UCL COMPREHENSIVE CLINICAL TRIALS UNIT

FINCH

A crisis planning and monitoring intervention to reduce compulsory hospital readmissions (FINCH study) - a randomised controlled feasibility study

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STATISTICAL ANALYSIS PLAN (SAP)

VERSION 1 06.02.24

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ABBREVIATIONS AND GLOSSARY

Adverse events	AEs
Brief Psychiatric Rating Scale	BPRS
Case Report Form	CRF
Chief Investigator	CI
Client Satisfaction Questionnaire	CSQ
Client Service Receipt Inventory	CSRI
Consolidated Standards of Reporting Trials	CONSORT
Data Monitoring Committee	DMC
General Data Protection Regulation	GDPR
Health Research Authority	HRA
Medical Research Council	MRC
National Institute of Health Research	NIHR
NHS Research Ethics Committee	REC
Personal Mental Health Worker	PMHW
Process of Recovery Questionnaire	QPR
Quality-Adjusted Life Years	QALYs
Randomised Controlled Trials	RCTs
Serious Adverse Event (SAE)	SAE
Template for Intervention Description and Replication	TIDIER
Treatment As Usual (TAU)	TAU
Trial Steering Committee (TSC)	TSC
University College London (UCL)	UCL

1 INTRODUCTION

This synopsis of the introduction and background to the study is extracted from the funding application and from the submitted protocol paper.

1.1 Background and rationale

Compulsory detentions in mental health inpatient units have been increasing over several decades in England, as in several other European countries (1). Official data suggest use of the Mental Health Act to detain people in hospital increased by 40% between 2006 and 2016 (2), with further yearly rises since 2016, when the method for enumerating admissions was changed (3). There is also a striking ethnic inequality in risk of being detained, with people from Black and Black British ethnic groups around four times as likely to be detained as White British people (2–5).

High rates of compulsory admission are an important problem because service users and carers recurrently report that this is a distressing and traumatising experience that greatly disrupts recovery and therapeutic alliances (6,7). Compulsory detention, and the coercion and disenfranchisement that are necessarily involved, also violates an otherwise highly regarded principle that mental health treatment should be freely chosen and as collaborative as possible. Thus, there is a strong case for keeping compulsory (also known as involuntary) admissions to a minimum. The experiences of ethnic minority communities are especially important, as high rates of coercive treatment, especially in Black/Black British communities, constitute another inequality and contribute to mistrust of mental health services and thus to disengagement (8). Compulsory admissions are also expensive, recently estimated as costing an average of £18,315 per admission (2), with limited clinical or social gains evident at one year follow up (9). Policy makers and service user advocates thus concur in prioritising prevention of compulsory admission.

Currently we lack strategies for preventing compulsory admission that are evidence-based and have been successfully implemented as part of standard mental health care in the UK or

elsewhere: there are surprisingly few published trials of interventions with compulsory admission as a primary, or even as a secondary outcome measure (10). There is considerable evidence that a group at high risk of compulsory admission is those who have already been detained at least once (11), making them a priority for interventions to reduce further compulsory detention. One approach has been the continuing of compulsion into the community, for example through Compulsory Treatment Orders in England. However, current evidence does not support this as a means of reducing compulsory admissions (10,12), and there is some evidence of disproportionate use in Black and Black British ethnic groups (5). When evidence from all available studies internationally is pooled through meta-analysis (13,14), the only kind of intervention that currently has substantial evidence for effectiveness in reducing compulsory admissions is advance planning for crises (often called crisis plans) and collaborative agreements (advance statements) with patients about what should happen if they are unwell in future. Such strategies were recommended for national roll-out in the Independent Review of the Mental Health Act in England, published in 2018 (4).

Informed by this evidence, our aim in this study is to develop and test in a feasibility study an intervention designed to reduce future compulsory detentions through support including person-centred crisis plans for people who have just had a mental health admission during which they were compulsorily detained. A particular concern, given inequalities in detention and in overall experiences of mental health care, is that the intervention should be suitable for and engaging to people from ethnic groups, such as Black African, Caribbean, and Black British backgrounds.

