM 1	Control	11
Support and Recovery Service (Speedwell, Lewisham)	201	112	51	15	SLaM 1	Intervention	14
Support and Recovery Service (North East Southwark)	139	100	22	14	SLaM 2	Control	11
Support and Recovery Service (St Giles - Central Southwark)	192	89	72	17	SLaM 2	Intervention	10
Support and Recovery Service (St Giles, North Southwark)	167	107	80	15	SLaM 2	Intervention	9
Support and Recovery Service (St Giles, South Southwark)	185	106	79	15	SLaM 2	Control	13
Community Forensic Team (Southwark)	67?	82	46	14	SLaM 2	Intervention	7
Supported living team (Southwark)	69	35	19	16	SLaM 2	Control	10
Psychosis team East (Croydon)	131	92	58	14	SLaM 3	Control	10
Psychosis team West (Croydon)	177	115	45	16	SLaM 3	Control	10
Recovery and Rehabilitation Service (Croydon)	95	75	36	15	SLaM 3	Control	14
Community Forensic Team (Croydon)	41?	47	27	14	SLaM 3	Intervention	11
Low intensity team (Croydon)	140	104	30	15	SLaM 3	Intervention	12
Community Forensic Team (Lewisham)	119	45	75	14	SLaM 4	Control	11
Support and Recovery Service (South Lambeth)	246	132	35	15	SLaM 4	Intervention	10
Support and Recovery Service (North Lambeth)	281	149	39	15	SLaM 4	Intervention	8
Placement Assessment and Monitoring Service (Lambeth)	151	84	40	15	SLaM 4	Control	8
Gloucester teams							
Stroud Recovery team (1 or 2 cluster)	772	152	18	15	2Gether 1	Intervention	12
Stroud (and Cotswolds) Assertive Outreach team	53	48	19	15	2Gether 1	Control	13
Cheltenham and North Cotswolds recovery team	600	168	20	15	2Gether 1	Intervention	12
Cheltenham and Tewkesbury recovery team	305	65	30	16	2Gether 1	Intervention	11
Cheltenham Assertive outreach team	68	68	35	14	2Gether 1	Control	11
Gloucester Recovery team (1 or 2 cluster)	747	85	26	15	2Gether 2	Intervention	11
Gloucester (and Forest) Assertive Outreach team	103	68	27	15	2Gether 2	Control	11
Forest of Dean Recovery	250	56	28	15	2Gether 2	Intervention	14
GRIP early intervention team	211	110	20	15	2Gether 2	Control	11
Total	**5,848**	**2,559**	**1,077**	**403**			**297**

Appendix Table 2: Recruitment and follow-up by team (n=27)

Dates of wave allocation: SLaM 1: 1.7.11; SLaM 2: 1.10.11; SLaM 3: 1.1.12; SLaM 4: 1.4.12; 2Gether 1: 1.11.11; 2Gether 2: 1.4.12

		Control		Intervention	
	n (%)	n	Mean (s.d.)	n	Mean (s.d.)
PATIENT-RATED OUTCOME MEASURES					
QPR Total	275 (69)	134	39.96 (10·2)	141	40·89 (9·9)
QPR Interpersonal	275 (69)	134	13·46 (2·6)	141	13·81 (2·7)
QPR Intrapersonal	275 (69)	134	45·30 (11·3)	141	46·044(11·5)
CANSAS-P Met	284 (72)	137	3·97 (3·1)	147	4·41 (3·2)
CANSAS-P Unmet	284 (72)	137	3·65 (3·3)	147	3·71 (3·0)
HHI	264 (66)	127	35·51 (5·7)	137	35·66 (5·1)
MANSA	240 (60)	113	4·74 (·92)	127	4·80 (0·95)
MHCS	252 (63)	120	67·26 (13·9)	132	67·20 (15·5)
WEMWBS	268 (68)	128	47·06 (10·2)	140	48·15 (10·5)
PATIENT-RATED EXPERIENCE MEASURES					
CSQ	275 (69)	137	25·10 (5·1)	138	26·07 (5.0)
INSPIRE Relationship	273 (69)	133	77·70 (17·3)	140	79·00 (17·7)
INSPIRE Support	282 (71)	137	63·59 (21·7)	145	62·61 (24·2)
STAFF-RATED OUTCOME MEASURES					
BPRS	257 (65)	118	31·27 (10·1)	139	31·16 (10·4)
CANSAS-S Met	346 (87)	177	5·82 (3·8)	169	5·86 (3·8)
CANSAS-S Unmet	346 (87)	177	3·12 (3·0)	169	2·54 (2·3)
GAF	362 (91)	171	64·15 (14·8)	191	67·69 (13·1)
HONOS	316 (80)	163	11·05 (6·9)	153	8·61 (5·5)
STAFF-LEVEL PROCESS EVALUATION MEASURES					
RKI	257	129	2·86 (0·4)	128	2.95 (0·4)
MICA	261	131	30·48 (6·92)	130	30.38 (7·2)
RPS					
Skills	230	114	2·91 (0·7)	116	2·84 (0·7)
Behavioural Intent	230	114	1·68 (0·3)	116	1·62 (0·4)
Behaviour	230	114	1·86 (0·8)	116	1·69 (0·8)

