

Title: A cluster randomised controlled trial of a staff training intervention in residential units for people with long-term mental illness in Portugal: the PromQual trial

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Background

Following deinstitutionalisation, community based residential facilities for people with long-term mental illness have been developed to provide accommodation, adequate treatment and rehabilitation programmes. However, concerns have been raised that the limited resources and inadequate focus on the psychosocial needs of users of these services put people with longer term and more complex mental needs at risk of “reinstitutionalisation” [1].

People with severe mental illness such as schizophrenia often present high levels of disability and are difficult to engage in everyday activities. Due to the negative symptoms and cognitive impairments associated with the illness, they spend many hours per day unoccupied, or doing simple, passive activities such as sleeping, eating, watching TV or listening to the radio [2, 3]. Physical illness and psychiatric comorbidity such as depression and substance use can also contribute to this disability. Many rehabilitation services have limited capacity to deal with the characteristics and psychosocial needs of people with severe mental illness [4]. High doses of antipsychotic medication, an under-stimulating environment and low activity may exacerbate positive and negative symptoms [5,6].

Activity-oriented therapies appear to be effective in improving negative symptoms [7] and quality of life [7,8]. Occupational therapy interventions addressing disability and promoting better living and social skills in people with schizophrenia appear to be helpful [9,10].

In Portugal, there has been an expansion of mental health services in the community and closure of psychiatric hospitals over the last 20 years. This involved the establishment of a network of community services including community mental health teams, day hospitals, day centres, and residential facilities. The implementation of the National Mental Health Plan 2007-2016 [11] also led to an increase in the numbers of residential facilities. A recent study [12], showed that 42 units with medium and high staff support had been established nationwide. Community-based units scored higher than those in hospital grounds on most dimensions of quality of care, and compared to similar units across Europe, the quality of care was generally equivalent [12]. However, scores for the dimensions of recovery-based practice and therapeutic environment were markedly lower when compared to countries where the implementation of community based care had started earlier, suggesting a need for improvement [12].

To address this important issue, we evaluated a staff training intervention developed in the UK[13] and adapted to the Portuguese setting, aimed at improving the level of services users' engagement in activity and the quality of care provided in longer term mental health residential units.

Objectives

Our main objective was to assess the efficacy of the staff training intervention aimed at increasing users' activities by means of a cluster randomised controlled trial.

Methods

This study [PROMoting QUALity of Care in Residential Units for People with Long-Term Mental Illness (PromQual)], was inspired by the Rehabilitation Effectiveness for Activities for Life (REAL) study in the UK [13,14], and includes some of its members in the research team. The Directorate-General of Health of the Ministry of Health endorsed and funded the study. The Ethical Committee of the NOVA Medical School approved the study.

Inclusion criteria: All the Portuguese residential units for people with long-term mental health problems with at least 12-hours on-site staff support per day were contacted and invited to participate.

Exclusion criteria: Units that provided specialist care (for example only for people with dementia or learning disability) and units with fewer than six residents were excluded. The later was due to the need to ensure adequate recruitment of service users for our sample size.

Service managers received written information about the study and had the opportunity to discuss it before giving written informed consent for their service's participation. Baseline data collection took place between March and July 2012, while four- and eight-month follow-up assessments were conducted from June to September 2013, and October 2013 to February 2014, respectively.

Data collection and instruments

Each unit whose manager consented to participate was assessed with the Portuguese version of the Quality Indicator for Rehabilitative Care (QuIRC), a web-based toolkit completed online by the unit manager (available at www.quirc.eu), assessing the quality of care of longer-term units for people with complex mental health problems on seven domains of care (Living Environment; Therapeutic Environment; Treatments and Interventions; Self-Management and Autonomy; Recovery-Based

Practice; Social Inclusion; Human Rights). The QuIRC has excellent inter-rater reliability and good internal validity [15]. It takes about 45 minutes to complete and comprises 145 questions about service provision (e.g. number of beds, average length of stay, built environment, treatments and interventions, staffing, staff turnover, training, and supervision); links with community organizations (e.g. colleges, employment agencies, sport and leisure facilities); the therapeutic milieu and recovery-based practices (e.g. collaborative care planning, service user involvement, promotion of service users independent living skills); and the protection of services users' human rights (e.g. privacy and dignity, legal rights and the use of restraint and seclusion). Domain scores are calculated from scores on 86 items and range from 0 to 100%, with higher scores meaning better quality of care. The remaining items provide descriptive data.

The unit's staff provided additional descriptive data on the users' demographic characteristics, psychiatric diagnosis, psychotropic drugs taken, and length of stay (LOS) in the unit.