In our group's review of relevant literature, (13) we found that while pooled meta-analysis indicates overall effectiveness for interventions based on crisis planning, there has been considerable variation between studies in effect size and in whether statistical significance was reached. Difficulties in implementing crisis planning interventions effectively were noted in several studies. In particular, in the largest UK trial, a crisis planning model that had initially appeared effective in a single site trial showed little evidence of effectiveness when tested across multiple sites at a larger scale (15–17). This was attributed to clinicians often failing to modify their routine practice to incorporate crisis planning as intended, and to

crisis plans rarely being referred to by clinicians or service users in subsequent care or help-seeking. Thus, it is likely that, to be reliably successful in reducing compulsory admission, crisis planning needs to be embedded in a framework that ensures it is delivered in practice, and that the crisis plans that are formulated are subsequently monitored and followed through.

Within our systematic review (13), we identified one trial as appearing to have a more intensive and developed approach to implementation than the rest, including strategies for continued monitoring for signs of crisis and for giving service users a voice. In this study, carried out in the multicultural Swiss city of Zürich (18,19), researchers designed and tested a programme of psychoeducation, crisis planning and monitoring by phone for people being discharged following a compulsory hospital admission. Findings were promising: over two years, 28% of people in this programme were compulsorily readmitted compared with 43% of controls receiving standard local care: with adjustment for other differences, the estimated relative risk of compulsory readmission for the treatment group was 0.55 (95% confidence interval: 0.33-0.94) (18). Importantly, the follow-up element of monthly monitoring phone calls by a "personal therapist" additional to the usual care team, built in a solution to the problem identified in other studies of crisis plans being neglected and under-used (15). However, the Zürich trial had some important limitations: it did not achieve the intended sample size, and differential drop-out rates create ambiguity in interpreting the statistically significant result. Despite this, it seemed sufficiently promising in a field in which robust research is sparse to form a starting point for our programme.

The aim of the FINCH study is to review and adapt the Zürich intervention to a UK context, and to examine the feasibility and acceptability of delivering the intervention and testing it through a randomised controlled trial. In adapting it, we aimed also to incorporate any other relevant evidence on self-management and crisis planning interventions, the perspectives of service users and carers with relevant lived experience and of professionals with relevant clinical experience, and any relevant policy directives and guidance.

1.2 Objectives

Feasibility Study

i. To assess the feasibility of the following parameters:
   a. recruitment
   b. randomisation
   c. retention

ii. To use recruitment and retention data as well as the proportion of participants in each arm of the trial who experience at least one episode of compulsory detention within 12 months of randomisation so as to estimate parameters for a power calculation of a proposed future, efficacy parallel arm prospective RCT.

iii. To report preliminary accumulated data relating to the following secondary outcomes:
   a. clinical outcomes,
   b. social outcomes, and
   c. health economic outcomes.

iv. To carry out an inferential test of the strength of the evidence against the null hypothesis that there is no difference in the proportion of participants who experience at least one episode of a compulsory admission in those randomised to the intervention versus the proportion of those randomised to the control arm. It is anticipated that the primary outcome for the proposed subsequent efficacy trial will be the difference in the risk of having at least one episode of compulsory re-admission between those randomised to enhanced treatment versus those randomised to the control arm.

2 STUDY METHODS

2.1 Trial design

FINCH is a parallel arm prospective double blinded feasibility randomised controlled trial of 12 months' follow-up duration.

2.2 Randomisation and blinding

Participants were randomised via a computer-generated allocation sequence to either the intervention or control group in a 1:1 ratio using block randomisation stratified by:

i. site (3:3:2 ratio inner London: outer London: North West England), and
ii. ethnicity (visible ethnic minority groups at higher risk of detention vs lower risk groups 1: 1 ratio).