Appendix Table 3. Mean (standard deviation) for non-imputed complete cases at follow-up (n=397)

n (%)	Baseline	Follow-up
PATIENT-RATED OUTCOME MEASURES		
QPR Total	38 (9)	128 (32)
CANSAS-P	13 (3)	119 (30)
HHI	41 (10)	139 (35)
MANSA	128 (32)	163 (40)
MHCS	68 (17)	151 (37)
WEMWBS	30 (7)	135 (34)
PATIENT-RATED EXPERIENCE MEASURES		
CSQ	23 (6)	128 (32)
INSPIRE Support	7 (2)	121 (30)
INSPIRE Relationship	26 (6)	130 (32)
STAFF-RATED OUTCOME MEASURES		
BPRS	54 (13)	146 (36)
CANSAS-S	16 (7)	57 (14)
GAF	24 (6)	76 (19)
HoNOS	37 (9)	87 (22)
SOCIODEMOGRAPHIC		
Age	27 (7)	
Ethnicity	3 (0·7)	
Accommodation type	4 (1)	
Employment	1 (0·3)	
Relationship status	0 (0)	
Use of mental health services	1 (0·3)	

Appendix Table 4. Missing data (n=403)

	Regression	
	b, p-value	(95%CI)
PATIENT-RATED OUTCOME MEASURES		
QPR Total	0·61, p=·57	(-1·49 to 2·71)
QPR Interpersonal	-0·09, p=·83	(-0·89 to 0·72)
QPR Intrapersonal	0·51, p=·66	(-1·76 to 2·78)
CANSAS-P Met	0·36, p=·53	(-0·77 to 1·48)
CANSAS-P Unmet	-0·21, p=·60	(-0·96 to 0·55)
HHI	0·60, p=·35	(-0·66 to 1·86)
MANSA	-0·06, p=·61	(-0·29 to 0·17)
MHCS	1·85, p=·25	(-1·28 to 4·98)
WEMWBS	0·74, p=·53	(-1·56 to 3·04)
PATIENT-RATED EXPERIENCE MEASURES		
CSQ	0·80, p=·15	(-0·29 to 1·89)
INSPIRE Support	-2·05, p=·50	(-9·99 to 3·90)
INSPIRE Relationship	-0.29, p=·90	(-4·63 to 4·06)
STAFF-RATED OUTCOME MEASURES		
BPRS	-1·76, p=·17	(-4·29 to 0·77)
CANSAS-S Met	-0·01, p=·99	(-1·22 to 1·22)
CANSAS-S Unmet	-0·68, p=·07	(-1·42 to -0·06)
GAF	5·32, p =·002	(2·03 to 8·61)
HONOS	-0·89, p=·20	(-2·25 to 0·47)

Appendix Table 5. Comparison between arms, adjusting for baseline levels, wave and covariates for imputed data (n=397; 190 control, 207 intervention)

