

**Statistical analysis plan**

**Trial Name**: Optimising team functioning, preventing relapse and enhancing recovery in crisis resolution teams: the CORE programme (CRT Optimisation and RElapse prevention)

**Phase:** CORE Phase 4: Evaluation of implementation of a CRT Resource Kit

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Version history

Version 1.0 13/01/2014

Version 1.1 14/05/2014

Version 1.2 26/06/2014

**Introduction**

The analysis of this trial will conform to the CONSORT1-3 statement and the appropriate standard operating procedures written by Priment Clinical Trials Unit. This analysis plan describes the analyses that will be undertaken as the main trial analyses which will be written up for the funders and a peer review journal. Further details on the trial can be found in the protocol which can be found at http://www.ucl.ac.uk/core-study/docs/p4-protocol

**Trial summary**

**Aim**

To investigate whether a CRT resource kit can improve service user satisfaction with the service and improve staff morale.

**Objectives**

* To evaluate the impact of implementing a CRT resource kit on service users’ experience of CRT care and acute service use
* To investigate whether CRT fidelity scores rise following resource kit implementation
* To investigate associations between CRT fidelity score and CRT service outcomes
* To investigate the impact of implementing a CRT resource kit on CRT staff morale and job satisfaction

**Study populations**

*Inclusion criteria*

Service users

* Have used the CRT for at least 7 days
* Can read and understand English
* Have capacity to provide informed consent
* Do not pose too high a risk to others to be interviewed by a researcher (on NHS premises or by phone or email)

Patient records

* Have been treated by a CRT that is part of the trial
* Have been admitted to: acute impatient mental health wards, Crisis Resolution Teams or other NHS acute mental health services such as crisis houses or acute day hospitals

Staff questionnaires

* Working in a CRT which is part of the trial

**Trial design**

This is a pilot cluster randomised trial including 25 CRTs from NHS Trusts, 15 of which will be randomised to receive the resource kit, and 10 to usual conditions. Data will be collected from staff and service user participants at two time points: a) within a six month period prior to the start of the intervention (baseline); b) in months 10-12 of the one-year trial intervention period. Data about CRT admissions and service use will be collected for two six month periods: a) the six months prior to the start of the intervention; and b) months 7-12 of the one-year trial intervention period. A CRT Fidelity Review (a one-day audit of service organisation and delivery) will be completed at two time points: a) within the six months prior to the start of the trial intervention (baseline); and b) in months 10-12 of the one-year trial intervention period.

Fifteen service users from each CRT will be recruited at baseline (N=375) and 15 service users will be recruited at the end of the intervention (N=375). These people will be different at the two time points.

All staff working in the CRT will be invited to take part in the staff survey. It is hoped that approximately 20 staff per CRT will respond to the questionnaire at each time point (N=500 at each time point). Some of these staff may be the same at both time points. It will be possible to link data from staff who participated at both time points.

This trial is expected to start collecting baseline data in June 2014 and the last intervention data is expected to be collected in October 2015.

**Sample size**

A sample of 375 participants (225 from 15 CRTs which have implemented the resource kit; 150 from 10 CRTs which have not) will give 97% power to detect a half a standard deviation (SD) difference in mean satisfaction score (3.5 points assuming a typical SD of 7.0), and 80% power to detect a difference of just over a third of a standard deviation, allowing for a moderately large ICC of 0.05.

**Randomisation**

The 25 teams will be randomised to either receive resource kit implementation (n=15) or usual conditions (n=10) using blocked randomisation. Randomisation of CRTs will be stratified by NHS Trust. In particular, the block sizes will be chosen so that every Trust with more than one team will have at least one team allocated to each trial arm. Randomisation will be conducted by a trial statistician otherwise not involved with data collection or delivering the study intervention, in accordance with advice from Priment, a UCL Clinical Trials Unit.

**Outcomes**

*Primary outcome*

Client Satisfaction Questionnaire (CSQ-8) (Service user)

*Secondary outcomes*

Continu-um (Service user)

Work-Related Acceptance and Action Questionnaire (staff)

Work Engagement Scale (staff)

General Health Questionnaire (staff)

Maslach Burnout Inventory (staff)

CORE CRT Fidelity Scale score (Fidelity Review)

Admission rates (number of admissions over 6 months) (patient records)

Bed use (number of inpatient bed days over 6 months) (patient records)

Readmission to acute care over 6 months (for a cohort of all service users admitted to the CRT over a one-month period (month 7 of the trial intervention period)) (patient records)

**Data collection**

The same data will be collected at baseline and outcome time points from the service users, staff and the CRT visits.