Some members of the study team are unblinded so that they can promptly deal with any issues relating to intervention delivery. As far as is possible the remaining study research assistants are blind to treatment allocation. The trial statistician is blind to treatment allocation. The principal statistician will be blinded to treatment allocation unless ungrouped results are requested by either the TSC or IDMC when they will become unblinded.

2.3 Sample size

We aimed to recruit 80 participants in line with recommendations by Consolidated Standards of Reporting Trials (CONSORT) guidelines for parallel-group RCTs (20). This sample size is deemed sufficient to examine the primary aim of the study, which is to assess feasibility parameters to inform decisions about a future fully powered confirmatory trial.

The study has a statistical power of 80% (with a one-sided alpha of 2.5%) of detecting a reduction in the risk of compulsory readmission from 50% to 20%. The true difference between the two groups is unknown but is not anticipated to be this large. The true difference observed from this study will help with the future sample size calculation of a proposed future parallel arm efficacy RCT (if it is considered feasible). This study is unlikely to be sufficiently powered to detect a statistically significant difference in the risk of re-admission between those randomised to treatment versus those randomised to the control arm.

There were no exclusions due to mental health diagnosis. The aim was to recruit 80 participants, at least half of whom were from ethnic groups who are at greater risk than White British patients of being compulsorily detained according to recent NHS data (5). The study aimed to recruit 30 participants from each London centre and 20 from the North West England centre.

2.4 Framework

FINCH is a feasibility trial, the primary purpose of which is to assess the feasibility of recruitment, retention and randomisation and to obtain the difference in risk of readmission between the two arms so as to provide the parameters for a subsequent parallel arm superiority study.

2.5 Statistical interim analyses and stopping guidance

There are no planned interim analyses and subject to approval by the Trial Steering Committee (TSC) it is not anticipated that an Independent Data Monitoring Committee (IDMC) will be convened.

The TSC includes a representative of the funder, clinicians, researchers, a lived experience participant and a statistician, which meets regularly to provide independent oversight of trial progress, safety, and analysis plans.

2.6 Timing of final analysis

Trial outcomes will be measured via clinical records and interviews with study researchers. Research interviews will be conducted at baseline prior to randomisation, and at 6 and 12 months after randomisation; the latter timepoint is when outcomes for the primary endpoint will be collected. Further data collection and analysis will occur after the end of the study (i.e. 24 months after the patient was randomised to treatment).

Statistical analysis will commence once all data for the primary endpoint at 12 months has been collected and entered into the trial database, all data queries have been resolved and database lock has occurred.

2.7 Timing of outcome assessments

Figure 1: SPIRIT Figure – Schedule of Enrolment, Interventions, and Assessments.

	Screening (Pretreatment assessment)	**Intervention phase**	**6-month post baseline (post-randomisation)**	**Follow-up at 12-month post randomisation (time at which primary endpoint is collected)**	**Follow-up at 24-month post randomisation (collection and analysis of secondary exploratory outcomes)**
	Day 1 - 7	Week 1 - 52	Week 24	Week 52	Week 104
Informed Consent	X				
Eligibility confirmation	X				
Randomisation	X				
Compulsory admission				X	X
CSQ	X		X	X	
QPR	X		X	X	
REQOL	X		X	X	
MHCS	X		X	X	
CSRI	X		X	X	
Intervention delivery		X			
Qualitative interview (intervention arm only)			X*		

3 STATISTICAL PRINCIPLES

3.1 Confidence intervals and p-values

All applicable statistical tests will be 2-sided and all p-values from hypothesis testing will be exact. The main treatment effect will be tested at the 5% overall (2.5% for each side of a two-sided test) in line with the sample size calculation. All confidence intervals presented will be 95% and two-sided.

3.2 Analysis population

The analysis population for the feasibility study (recruitment, risk of refusal to consent to enter study, retention, randomisation etc.) will consist of all eligible participants whose eligibility was confirmed.

The feasibility outcomes of recruitment and randomisation will be presented by grouped data.

Retention data will be presented in both grouped and ungrouped data.