Those users who gave their written informed consent participated in a face-to-face interview taking about 30 minutes. The following scales were used: the Resident Choice Scale (RCS) [16] which rates Autonomy, assesses the degree to which residents have choice over 22 aspects of daily activities and the running of the unit, each rated on a four-point scale with total scores from 22 to 88; the Manchester Short Assessment of Quality of Life (MANSA) [17], which assesses 12 domains of Quality of Life on a scale from 1 (couldn't be worse) to 7 (couldn't be better), giving a total mean score ranging from 1 to 7; Your Treatment and Care (YTC) questionnaire [18], which assesses a person's Experiences of Care, contains 25 items that are noted as being present or not, providing a total score from between 0 to and 25; the General Milieu Index (GMI) [19], which assesses Service users' views on the unit's therapeutic culture milieu, and comprises four items rated between 1 and 5, providing a total score between 4 and 20. The interviewer also assessed each service user's functioning using the Global Assessment of Functioning (GAF) [20], in order to use this as a potential mediator between service quality and clinical outcomes in the analysis (the researcher rates the person's overall symptoms and functioning on a scale from 1 to 100).

The level of knowledge of units' staff assigned to receive the staff training intervention was assessed using a questionnaire comprising 10 multiple-choice questions and 12 true-false statements created for

the effect. The themes included recovery based practice, the importance of activities, quality of care, stigma, and human rights. The level of knowledge of the staff was assessed before and after the training workshops. Scores range from 0 to 22, with higher scores reflecting greater knowledge.

Trial Design

We used a single-blind two-arm cluster randomised controlled trial design with residential mental health units as the unit of randomisation. The trial was registered with Current Controlled Trials (Ref NCT02366117), accessible at [http:// www.clinicaltrials.gov/ct2/show/NCT02366117](http://www.clinicaltrials.gov/ct2/show/NCT02366117)

Study setting and sample

A survey of all the residential units for people with long-term mental disorders with at least 12 hours on-site staff support per day was previously carried out across Portugal [12]. This identified 42 residential units eligible for the trial, all of which were included. They had a median number of 9 beds and were assessed using the QuIRC completed by the unit manager.

Recruitment and randomisation

As several of the 42 facilities surveyed shared the same staff, 23 clusters of residential units were eligible for the trial and considered for randomisation. Simple random sampling was used to select one unit from each of these 23 clusters to receive the intervention or treatment as usual. Units that agreed to participate were randomly allocated to receive the staff training intervention (intervention group) or to continue with treatment as usual (control group). In this case, stratified randomisation using minimisation was carried out by the study statistician (AP), independently of the research team. This sampling method assigns patients to intervention and control groups, to minimize differences between them, not only in the number of patients but also in patients' characteristics known to influence the outcome. Accordingly, units' and service users' baseline information was considered in this minimisation process, namely the total mean QUIRC scores, number of beds, whether staffed 24 hours, median GAF scores, median length of stay, and median Time Use Diary scores. Before randomisation, each unit was randomly assigned a unique identification number.

Regarding the recruitment of users, in units with 10 or fewer beds all the service users were invited to participate. In larger units, a simple random sample of ten users was selected and then approached to participate in the study.

Study intervention

Intervention units: Units allocated to this arm received the staff training intervention, initially developed by Dr Sarah Cook and Dr Cathy Hill from Sheffield Hallam University in England and adapted for the Portuguese context by GC, HK, JCA, MK, with consulting experts (JO, IF). The intervention comprised three phases (predisposing; enabling; reinforcing) and has been described in detail elsewhere [10, 15]. In summary, the **Predisposing Stage** aimed to gain support for the intervention from the senior unit managers and clinicians [21] through a one-day workshop facilitated by two members of the research team (GC and MF), in Lisbon. Two-day workshops were also carried out (GC and MF) for the remaining staff of the units in the intervention group in order to increase knowledge on the following themes: the impact of severe mental illness and negative symptoms on cognition and motivation; the importance of rehabilitation programmes for long-term psychiatric patients; activity as an important tool to decrease negative symptoms and improve quality of life and satisfaction with care; the Recovery approach; and how to motivate the units' users to participate in more activities. **The Enabling Stage** aimed at identifying and addressing barriers to change through team-level action planning and training in appropriate new skills [22]. This was delivered by one of three intervention teams comprising a senior occupational therapist (OT), an activity worker and a user expert. The OT and activity worker spent four weeks in each unit and first reviewed the unit's resources and practices related to service user activities. Together with the user expert, they facilitated a one-day training course for nurses and unqualified staff of the unit, which demonstrated occupational therapy and motivational techniques [23, 24] to encourage service user engagement in activities. The OT and the activity worker worked with staff in the unit daily for the rest of the four weeks to model and give "hands on" support for staff to gain confidence in the implementation of these techniques. **The Reinforcing Stage** involved maintaining the changes made to practice [25]. In the fourth week, the intervention team facilitated a half-day workshop to review the intervention with the unit manager and staff and to agree the best way to incorporate the skills acquired into the unit's usual structures and processes. Reflecting this, an Action Plan was drawn up by the intervention team's OT. A staff member from the unit was identified to oversee delivery of the Action Plan in the unit after the intervention team left. Email support to the unit was available from the PromQual team over the subsequent 8 months. A prompt email was sent by the OT of PromQual team every month to