*Service users*

Age

Sex

Ethnicity

Previous use of the CRT

Inpatient admissions

Client Satisfaction Questionnaire (CSQ-8)

Continu-um

*Patient records*

At all CRTs, anonymised service use data will be collected from NHS Trust patient record systems regarding all acute hospital admissions for the geographical sector and bed use over a six month period at baseline and outcome time points. Anonymised data regarding readmissions to acute care (ie readmissions to acute impatient mental health wards, Crisis Resolution Teams or other NHS acute mental health services such as crisis houses or acute day hospitals) over a six month period will be collected at baseline and outcome time points from patient record systems for all service users admitted to the CRT over a one month period.

*Staff questionnaire*

Age

Sex

Ethnicity

Professional group

Grade

Experience in the NHS

Experience in CRTs

Experience in the current CRT team

The Work-Related Acceptance and Action Questionnaire

The Utrecht Work Engagement Scale

The General Health Questionnaire 12

The Maslach Burnout Inventory

*CRT visits*

CORE CRT Fidelity score

**Data entry**

Data from the service users and staff will be entered into SPSS by researchers in London and Bristol using identical data entry systems. There will be separate datasets created for the staff and service user data. These will be set up so that it mirrors the data collection schedule. Data will be checked for consistency, missing and illegal values by the Statistician before analysis and any problems reported to the Trial Manager, who will rectify them (which may involve confirming values with the researchers) as appropriate before data analysis. The Trial Manager will keep a list of changes made to the dataset.

Service user admissions data and CRT catchment area population size will be downloaded by the informatics departments of the appropriate NHS trusts. This will be sent to the Trial Manager by electronic transfer. Each Trust may supply these in different formats; meaning substantial data management might be necessary. It is known that data can be supplied by Camden and Islington in Excel. An admission rate for each CRT will be calculated by aggregating data on all admissions over six months over catchment area population size.. The data on readmissions over six months for all patients admitted to the CRT during a one month period will be individual level data.

**Statistical analyses**

*General principles*

The assumptions underpinning each statistical method will be checked. For example, normality and equality of variances will be checked for t-tests. The use of transformations or non-parametric methods will be considered if assumptions do not hold. Adjusted analyses will be performed if baseline imbalances are observed. The impact of missing data will be explored in all analyses; sensitivity analyses as appropriate.

The primary analyses will be complete case. All analyses will be on an intention to treat basis. Data will be analysed using Stata4.

*CONSORT*

The CONSORT1-3 flow diagram will be constructed by/ in collaboration with the Trial Manager who will have logs of service users and staff who take part in the study at baseline and after the intervention. It will include number of service users screened and consenting at baseline and the end of the study and numbers of staff invited and completing questionnaires at both time points.

*Descriptive statistics*

Initial analyses will look at summary statistics for all service user and staff questionnaire variables, both overall and by randomised group. Summary statistics for continuous variables will be mean, median, SD, lower quartile, upper quartile, and percentage within each category. No statistical significance tests for baseline characteristics by randomised group will be performed, but balance will be assessed visually.

*Primary outcome*

We will test the hypothesis that mean total satisfaction with CRT care will be greater in teams that have introduced the CRT resource kit. This analysis will use linear random effects modelling, with a random effect for CRT controlling for mean baseline CSQ-8 score by CRT.

*Secondary outcomes*

Service user data

We will compare the mean Continu-um score between teams which have introduced the resource kit and teams which have not. The analysis will be as described for the primary outcome.

Patient records

We will use routine data from local electronic systems to compare difference in service use patterns in each CRT catchment area between areas that have implemented the resource kit and the control areas that have not. Admission rate and bed use, will be measured over a 6 month period both before and after resource kit introduction in the experimental areas. We will also explore whether there is any evidence of differences between experimental and control areas in extent of change in rates of compulsory detention under the Mental Health Act and of readmissions within 6 months of an initial admission to acute care. Other routinely collected indicators of CRT functioning, such as referral sources and caseload composition will also be examined as part of an exploration of the impact of the resource kit on service use. Data will be analysed using Poisson random effects modelling. Baseline admission rate or bed use will be set as the exposure variable as appropriate. A sensitivity analysis using the catchment area size as the exposure will be carried out.

If differences between the two groups are found national reference costs will be applied to resource use (admission, bed days and re admissions) to calculate the cost difference between resource kit implementation and control areas. A difference in difference model will be used, looking at before and after effects in the two areas using the most appropriate statistical model as determined by Akaike information criteria (AIC) and Bayesian information criteria (BIC) values. This is likely to be a general linear model with log link and family gamma. The model will take the same form as the Poisson model above.

Staff questionnaire

We will test the hypotheses that: mean staff psychological wellbeing, measured by the General Health Questionnaire, Work-Related Acceptance and Action Questionnaire and positive work engagement, measured by the Utrecht Work Engagement Scale are greater in CRTs receiving the resource kit than in control CRTs. Also that mean staff burnout, measured by the Maslach Burnout Inventory is lower in CRTs receiving the resource kit than in control CRTs. We will use data collected from CRT staff at study baseline, before the introduction of the resource kit, to assess whether there are baseline differences between the two groups of teams for which adjustments should be made. If baseline measures of the outcome need to be controlled for, these will be in the form of mean score for staff in the given CRT. Data will be analysed using linear random effects modelling with a random effect for CRT.

