Written by Louise Marston and Rumana Omar
Last updated on 10/07/2013 after a meeting with Helen Killaspy, Michael King and Rumana Omar.

Introduction

The Rehabilitation Effectiveness for Activities for Life (REAL) is a multicentre national (England only) programme of research into mental health rehabilitation units. The project has four phases. This analysis plan only concerns Phase 3; a cluster randomised trial of usual care versus a staff training intervention to encourage increased service user activity (the "GetREAL" intervention). This analysis plan does not cover the economic analysis.

The analysis of this cluster randomised trial will follow the CONSORT statement guidelines and the associated extension for cluster randomised trials. [79,80] It will also follow the appropriate standard operating procedures written by the Joint Research Office.

Objectives

1. To investigate whether the GetREAL staff training intervention is associated with greater service user activity.
2. To determine whether the GetREAL staff training intervention is associated with improved clinical outcomes at the end of follow up.
3. To examine whether the GetREAL staff training intervention is associated with improved social outcomes at the end of follow up.
4. To investigate whether the GetREAL staff training intervention is associated with improvement in the quality of mental health rehabilitation units.

Primary outcome

Service users' engagement in activities will be assessed using the Time Budget Diary.[74] This measure collects information from service users on how they have been using their time in the previous week in four sessions of the day (morning, middle of the day, afternoon and evening). For each part of the day all activities are listed and are scored according to complexity and time spent engaged in the activity. Scores for each session range from 0 to 4 with 0 representing activities such as lying, sleeping, sitting, thinking and 4 representing a number of independent tasks which fill the time period and require motivation, planning and engagement, with some variation in tasks. These are summed to give a score between 0 and 112.

AMENDMENT 09/01/2012 after consulting Suzanne Jolley (personal communication via Email) regarding missing data in the Time Budget Diary, she says this should be minimised at the time of data collection by asking about what service users do usually at that time. Depending on the extent and nature of the missing data, it will be decided at a later stage whether this information should be included in the statistical analyses.

Those that have capacity to give consent will complete their own diary and the staff on the unit will also complete a diary for that service user using case notes. Those that do not have capacity to give consent will have their time budget diary completed by the staff using case notes. Those who refuse consent will not have a time budget diary completed by the staff. Therefore, the primary outcome should be complete in each unit except those who refuse consent.

Secondary outcomes

Life Skills Profile (LSP)[75] is a set of 39 staff rated items which are answered using a four point likert scale with the most socially acceptable/ positive response scoring 4

and the least socially acceptable/ most negative response scoring 1. This measure can be summed to give an overall score ranging between 39 and 156. There are also subscales for this measure; these are composed as follows:

- Self-care is the sum of scores for items 10, 12, 13, 14, 15, 16, 23, 24, 26, 30 (possible range 10 to 40)
- Non-turbulence is the sum of scores for items 5, 6, 25, 27, 28, 29, 32, 34, 35, 36, 37, 38 (possible range 12 to 48)
- Social contact is the sum of scores for items 3, 4, 20, 21, 22, 39 (possible range 6 to 24)
- Communication is the sum of scores for items 1, 2, 7, 8, 9, 11 (possible range 6 to 24)
- Responsibility is the sum of scores for items 17, 18, 19, 31, 33 (possible range 5 to 20)

Length of admission will be recorded from the case notes for each service user on the unit.

Service user turnover data will be gained from unit managers.

Proportion discharged to an out of area placement in the last 12 months will be gained from unit managers

Staff attitudes towards each service users' progress will be assessed using the question "I expect this person to be able to move on to a more independent setting within the next 12 months". The response is in the form of a five point likert scale.

Staff turnover will be gained from unit managers.

Unit quality as measured by the Quality Indicator for Rehabilitative Care (QuIRC)[43] will be reported by the unit managers. This is a tool with 145 questions on service provision (for example, number of beds, average length of stay, built environment, treatments and interventions, staffing, staff turnover, training, supervision and disciplinaries); links with community organisations (for example, colleges, employment agencies, sport and leisure facilities); the therapeutic milieu and recovery based practices (for example, collaborative care planning, service user involvement, promotion of service users' independent living skills); the protection of service users' human rights (for example, their privacy and dignity, their legal rights and the use of restraint and seclusion). Domain scores are calculated from scores on 86 items, the remainder providing descriptive data. The overall QuIRC and all the domain scores are expressed as a percentage between 1 and 100. Only the domain scores will be used in analysis.

Trial design
This is a cluster randomised trial, with the unit of randomisation being the rehabilitation unit. Units are randomised to either receiving the GetREAL intervention or no intervention (usual practice).

Inclusion criteria
The inclusion criteria are at the unit level. All service users in eligible units are eligible for inclusion
- An overall QuIRC score below the median in Phase 1.