encourage contact. The PromQual teams received bi-monthly supervision from senior members of the research team (MJC and GC).

Our intervention differed from the UK one in two aspects: it included workshops for the managers and the general staff of the units in the Predisposing phase, and the “hands-on intervention” was 4-weeks long instead of 5-weeks.

Control units: Units allocated to this arm continued with their usual service and were able to use any resources at their disposal to provide maximum care for service users. There were no restrictions on the work of these teams.

Treatment fidelity

At the end of each unit’s intervention period, the supervising OT (MJC) completed a proforma together with the PromQual team’s OT and a senior member of the research team who had promoted and attended the training workshops (GC). This recorded the delivery of 24 specific aspects of the PromQual intervention with each item completed achieving a score of 1 (Supplemental table).

Informed consent and masking of researchers

The researchers approached the units’ users to explain the study purpose, and to give them a participant information sheet and the opportunity to ask questions about the study. Service users that declined participation despite having capacity to give informed consent, and those that had no capacity, were not interviewed at baseline and follow-up data collection. In such cases, in units with more than 10 users, another potential participant was randomly selected. We made concerted efforts to minimise unmasking of our researchers. Both the unit staff and the service users were instructed not to reveal to the researchers whether they had received the training intervention. Any unmasking of researchers was reported to the programme management group to assign a new researcher to evaluate that unit at follow-up. Unmasking was assessed by asking the researchers to record whether they had any information that would potentially unmask them to the allocation of each unit to the control or intervention group at four- and eight-month follow-up data. No unmasking was reported.

Primary outcome

The primary outcome was the degree to which service users were engaged in activity over the previous week, assessed using the Time Use Diary (TUD) [26], and completed retrospectively during a

structured interview with the service user. This instrument rates the service users' activities during four periods of each day: morning, lunchtime, afternoon and evening. The degree of engagement in activity as well as the complexity of the activity is rated on a scale of 0 to 4 for each time period, giving a maximum possible score of 112, higher scores reflecting a higher and more complex level of activity. The TUD was reassessed at 4 and 8-months.

Secondary outcome

Service quality was assessed by asking the unit manager to complete the QuIRC at the eight-month follow-up. Service users' Quality of Life was assessed by the MANSAs mean scores obtained from the service users' interviews at eight-months.

Data collection

Descriptive data on all service users were collected from staff and service users as follows: demographic characteristics (age, gender, and occupation); diagnosis; and length of current admission. Primary and secondary outcome measures were completed as described above. Potential mediators of outcomes were also assessed including the staffing level of the unit (collected from the unit manager), and service users' overall functioning assessed using the Global Assessment of Functioning scale (GAF) [20], which was completed by researchers. Researchers blind to the intervention collected the follow-up data.

Data management

Data were entered into the study's Excel databases by the researchers. Range and logic checks were built in to assist with data cleaning. Ten percent of baseline data were double entered to check for data entry errors with an error rate set at 5%, above which all data would be double entered. As the error rate was 1% no further double data entry was required.

Power and sample size

Our primary analysis aimed to compare the mean values of Time Use Diary scores at baseline and at four and eight-month follow-ups. Because a greater difference between baseline and four-month follow-up than between baseline and eight-month follow-up was expected, the required sample size

was calculated based on the expected efficacy of the trial at eight-months follow-up. In order to calculate a sample size for the trial at 80% power and a significance level of 0.05, we assumed an intra-cluster correlation coefficient (ICC) of 0.04 [14] and an average cluster size of 10 (i.e. 10 patients participating per unit). We anticipated a mean TUD score of 51 (SD 11) at baseline by inflating the mean obtained by Killaspy et al. [14] by 10%. We did this on the basis that since Killaspy et al. had selected units for training that scored below the median QuIRC score (i.e. lower quality units), their service users could, as a consequence, have had lower Time Use Diary scores. Thus, in order to show a 15% increase in scores at eight-month follow-up (attaining a mean of 59, SD 11) and assuming a 10% loss to follow-up, we required 66 service users in each arm from a minimum of 6 clusters (residential units).