Inferential analyses will be conducted, if appropriate, following the Intention-To-Treat (ITT) principle where all randomised patients are analysed in their allocated group.

4 TRIAL POPULATION

4.1 Screening, recruitment, withdrawal/follow-up

Patients screened but not enrolled in the trial and reasons for exclusions will be reported, and recruitment will be presented by centre and month.

The number of patients who have been withdrawn or were unwilling to continue trial follow-up will be reported by treatment arm.

The throughput of patients from those screened, enrolled, assessed for trial endpoints, and included in the analysis, will be summarised in a CONSORT flowchart.

4.2 Eligibility

4.2.1 Participant Eligibility Criteria

Eligible participants were current inpatients who:

i. had been compulsorily detained under Section 2 or Section 3 of the Mental Health Act during their current hospital admission (these Sections allow for respectively 28 days detention for assessment or a renewable 6-month detention period for treatment);
ii. were due to have received community mental health care locally post-discharge;
iii. were at least 18 years of age;
iv. had capacity at the time of recruitment to give informed consent to participation in the trial and to receive the study intervention.

Participants were excluded if they:

i. were already receiving an intensive psychosocial intervention that focuses on crisis reduction, or
ii. had a diagnosis of dementia or a brain injury, or
iii. did not speak sufficient English to take part without an interpreter.

4.3 Baseline patient characteristics

The list of baseline characteristics to be summarised is provided in Appendix A (Table 1) at the end of this document.

Baseline characteristics will be summarised for all patients in the study. Summary measures for the baseline characteristics will be presented as mean and standard deviation for continuous (approximate) normally distributed variables, medians and interquartile ranges for non-normally distributed continuous variables, and frequencies and percentages for categorical variables. We will plot histograms of continuous variables to assess normality.

Baseline characteristics will also include the percentage of patients within each of the categories defined as stratification factors: centre and risk of detention status (high risk versus low risk).

5 ANALYSIS

5.1 Outcome definitions

5.1.1 Primary outcome

The primary goal will be to assess feasibility outcomes. Data on planned outcomes for a future randomised controlled trial of the intervention will also be collected, allowing assessment of the feasibility of intervention delivery and trial processes, collection of data needed to inform a power calculation for a definitive trial, and a preliminary assessment of the likelihood of a positive result from a definitive trial.

5.1.2 Feasibility Outcomes

Detailed feasibility parameters will be recorded. These will include rates and routes of identification of potentially eligible participants at each site, recruitment and acceptance of randomisation, rates, and patterns of attrition from treatment and trial assessments, delivery of each intervention component, completion rates for individual outcome measures, rates of serious adverse events in each arm of the trial, and event rates for the planned primary trial outcome of compulsory readmission.

Outcomes will be measured via clinical records and interviews with study researchers. Research interviews will be conducted at baseline prior to randomisation, and at 6 and 12

months after randomisation. A final follow-up point at 24 months will involve health record data only.

5.1.2.1 Future Primary Trial Outcome

The planned primary outcome for a future definitive trial is whether the participant has been compulsorily detained in hospital under Sections 2, 3 or 37/38 of the Mental Health Act within one year of randomisation. These data will be extracted from participants' health records.

5.1.2.2 Secondary (supportive and exploratory) outcomes

5.1.2.2.1 From health records:

The following will be obtained from electronic data about patients held by Trusts:

a) Compulsory admission within 24 months of randomisation.
b) Whether participants remain engaged with services

5.1.2.2.2 From research interviews:

The remaining secondary outcome measures will be collected by a research assistant blind to treatment allocation. The following measures will be administered during a face to face, video, or phone interview (depending on service user preference, with face-to-face or video call preferred if possible):

a) Satisfaction with services will be examined using the Client Satisfaction Questionnaire (CSQ) (29). This is an 8-item scale where participants can rate their satisfaction with various aspects of their care on a 4-point Likert scale.
b) Self-rated recovery will be measured by the 15-item Questionnaire about the Process of Recovery (QPR) (30). Participants can score from 0 (disagree strongly) to 4 (agree strongly) on each item and score up to a maximum of 40 on the scale.
c) Self-management confidence will be measured using the Mental Health confidence scale (31). Participants report their confidence in managing their mental health for 16-tems rated on a Likert scale from very non-confident to very confident.