- More than 7 beds
- Was not involved in Phase 2 of the REAL study (the development of the GetREAL intervention)

Note: data will be collected about those who do not have the capacity to consent from the staff and/ or case notes (expected to be a relatively small percentage). No data will be collected on or about those who explicitly refuse consent to take part in the study.

There are no exclusion criteria.

Randomisation

The Statistician will tell the Project Manager/ Principal Investigator which units are eligible for randomisation. They will approach units to gain their consent to take part in the study. Randomisation will be carried out using the Aberdeen Randomisation Service; independently of the Statistician; who will be blind to study allocation. Forty units were randomised (approximately 50% to each of intervention and usual care); to include at least 412 service users. Randomisation/ start of the intervention will be staggered so that there is time for the GetREAL teams to visit the intervention units and Research Associates to collect baseline data prior to that.

Randomised treatments

Units in the intervention arm will receive the GetREAL training. One of two GetREAL teams will spend five weeks in each unit. The teams comprise an occupational therapist, activity worker and service user researcher. They will work with the staff using a flexible but manualised programme to enable change in the unit to encourage staff to engage service users and thus increase their levels of activity.

Units in the usual service arm will continue providing the care they usually provide and are free to use any resources available to them to provide the best care for their service users.

Data collection

Baseline
Baseline data will be collected by the Research Associates soon after randomisation and before the GetREAL teams start in the intervention units. Some service users may give partial consent; meaning that they do not consent to the Research Associates looking at their case notes. The data that will be unobtainable for this group will be the demographics and service use history.

Service user data collected from the staff
- Demographics (age, gender, ethnic group)
- Diagnosis
- Length of history
- Length of current admission
- Life Skills Profile[75]
- Substance use, assessed using the Clinician Alcohol and Drug Use Scales[76]
- Challenging behaviours which may make community placement difficult, assessed using the staff rated Special Problems Rating Scale[77]
- Activities in the previous week via the Time Budget Diary[74]Staff attitudes towards service user progress, assessed using a likert scale graded 1 to 5 in response to the statement: "I expect this person to be able to move on to a more independent setting within the next 12 months"

Service user data collected from the service user
- Activities in the previous week via the Time Budget Diary[74]

Unit data
- QuIRC[43]
- Fidelity measure. This will comprise of a score from the fidelity questionnaire filled in by the GetREAL teams for the intervention groups. On looking at the data, it was clear that most units scored highly and that some items were scored as 1 (yes) by all units. Therefore, it was proposed that items where all units scored 1 were omitted (items 4, 8, 9, 12, 15, 16, 19, 20, 22), and recalculate the total percentage score with the remaining items. All units in the usual service arm will receive a score of 0.

12 months post randomisation
The same questionnaires and instruments used at baseline will be used at 12 months post randomisation (with the exception of the fidelity measure). Some of the service users will be different to those present at baseline; as some present at baseline will have been discharged and new service users will have been admitted. All service users present at 12 months post randomisation will be included in the follow up data collection unless they refuse consent.

Trial period
The trial commenced in April 2011. The GetREAL teams will have finished delivering the intervention by the end of August 2012. Follow up at 12 months post randomisation will be completed by the end of July 2013. Data entry/ cleaning will take place in August 2013 and analysis will commence in late September 2013.

Blinding of the study team to randomised allocation
The Statistician will remain blind to allocation until the statistical analyses are complete and have been agreed. The Research Associates should also be blind to allocation unless they are inadvertently told the allocation (this had happened several times by the end of September 2011) until they have finished follow up data collection.

Data entry
Most data will be entered by the Research Associates to a Microsoft Access. Any possible errors in data entry found by the Statistician will be referred to the Research Associates to check their data collection sheets, correct the database and resend it to the Statistician.

Up to 5% of the data will be double entered by two people. This will be compared by the Statistician. If the percentage of differences between the two datasets is small (up to 5%) then no more data will be entered, but differences found will be examined and corrected. If this is larger, then more data will be entered to ensure the integrity of the data resulting from the trial.

Total scores of standardised measures will be calculated using Stata. A Stata do file will be created to produce these calculations and stored. The senior statistician will check a few of these calculations at random. Explanations for any deviations will be sought from the Research Associates, who will check their data extraction sheets, amend the data and resend to the Statistician as appropriate.

Data that form the 145 items of the QuIRC will be entered directly into the QuIRC website (http://www.quirc.eu/) and the resulting data extracted by the Project

Manager/ Research Associates and sent to the Statistician for analysis. If there are any queries relating to these data from the Statistician, they will be referred to the Project Manager/ Research Associates, who will check them, correct the data and send back to the Statistician.

The randomised group variable will be supplied by the Principal Investigator or the Project Manager in a form that can easily be merged with the other variables
- Same variable name and format for the unit variable.
- Randomised group variable in numeric format, unlabelled to prevent unblinding of the Statistician.