Data analysis

Descriptive characteristics were summarised using mean (SD), median (IQR: P₂₅- P₇₅) or number (%) as appropriate. Random effects linear regression models were used to compare service users' TUD scores between trial arms at four and eight months separately, while adjusting for baseline scores. Some service users assessed at baseline were not present at the follow-ups. Therefore, following the method of Killaspy et al. [14], we used the mean baseline score for each unit (based on the service users present in the unit at the baseline data collection point) in the models rather than scores for individual residents.

The effect of the intervention on QuIRC dimension scores and MANSAs score was evaluated by linear regression models. Student's t-test was used to assess the efficacy of the training workshops.

The main trial analyses were carried out on an intention-to-treat basis. A *p*-value <0.05 was considered significant. The Statistical Package for the Social Science for Windows (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.) and Stata (Release 13, College Station, TX) were used.

We followed the CONSORT statement extension for Cluster Trials for reporting the results of our study. There were no changes to the protocol after the study began.

Results

All 23 participating units were surveyed at the 4-month and 8-month follow-ups. All service user interviews were completed within 2.1 (SD=1.1) months of the manager's assessment of the unit.

Unit characteristics

Table 1 shows the main characteristics of the units at baseline and 8-month follow-up. The majority of the 23 units included were situated in the community. Twelve units were randomly assigned to the control and 11 to the intervention group. At baseline the median number of beds was 11 per unit, with a minimum of 6 and a maximum of 37, and a median of 100% occupation. All units offered access to a clinical psychologist, a nurse, and a social worker either inside or outside the unit at baseline. The majority of the units offered access to a psychiatrist, a support worker, and an art therapist inside or outside the unit. Only a few units offered access to a counsellor/psychotherapist. While some units carried out the same activity and rehabilitation programme for all the residents, the majority of the units carried out individualised programmes for each resident (Table 1).

The median percent staff turnover in the previous two years (Table 1) was 8.3 in the control group and 10.0 in the intervention group. The median percent service user turnover in the previous two years was 9.3 and 0.0 in the control and intervention groups respectively.

Quality of care measured by the QuIRC (Table 2) at baseline showed mean scores above 50% in the dimensions Living Environment, Self-Management and Autonomy, Social Inclusion, and Human Rights in both control and intervention groups.

Service users' characteristics

At baseline, service users were mainly men with a diagnosis of schizophrenia or schizoaffective disorders (Table 3), most of whom had been in the units between four and five years. There was an imbalance in service user's age between the trial arms at baseline and there were also slight imbalances in some of the unit's characteristics. These imbalances were not unexpected given this was a cluster randomised trial. There were no statistically significant differences between the intervention and the control group in the GAF, MANSA, RCS, YTC, GMI and TUD mean scores at baseline.

Results of the workshops' training

Knowledge mean scores, assessed before and after the workshops, were higher both in the general staff (pre- 11.0 vs. post- 12.5, $p \leq 0.01$) and in the managers of the services receiving the intervention (13.2 vs. 14.9, $p = 0.078$).

Training fidelity

Training fidelity for the different components during each stage of the intervention was high, with 19 out of 24 components reaching 90 to 100% fidelity and the remaining components reaching 70 to 85% (supplemental table).

Results of the trial

Primary outcome: At the four-month follow-up, TUD mean scores were 55.1 (8.6) in the intervention, and 53.2 (12.0) in the control group (regression coefficient estimate = 0.16; 95% CI: -4.72, 5.05; $p = 0.948$, adjusted by mean TUD baseline score) (not shown in Tables). There was also no statistical difference in the TUD mean scores between the trial arms in levels of activity at eight-months (Table 3), after adjustment for baseline mean scores.

Secondary outcomes: most of the QuIRC dimension scores at the eight-month follow-up were higher in the intervention than control group, but without reaching statistical significance (Table 2). The MANSAs mean scores (Table 3) did not differ significantly between the two groups at eight months.

There were also no statistically significant differences in the RCS, YTC, and GMI mean scores between the intervention and the control group at eight-month follow-up.