d) Quality of life will be measured by the REQOL-10 (32) and EQ-5D-5L (33). They are both widely used measures in clinical trials with populations with severe mental health problems. On the REQOL, participants rate their quality of life on 10-items from 0 to 4. A participant can score a total of 40 and this information can be used to derive disability-adjusted life years (QALYs) via an algorithm which generates a weight which is then combined with time and area under the curve methods. The EQ-5D-5L is converted to a weight based on preferences for health states derived from it. The weight is combined with time to generate (QALYs) as with the REQOL.

e) Psychiatric symptoms will be assessed using the Brief Psychiatric Rating Scale (BPRS) (34). Participants are rated by a researcher/research assistant on 18 items from 0/ NA (not assessed) to 7 (extremely severe) to give an overall score of psychiatric symptoms.

5.1.2.3 Health Economic Analysis

Service use data will be collected using an adapted version of the Client Service Receipt Inventory (CSRI) (35). The CSRI is used at baseline, and at 6- and 12-month follow-up. Costs will be calculated by combining this information with appropriate unit costs (e.g.,. The costs of the intervention will be calculated from information on staff time and other requirements.

Descriptive data such as demographic and clinical/service user characteristics will also be recorded, including Community Treatment Order status, previous admission and compulsory detention history clinical diagnosis, and demographic data including age, sex and ethnic group.

5.1.3 Rationale and details for outcome measures

This study seeks to prevent compulsory detention and the endpoint is a measure of this outcome. The secondary supportive outcomes are appropriate as they address supportive issues that may be related to decisions about detention (e.g. mental state, service use etc)

5.2 Analysis methods

The results of the analyses will be reported following the principle of the ICH E3 guidelines on the Structure and Content of Clinical Study Reports[4]. Dummy tables are presented in the Appendix.

5.2.1 Adjustment factors

The primary outcome model will be adjusted for centre and risk status for detention (high risk versus low-risk ethnicities).

5.2.2 Primary outcome analysis

This pilot study will not have sufficient statistical power to assess the effectiveness of the intervention but will allow an assessment of whether the direction and magnitude of any effect found for the proposed primary outcome are consistent with a hypothesis that the programme is effective in reducing repeat detentions. For this reason and to test the analysis envisaged for a future, fully powered, effectiveness RCT, primary outcome at follow will be compared between study arms, using appropriate multi-level models.

Our planned analysis is multi-level modelling, allowing for clustering of residuals between centres by introducing the variable coding for centre as a random intercept. We will enter all other stratification variables as fixed effects.

5.2.3 Missing Data

Patterns of missingness in recorded data will be reported as part of the feasibility outcome of ability to retain participants in the study. Reasons for missingness will be investigated and reported.

5.2.4 Sensitivity analysis of primary outcome

We will assess the robustness of the results to missing data by carrying out sensitivity analyses in which the missing data are assigned extreme values so as to determine the effect of potential extreme missing values on the stability of the reported results. We will assess the effect of time by analysing results with time to detention as a random slope variable.

5.2.5 Secondary outcome analysis

We will perform ANCOVA analyses for outcome variables that are continuous (and whose residuals are normally distributed) adjusted for centre and risk of redetention (high risk versus low risk). We will carry out time to event analyses to assess if the time to re-detention is different between those randomised to either treatment using Cox regression models. Kaplan Meier curves will be presented, and exploratory analyses carried out to ensure that the assumptions of survival analyses are met. Time to re-detention will be summarised as mean (sd) in the report of the results of secondary analyses.

We will perform logistic regression analyses for binary outcomes adjusted for centre and risk of detention (high risk versus low risk).