Statistical analyses
The CONSORT flow diagram will be constructed by/ in collaboration with the Project Manager/ Research Associates who will have logs of units and service users who do and do not agree to take part in the study. It will include number of units randomised to each arm of the trial, and the number of service users it encompassed at baseline and follow up, the number without the capacity to respond for themselves and those who explicitly refused.

All analyses will be on an intention to treat basis.

Analyses will be conducted using Stata version 13.

Descriptive analyses
Service user level data
It is expected that there will be data on more than 400 service users.

The distribution of continuous variables will be explored, both overall and by randomised group, with measures of central tendency, and variability. For categorical variables initial examination of the data will calculate frequencies and percentages with given characteristics, both overall and by randomised group. Large differences between randomised groups will be noted.

Unit level data
There were 40 units recruited to this cluster randomised trial.

For categorical data; overall percentages for each variable will be calculated. Then these will be cross tabulated with the randomisation variable to determine the percentages with each characteristic in each group. Once the data have been explored, the possibility of collapsing the variables with more than two categories will be considered because of the small number of units (clusters) in the study (40).

The distributions of continuous variables will be explored overall and by randomised group using means, standard deviations, minimum, maximum and median and interquartile ranges.

Analysis of the primary outcome

Missing data investigation
Investigations will be carried out to discover the predictors of missingness (in terms of self-completion) for the Time Budget Diary. This will look at individual level factors at follow up as well as unit level factors. Unadjusted logistic random effects analysis

to determine whether a given factor is a predictor of missingness will be carried out, with the random effect to take into account clustering by unit.

Missing data note
We are aware that those who declined to take part in the trial did receive the intervention or usual care on the unit by virtue of the fact that they were present, however we are not going to impute data for these people since we have no individual level data to base imputation on. This is a limitation of the trial; however, the level of declining is similar in the intervention and usual care groups.

The primary analysis will be at the individual level. Random effects linear regression to account for clustering by unit will be used for the primary outcome adjusted for the unit mean baseline value of the Time Budget Diary score to evaluate the effect of the intervention. This is because some of the service users at 12 months will be different to those present at baseline; as some present at baseline will have been discharged and new service users will have been admitted. Analysis will be adjusted for predictors of missingness associated with the outcome if necessary to preserve the missing at random mechanism. Assumptions of normality of residuals will be investigated.

The agreement between the staff and service user Time Budget Diary scores at the individual level will be examined by plotting the two scores against each other (for those who have staff and service user completed diaries). If the data roughly form a straight line on a scatterplot, then the staff diaries will be substituted for the service users' diaries where the service users are deemed not to have sufficient capacity to complete the diary themselves. If there is considerable deviation from a straight line, the service user data will be imputed. This will either be carried out using:
- Multiple imputation, including all variables that might inform the values of service user diary scores or be predictors of missingness of service user diary scores (using results from the initial analyses and clinical judgement). A priori it has been decided this will include the Life Skills Profile score and the length of illness. Age will not be included as it is likely to be highly correlated with the length of illness.
- Regression imputation whereby linear regression between the individual service users' diary scores (outcome) and their staff rated diary scores (predictor) will be carried out, controlling for other factors as appropriate.

There will be three analyses of the primary outcome:
- Complete case (of service user Time Budget Diaries), including staff rated Time Budget Diaries for those who lack capacity to complete the diary providing that the conditions above are satisfied. The analysis will adjust for predictors of missingness associated with the outcome. **This will be the primary analysis**.
- Analysis after imputing the outcome (Time Budget Diary score) for service users who did not have capacity to complete the Time Budget Diary themselves
- Using the staff completed Time Budget Diary scores (only) for all service users who were included in the trial.

However, if there is no difference between the staff and service users' Time Budget Diaries, then 2 and 3 above will not be carried out because there will not be any gains statistically (over and above precision) of doing so.

Supportive analyses

In addition, there will be two supportive analyses of the primary outcome. These will be carried out on the out using the primary outcome (score on the Time Budget Diary) and adjustment factors as in 1 (the primary analysis detailed above).

1.   Adjusting for unit staff turnover (as a percentage) over the previous 12 months collected at follow up.   This is included as a quality measure; it is hypothesised that if staff turnover is high then there may not have been many staff exposed to the intervention, which may affect the outcome.
2.   Adjusting for the length of admission in the unit at the 12 month follow-up and the level of unit treatment fidelity.
3.   Conducting a unit level analysis using ANCOVA, weighted by cluster size

Analysis of the secondary outcomes
For the individual level continuous secondary outcomes (Life Skills Profile and length of admission), random effects linear regression will be carried out. The staff attitude towards service user's progress is collected on a five point likert scale. This will be dichotomised to "likely" or "very likely" versus "neither likely nor unlikely", "unlikely" or "very unlikely" and analysed using random effects logistic regression, with unit being the random effect for all analyses.

Unit level outcomes will be analysed using linear regression.

The results from the secondary analyses will be treated as exploratory and only estimates and 95% confidence intervals will be reported (no p-values).