		Control		Intervention		Regression		ICC	Cohen's d
	n	n	Mean (s.e.)	n	Mean (s.e.)	b, p-value	(95%C.I.)		
PATIENT-RATED OUTCOME MEASURES									
QPR Total	255	121	40·10 (·64)	134	40·76 (·60)	0·66, p=·46	(-1·09 to 2·41)	0	·07
QPR Interpersonal	255	121	13·65 (·22)	134	13·60 (·22)	-0·05, p=·87	(-0·67 to 0·57)	·01	·02
QPR Intrapersonal	255	121	46·51 (·70)	134	46·04 (·66)	0·53, p=·59	(-1·39 to 2·44)	0	·04
CANSAS-P Met	271	129	4·13 (·33)	142	4·41 (·31)	0·28, p=·54	(-0·61 to 1·17)	·05	·09
CANSAS-P Unmet	271	129	3·88 (·25)	142	3·69 (·24)	-0·19, p=·59	(-0·88 to 0·50)	·02	·06
HHI	242	113	35·41 (·45)	129	36·04 (·42)	0·63, p=·32	(-0·60 to 1·86)	·03	·12
MANSA	182	84	4·80 (·08)	98	4·88 (·07)	0·07, p=·49	(-0·13 to 0·28)	0	·09
MHCS	221	104	67·06 (1·14)	117	67·81 (1·08)	0·75, p=·64	(-2·36 to 3·86)	·03	·05
WEMWBS	269	121	47·24 (·69)	136	48·09 (·65)	0·85, p=·37	(-1·03 to 2·73)	0	·08
PATIENT-RATED EXPERIENCE MEASURES									
CSQ	260	127	25·31 (·34)	133	25·99 (·33)	0·68, p=·16	(-0·27 to 1·63)	0	·13
INSPIRE Relationship	257	125	78.68 (1·31)	132	78.34 (1·27)	-0·34, p=·85	(-3·96 to 3·28)	0	·02
INSPIRE Support	278	135	64·57 (1·74)	143	61·53 (1·70)	-3·04, p=·22	(-7·88 to 1·79)	0	·13
STAFF-RATED OUTCOME MEASURES									
BPRS	226	103	32·07 (·80)	123	30·72 (·73)	-1·35, p=·22	(-3·51 to 0·81)	0	·13
CANSAS-S Met	256	172	5·73 (·43)	156	5·79 (·42)	0·06, p=·92	(-1·13 to 1·25)	·12	·02
CANSAS-S Unmet	328	172	3·13 (·27)	156	2·26 (·27)	**-0·87, p=·03**	**(-1·63 to -0·11)**	**·11**	**·32**
GAF	309	169	61·84 (1·06)	140	67·97 (1·16)	**6·13, p<·001**	**(3·03 to 9·23)**	**·01**	**·41**
HONOS	289	154	10·50 (·46)	135	9·17 (·49)	-1·33, p=·05	(-2·67 to 0·01)	·03	·21

Appendix Table 6: ITT comparison for complete cases between arms at follow-up, adjusted for baseline scores and wave

Service	Cost per contact (2012/13 £)	Source
GP (surgery)	41	Curtis (2013)
GP (home)	104	Curtis (2013)
Care coordinator	37	Curtis (2013)
Psychiatrist	100	Curtis (2013)
Other doctor	135	Curtis (2013)
Psychologist	134	Curtis (2013)
Social worker	113	Curtis (2013)
Nurse	37	Curtis (2013)
Occupational therapist	73	Curtis (2013)
Support worker (base)	21	Curtis (2013)
Support worker (home)	30	Curtis (2013)
Vocational worker	30	Curtis (2013)
Drug and alcohol advisor	54	Curtis (2013)
Other therapist	58	Curtis (2013)
Psychiatric inpatient	345	Derived from NHS Reference Costs (2007)
Physical inpatient	577	Derived from NHS Reference Costs (2007)
Specialist team (EI)	185	Curtis (2013)
Specialist team (ACT)	133	Curtis (2013)
Specialist team (crisis)	192	Curtis (2013)
Day care	9·50 per hour	Curtis (2013)

Appendix Table 7. Unit costs

References

Curtis L. Unit costs of health and social care. Canterbury: PSSRU; 2013.

NHS reference costs (2007): http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082571

	Baseline		Follow-up	
	Control	**Intervention**	**Control**	**Intervention**
Intervention	-	-	-	120 (92)
GP	120 (158)	125 (145)	115 (194)	111 (128)
Care coordinator	542 (484)	357 (291)	401 (470)	247 (264)
Psychiatrist	157 (250)	191 (285)	156 (205)	127 (220)
Other doctor	161 (1089)	66 (156)	39 (112)	58 (180)
Psychologist	190 (684)	117 (505)	186 (661)	69 (349)
Social worker	45 (189)	93 (405)	36 (266)	50 (279)
Nurse	93 (613)	23 (104)	110 (610)	76 (568)
Occupational therapist	63 (303)	41 (241)	31 (181)	104 (1118)
Support worker	176 (448)	178 (717)	427 (1213)	267 (928)
Vocational worker	9 (63)	21 (84)	62 (497)	10 (51)
Drug and alcohol advisor	32 (241)	11 (68)	31 (244)	27 (182)
Other therapist	138 (981)	43 (235)	37 (230)	28 (158)
Psychiatric inpatient	1195 (6228)	988 (3740)	1279 (7245)	889 (6479)
Physical inpatient	93 (619)	87 (481)	454 (3207)	174 (1143)
Specialist team	435 (2440)	236 (1299)	161 (707)	92 (555)
Day care	305 (697)	400 (842)	326 (988)	302 (758)
Total	**3754 (7919)**	**2977 (4305)**	**3853 (8320)**	**2752 (8797)**

Appendix Table 8. Mean (s.d.) service costs in the six prior to baseline and the six months prior to one-year follow-up (2012/13 £s) (n=266)