Adverse events will be summarised in terms of the number of (serious) adverse events per person for each arm, per arm overall, per site for each arm, as well as the number of participants with any (serious) adverse events in each randomised group and compared using an appropriate statistical test (e.g. Fisher's exact text, chi squared test, logistic regression modelling etc.). The odds ratio of any participant having at least one adverse event in one arm compared to the other (and 95% CI) will be presented.

Service use data and costs will be compared between the groups using descriptive statistics. The difference in total cost will be derived from a model regressing follow-up cost on group and baseline costs. QALYs will be compared between groups adjusting for baseline EQ-5D-

5L/REQOL scores. Cost-effectiveness will be assessed by dividing incremental costs by incremental QALYs and repeating this process 5000 times using bootstrapping. The bootstrapped incremental cost-QALY combinations will be plotted on a cost-effectiveness plane to indicate uncertainty around the results.

5.2.6 Subgroup analysis

We will conduct tests for interaction between the assigned group and each of the stratification variables.

5.2.7 Exploratory outcome analysis

Further post-hoc supportive analysis will be carried out based on the research findings.

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7 REVISION HISTORY

Version	Date	Edited by	Comments	Timing in relation to first unblinded interim monitoring	Timing in relation to unblinding of Trial Statistician(s)
0.1	22 March 2023	RG	First draft	Prior	Prior

8 APPENDICES

8.1 Baseline Characteristics

Table 1: Baseline Characteristics

	Treatment (n =)	Control (n =)	Total (N =)
	n (%)	n (%)	n (%)
Site			
- Inner London			
- Outer London			
- North West England			
Age (years)			
- [18 - 25)			
- [25 – 35)			
- [35 – 45)			
- [45 – 55)			
- [55 – 65)			

	Treatment (n =) n (%)	Control (n =) n (%)	Total (N =) n (%)
- [65 – 75)			
- >= 75			
Gender			
- Female			
- Male			
Risk Status			
- High Risk			
- Low Risk			
-			
-			

8.2 Feasibility Outcomes

Table 2: Recruitment and Randomisation

Number of participants identified as eligible	
Number of participants who did not consent to enter study	
Number of participants randomized to treatment	
Number of participants retained	
Number of participants consented to enter study	
Number of participants randomized	
Number of participants randomised to control	

Table 3: Retention through study

	Intervention (n =)	Control (n =)	Total (n =)
	n (%)	n (%)	n (%)
Retention at 3 months			
Retention at 6 months			
Retention at 9 months			
Retention at 12 months			
Retention at 24 months			

8.3 Inferential Analyses

12 Months

i. **Table 4: Unadjusted Analysis at 12 Months**

Arm	Events in arm N	Total number in arm N	Odds Ratio	95% CI
Control			1	
Intervention				

ii. **Table 5: Adjusted Analysis at 12 Months**

Arm	Events in arm N	Total number in arm N	Odds Ratio	95% CI
Control			1	
Intervention				

Analyses adjusted for centre and baseline risk of redetention (stratification variables)

24 Months

i. **Table 6: Unadjusted Analysis at 24 Months**

Arm	Events in arm N	Total number in arm N	Odds Ratio	95% CI
Control			1	
Intervention				

ii. **Table 7: Adjusted Analysis at 24 Months**

Arm	Events in arm N	Total number in arm N	Odds Ratio	95% CI
Control			1	
Intervention				

Analyses adjusted for centre and baseline risk of redetention (stratification variables)

8.4 Adverse Events and Serious Adverse Events

Table 8: Total Number of Adverse Events per Site per Arm

	Treatment (n =)	Control (n =)	Total (N =)
	n (%)	n (%)	n (%)
Site			
- Inner London			
- Outer London			
- North West England			
Total			

Table 9: Total Number of Adverse Events for each person per Arm

	Treatment (n =)	Control (n =)	Total (N =)
	n (%)	n (%)	n (%)
Number of Adverse Events - **5** - **4** - **3** - **2** - **1** - **0**			