Baseline age of users ($p < 0.001$), and service users' activity level (TUD) ($p < 0.001$) influenced the final results. The coefficient estimate of the Intervention group was 3.05 meaning that, on average, the TUD score at 8-month FU, was 3.05 points higher when compared with the Control group, but this difference was not statistically significant ($p = 0.281$). As for age, the results show that there was a statistically significant decrease of 0.23 in the TUD score at eight-month follow-up for each one-year increase in service users' age ($p < 0.001$). Similarly, for each one-point increase in service users' baseline TUD score, there was on average a statistically significant increase of 0.68 in the TUD score at eight-month follow-up ($p < 0.001$).

Discussion

This study has shown that it is possible to train staff of longer term residential mental health units to carry out an intervention to improve service users' engagement in activities. However, when tested in a randomised controlled trial, the intervention was not found to be effective.

Our intervention lacked efficacy despite high treatment fidelity across the units (supplementary table). A similar study [13] carried out in 40 inpatient mental health rehabilitation units throughout the UK, included a slightly longer Enabling Stage of training (5-weeks) but also found no significant difference between intervention and comparison units at 12-month follow-up in terms of service user engagement in activities, despite high fidelity implementation and positive feedback from unit staff. A qualitative investigation of possible reasons for this concluded that staff did not continue to implement the changes in practice after the Enabling Stage, once the intervention teams left [27]. As the PromQual study started before the results of the UK trial were known and before the qualitative process evaluation had been carried out, the learning from this could not, unfortunately, be incorporated into PromQual.

The results of our multilevel regression analysis suggested that the intervention may have obtained greater efficacy amongst younger patients and those that had a higher level of activity at recruitment. This infers that those with a longer history and more severe symptoms that impair motivation (more severe negative symptoms) may be especially resistant to treatment. The multilevel regression analysis included the percent service user turnover due to its significant difference between the two groups at baseline, but it showed no impact in the results.

The main strength of the present study was the inclusion of all the existing units in Portugal. Its main limitations were the small number of existing units, and the need to merge them for intervention purposes. Due to that fact, all units were included and not, as in the UK study [13], only those that had QuIRC assessment scores below the median at baseline, with a potential impact in the efficacy of the study. Of course, this difference had one advantage in that all units were considered to be open to improvement and thus our results have greater generalisability, at least in Portugal.

In our opinion, several factors contributed to the difficulty in making changes in staff attitudes. In the first place the small number of staff per unit and the financial constraints of the units in enrolling more

professionals. This study was carried out during a period of economic crisis when the National Mental Health Plan in Portugal, which aimed to increase the number of residential mental health units and provide greater support through services in the community, was suspended.

Second, the lack of regular training and information for the staff about the recovery model and motivational approaches, identified during the workshops, could play an important role in preventing changes in the staff attitudes. Third, the monthly contact by email of the intervention team with the designated staff members during the Reinforcing Stage, was not reciprocated, preventing further reinforcement of the intervention. This could have been due to the work overload and/or the lack of interest in pursuing the new model of intervention. Fourth, an important obstacle to change in these service users' level of activity might well have been the severity of their impairments and the longer-term nature of their mental health problems. This is seen in their high baseline GAF scores and long lengths of stay in the units.

Finally, another limitation was the minimal involvement of service users in the delivery of the intervention, and future adaptation of the intervention should address this aspect.

Conclusions

Our staff training intervention to increase service users' engagement in activities in longer term mental health residences was not effective. The training led to an increase in staff knowledge about relevant aspects of care for this group but this did not lead to lasting change in practice that could enable service users. This is concordant with the negative results of a similar UK study [13]. Given the high level of disability of this group, further research in this area is needed to develop and test interventions that can promote recovery.

Author contributions: GC, AP, HK, MK, and JCA designed the study. GC, MF and GT oversaw data collection. GC and AP conducted the analyses and conceptualized and wrote most of the manuscript. All authors revised the manuscript and approved its final version.

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Figure 1. Recruitment of Units and Patients at Baseline