If there are sufficient staff members filling in the questionnaires at both time points, separate paired analyses will be carried out using the data from these people only.

*Exploratory Analyses*

We will explore, the extent to which team fidelity score can explain variations in individual satisfaction with care. This analysis will use linear random effects modelling, with a random effect for CRT.

*Missing data*

It is not envisaged that we will impute missing data. However, if there were substantial missing data for any of the outcomes, these data would be explored further.

**References**

1 Schulz KF, Altman DG, Moher D, for the CONSORT Group CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials BMJ2010;340:c332

2 Campbell MK, Elbourne DR, Altman DG CONSORT statement: extension to cluster randomised trials. BMJ 2004;328(7441):702-708.

3 Campbell MK, Piaggio G, Elbourne DR, Altman DG for the CONSORT Group. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345:e5661

4 StataCorp Stata Statistical Software: Release 13. 2013 College Station, TX: StataCorp LP

**Appendix**

Further details on the outcome measures

**Primary outcome**

*Satisfaction with services*

The Client Satisfaction Questionnaire (CSQ-8). This is an eight item questionnaire, with four possible answers given which participants have to circle one of them. Each question is scored from 1 to 4, with 1 indicating least satisfied and 4 indicating most satisfied. Individual item scores are summed to give an overall score between 8 and 32, with higher scores indicating greater satisfaction. It is expected that this measure will have a mean score slightly above the midpoint, although Normally distributed. The usual practice with regard to missing items on the CSQ-8 is to impute pro rata a maximum of two items using the mean of the other items.

*Atkisson C, Zwick R The Client Satisfaction Questionnaire: Psychometric Properties and Correlations with Service Utilisation and Psychotherapy Outcome. Evaluation and Programme Planning 1982;5:233-237.*

**Secondary outcomes**

Continu-um consists of 16 topics, with responses given as five point Likert scales, scored 1 to 5, giving a possible range of 16 to 80. If up to two items are missing, they are imputed pro rata with the mean of the other items.

*Rose D, Sweeney A, Leese M, Clement S, Jones IR, Burns T, et al. Developing a user-generated measure of continuity of care: brief report. Acta Psychiatr Scand. 2009;119:320–324*

Work-Related Acceptance and Action Questionnaire (WAAQ). This is a seven item measure, with each response scored on a likert scale, with 1 indicating never true and 7 indicating always true. These are summed to give a score between 7 and 49, with higher scores indicating greater levels of work related psychological flexibility.

*Bond F, Lloyd J, Guenole N The Work-related Acceptance and Action Questionnaire (WAAQ): Initial psychometric findings and their implications for measuring psychological flexibility in specific contexts Journal of Occupational and Organisational Psychology 86(3) 331-347*

Utrecht Work Engagement Scale (UWES-9). This is a nine item measure which is scored on a seven point likert scale with 0 indicating never and 6 indicating always. These are summed to give a total score between 0 and 54. There are three subscales vigour (VI), dedication (DE) and absorption (AB), each with three items. These are detailed below:

At my work, I feel bursting with energy (VI)

At my job, I feel strong and vigorous (VI)

I am enthusiastic about my job (DE)

My job inspires me (DE)

When I get up in the morning, I feel like going to work (VI)

I feel happy when I am working intensely (AB)

I am proud of the work that I do (DE)

I am immersed in my work (AB)

I get carried away when I am working (AB)

*Schaufeli W, Bakker A, Salanova M (2006) “The measurement of work engagement with a short questionnaire” Educational and psychological measurement 66(4) 701-716*

General Health Questionnaire (GHQ12)

This is a 12-item measure of mental wellbeing. Each item is scored on a 4-point likert scale, but the authors recommend converting each item score into a binary score, with responses scored 0, 0, 1, 1 and missing items scored as 0. The scale then yields a total score ranging from 0-12.

*Goldberg D, Williams P (1988). The General Health Questionnaire Windsor: NFER-Nelson*

Maslach Burnout Inventory is a 22 item instrument of staff morale, providing information about emotional exhaustion, cynicism, and perceived personal accomplishment. It is scored on a seven point likert scale with 0 indicating never and 6 indicating every day. These are summed to give a score ranging from 0 to 132.

*Maslach C, Jackson S, (1981) The Maslach Burnout Inventory. California, Consulting Psychologists Press*

CORE CRT Fidelity Scale is a 39-item measure developed for this study. It assesses Crisis Resolution Teams’ adherence to a model of good practice. Each item is scored on a scale of 1 to 5, with 5 indicating excellent fidelity and 1 very low fidelity, and yielding a total score ranging from 39 – 195.