Table 10: Number of Patients with any Adverse Event per Arm

	Treatment (n =)	Control (n =)	Total (N =)
	n (%)	n (%)	n (%)
Number of participants reporting any adverse event			

Table 11: Serious Adverse Events

	Treatment (n =)	Control (n =)	Total (N =)
	n (%)	n (%)	n (%)
Death			
Life Threatening Event			
Hospitalisation			
Persistent or significant disability or incapacity			
Congenital anomaly or birth defect			
Other			

8.5 Health Economic Outcomes

Table 12: Service use and costs at baseline

	Treatment			Control		
	N (%) using service	Mean (sd) contacts	Mean (sd) costs	N (%) using service	Mean (sd) contacts	Mean (sd) costs
General practitioner (GP)						
Psychiatrist						
Other doctor						
Psychologist						
Drug & alcohol advisor						
Other counsellor / therapist						
Social worker						
Mental health nurse						
Occupational therapist						
Other professional in mental health team						
Drug / alcohol service						
Community mental health centre						
Day care centre / day hospital						
Drop-in centre						
Self-help / support group						
Class/group at a leisure centre						
Adult education class						
Other day care activity provided by team						
Inpatient						
A&E						
Psychotropic medication						
Lost work days						

Table 13: Service use and costs at 6m follow-up

	Treatment			Control		
	N (%) using service	**Mean (sd) contacts**	**Mean (sd) costs**	**N (%) using service**	**Mean (sd) contacts**	**Mean (sd) costs**
General practitioner (GP)						
Psychiatrist						
Other doctor						
Psychologist						
Drug & alcohol advisor						
Other counsellor / therapist						
Social worker						
Mental health nurse						
Occupational therapist						
Other professional in mental health team						
Drug / alcohol service						
Community mental health centre						
Day care centre / day hospital						
Drop-in centre						
Self-help / support group						
Class/group at a leisure centre						
Adult education class						
Other day care activity provided by team						
Inpatient						
A&E						
Psychotropic medication						
Lost work days						

Table 14: Service use and costs at 12m follow-up

	Treatment			Control		
	N (%) using service	**Mean (sd) contacts**	**Mean (sd) costs**	**N (%) using service**	**Mean (sd) contacts**	**Mean (sd) costs**
General practitioner (GP)						
Psychiatrist						
Other doctor						
Psychologist						
Drug & alcohol advisor						
Other counsellor / therapist						
Social worker						
Mental health nurse						
Occupational therapist						
Other professional in mental health team						
Drug / alcohol service						
Community mental health centre						
Day care centre / day hospital						
Drop-in centre						
Self-help / support group						
Class/group at a leisure centre						
Adult education class						
Other day care activity provided by team						
Inpatient						
A&E						
Psychotropic medication						
Lost work days						

Table 15: Mean (sd) ReQoL and EQ-5D-5L scores

	ReQoL		EQ-5D-5L	
	Treatment	Control	Treatment	Control
Baseline				
6m follow-up				
12m follow-up				

8.6 Secondary Outcomes

Table 13: Secondary outcomes

	Treatment (n =)	Control (n =)	Total (N =)
	Mean (sd)	**Mean (sd)**	**Mean (sd)**
CSQ Total			
- Pre-Screening			
- 6 Months			
- 12 Months			
PQR Total			
- Pre-Screening			
- 6 Months			
- 12 Months			
MHCS Total			
- Pre-Screening			
- 6 Months			
- 12 Months			
REQOL-10 Total			
- Pre-Screening			
- 6 Months			
- 12 Months			
EQ-5D-5L Total			
- Pre-Screening			
- 6 Months			
- 12 Months			

	Treatment (n =)	Control (n =)	Total (N =)
	Mean (sd)	**Mean (sd)**	**Mean (sd)**
CSRI Total			
- Pre-Screening			
- 6 Months			
- 12 Months			
BPRS Total			
- Pre-Screening			
- 6 Months			
- 12 Months			