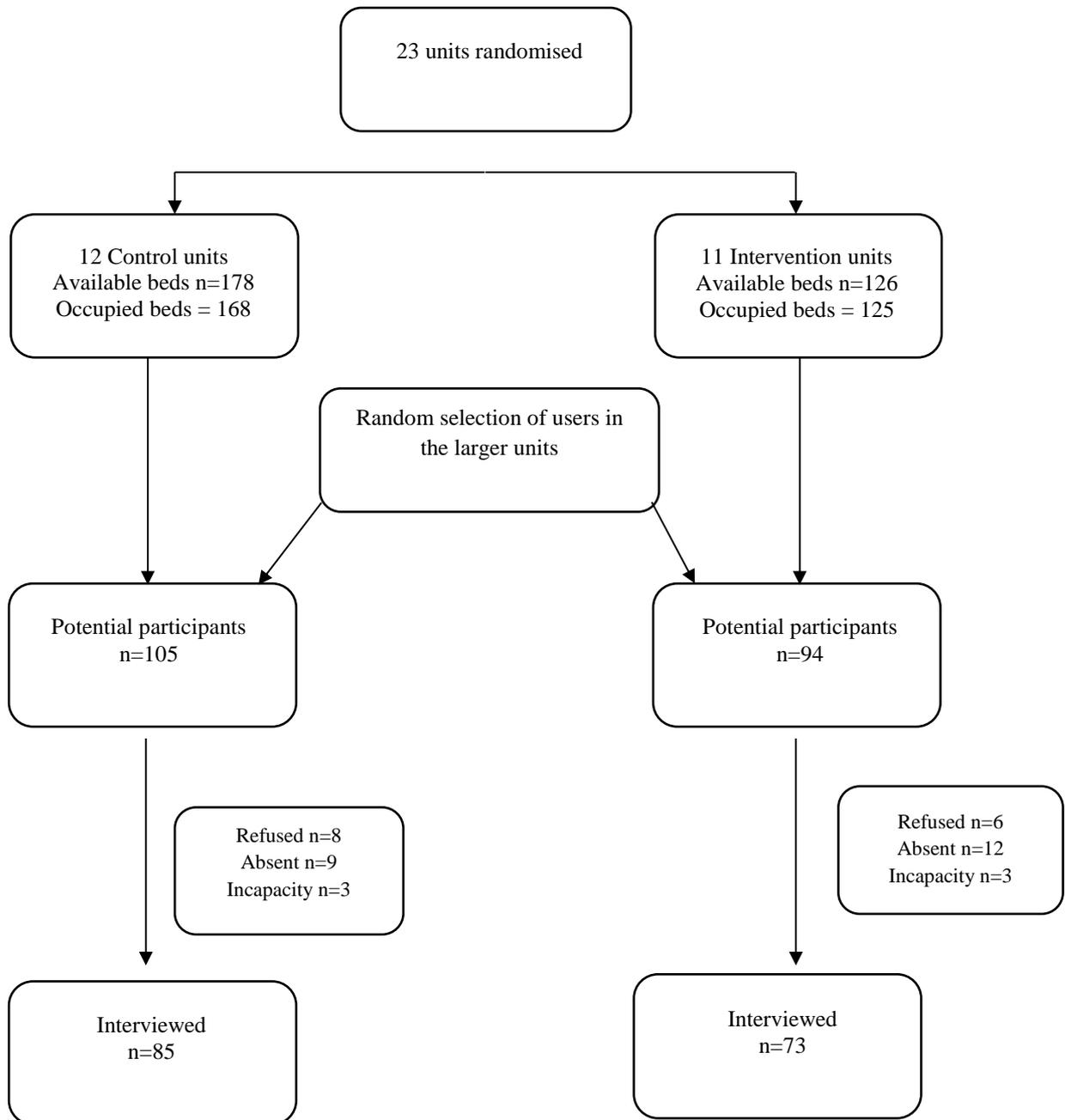


Figure 2. Recruitment of service users at 8-month follow-up

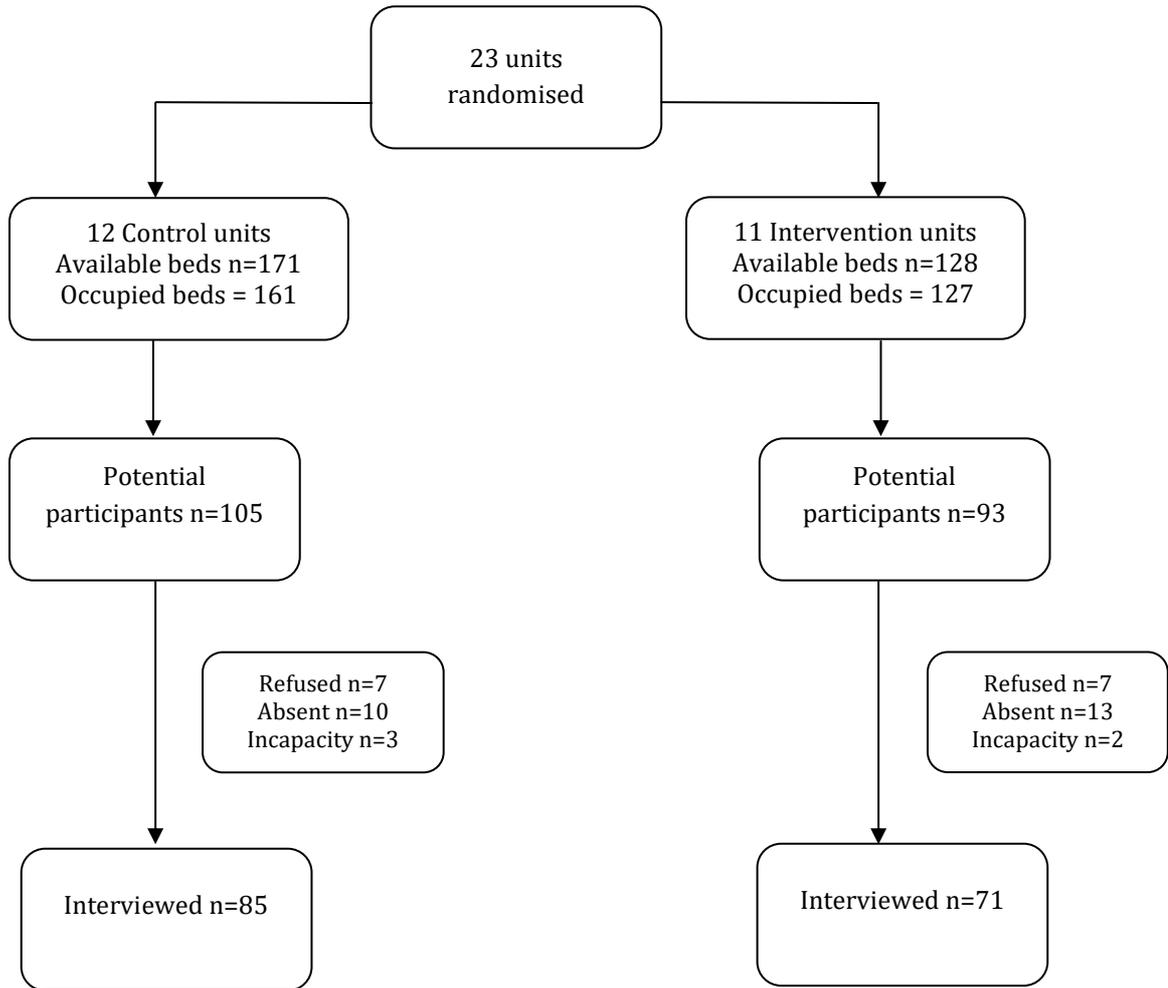


Table 1. Unit characteristics at baseline and 8-month follow-up

Variable	Baseline		8-month follow-up	
	Control units, n=12	Intervention units, n=11	Control units, n=12	Intervention units, n=11
Unit type, n (%)				
Hospital ward	4 (33.3)	2 (18.2)	4 (33.3)	2 (18.2)
Community based	8 (66.7)	9 (81.8)	8 (66.7)	9 (81.8)
Beds				
Beds on the unit, median [min-max]	11 [6-37]	10 [6-21]	11 [6-37]	10 [6-21]
% beds occupied, median (P ₂₅ -P ₇₅)	100.0 (86.8-100.0)	100.0 (100.0-100.0)	100.0 (86.8-100.0)	100.0 (100.0-100.0)
Unit's Staffing	n (%)	n (%)	n (%)	n (%)
Psychiatrist	6 (50.0)	2 (18.2)	5 (41.7)	4 (36.4)
Clinical psychologist	7 (58.3)	8 (72.7)	7 (58.3)	10 (90.9)
Occupational therapist	7 (58.3)	3 (27.3)	8 (66.7)	7 (63.6)
Nurse	9 (75.0)	3 (27.3)	8 (66.7)	5 (45.5)
Support worker	10 (83.3)	10 (90.9)	11 (91.7)	9 (81.8)
Social worker	2 (16.7)	5 (45.5)	10 (83.3)	9 (81.8)
Access to professionals outside the unit				
Psychiatrist	5 (41.7)	9 (81.8)	7 (58.3)	4 (36.4)
Clinical psychologist	5 (41.7)	3 (27.3)	5 (41.7)	1 (9.1)
Occupational therapist	3 (25.0)	4 (36.4)	3 (25.0)	3 (27.3)
Nurse	3 (25.0)	7 (63.6)	4 (33.3)	3 (27.3)
Support worker	1 (8.3)	1 (9.1)	0	0
Social worker	10 (83.3)	6 (54.5)	2 (16.7)	2 (18.2)
Access to professionals inside or outside the unit				

Counsellor/ psycho-therapist	3 (25.0)	5 (35.5)	4 (33.3)	4 (36.4)
Art therapist	7 (58.3)	5 (61.4)	6 (50.0)	4 (36.4)
Activities Support	n (%)	n (%)	n (%)	n (%)
Same program for all residents	5 (41.7)	6 (54.5)	5 (41.7)	6 (54.5)
Different program for each resident	8 (66.7)	9 (81.8)	9 (75.0)	10 (90.9)
Turnover last two years	Median, IQR	Median, IQR	Median, IQR	Median, IQR
% Staff turnover	8.3 (0-17.1)	10 (0-133.3)	0 (0-263.0)	8.3 (0-57.1)
% Patient turnover	9.3 (0-16.1)	0 (0-28.6)	7.6 (0-21.7)	8.3 (0-16.7)

IQR, Interquartile Range

Table 2. Comparison of the QuIRC dimensions scores (secondary outcome measure) in the intervention and the control group at baseline and 8-month follow-up, mean (SD)

QuIRC Dimensions	Group	Baseline	8-Month	Coefficient estimates (95%CI)
Living Environment	Intervention (n=11)	65.8 (12.8)	66.4 (8.7)	5.15 (-4.71, 15.02)
	Control (n=12)	59.5 (11.4)	57.6 (15.5)	
Therapeutic Environment	Intervention	44.9 (12.8)	47.5 (7.7)	4.41 (-1.34, 10.17)
	Control	45.1 (10.9)	43.2 (10.5)	
Self-Management & Autonomy	Intervention	55.5 (16.5)	60.3 (13.3)	5.10 (-2.70, 12.90)
	Control	51.7 (16.9)	52.4 (16.0)	
Social Inclusion	Intervention	53.9 (15.2)	54.7 (15.9)	7.82 (-0.42, 16.07)
	Control	50.1 (13.3)	43.8 (13.3)	
Human Rights	Intervention	52.5 (12.4)	54.7 (11.5)	3.77 (-3.83, 11.37)
	Control	52.5 (12.9)	50.9 (16.4)	
Therapeutic Interventions	Intervention	51.3 (15.5)	53.9 (9.5)	6.02 (-2.75, 14.79)
	Control	48.3 (13.7)	46.7 (12.7)	
Recovery-Based Practice	Intervention	44.1 (16.0)	48.1 (12.3)	3.79 (-3.41, 10.99)
	Control	41.5 (12.2)	42.4 (13.4)	

p-values corresponding to the intervention effect on the QuIRC dimensions scores adjusted by the QuIRC baseline dimensions' scores

Table 3. Patient characteristics and quality of life dimensions, n (%), mean (SD), median (IQR)

	Baseline		8-month follow-up	
	N=157		N=151	
	Control units n=84 (53.5%)	Intervention units n=73 (46.5%)	Control units n=82 (54.3%)	Intervention units n=69 (45.7%)
Gender (male), n (%)	50 (59.5%)	49 (67.1%)	48 (58.5%)	50 (72.5%)
Age (years), mean (SD)	53.0 (12.0)	46.4 (9.4)	53.3 (12.7)	49.5 (8.9)
Professional status, n (%)				
With occupation	10* (12.8%)	13* (18.8%)	10 (12.3%)	14 (20.3%)
Unemployed	5 (6.4%)	11 (15.9%)	9 (11.1%)	14 (20.3%)
Retired	63 (80.8%)	45 (65.2%)	62 (76.5%)	41 (59.4%)
Diagnosis				
Schizophrenia and schizoaffective disorders (F20-F29)	61 (72.6%)	53 (72.6%)	38** (71.7%)	33** (67.3%)
Length current admission (yrs.), median (IQR)	5.5 (1.0-11.0)	4.0 (1.0-6.0)	4.0 (1.0-10.0)	6.0 (1.5- 7.0)
Functioning, activity and quality of life, mean scores (SD)				
Time Use Diary (primary outcome measure)	51.3 (12.1)	53.6 (9.4)	49.1 (12.2)	54.2 (11.2)
MANSA (secondary outcome measure)	4.9 (0.8)	4.6 (0.9)	4.7 (0.8)	4.6 (0.8)
RCS	57.9 (10.4)	57.0 (9.8)	50.8 (11.0)	54.3 (10.5)
YTC	18.1 (4.6)	18.4 (4.5)	21.2 (4.2)	21.2 (4.5)
GMI	19.3 (4.5)	17.8 (5.1)	18.8 (3.7)	17.6 (4.4)

* Control Units n=78, Intervention Units n=69; ** Control Units n=53, Intervention Units n=49;

MANSA=Manchester Short Assessment of Quality of Life; RCS=Resident Choice Scale; YTC=Your Treatment and Care; GMI=General Milieu Index