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# The CORE Study Protocol: a stepped wedge cluster randomised controlled trial to test a co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness in the community mental health setting



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## Title Page

# The CORE Study Protocol: a stepped wedge cluster randomised controlled trial to test a co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness in the community mental health setting.

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## INTRODUCTION

User engagement in mental health service design is integral to developing systems that are user aligned and deliver high quality care. To date little evidence exists to determine if engagement through Experience Based Co-Design quality improvement methods results in changes to individual health outcomes. The CORE study aims to test if co-design improves individual psychosocial recovery outcomes.

## METHODS

A stepped wedge cluster randomised controlled trial over 30 months with four data collection time points (baseline, 9month, 18month and 27 month). Clusters are randomised to one of three waves to receive an intervention (Mental Health Experience Co-Design, MH ECO). Sample size will be 60 staff, 252 users and 252 carers of service users. Qualitative and quantitative data are collected over the 30 months to inform outcomes and the nested process evaluation. The primary outcome is improvement in recovery score for service users. Secondary outcomes are improvements to mental health and well being of users and carers, changes to staff attitudes and recovery orientation of services. Routinely collected data about health service use, medications and hospitalisations is also sought. A linear mixed effects model will be used to compare the intervention and usual care periods for continuous outcomes and generalized linear mixed effects model for binary outcomes. Participants will be analysed in the group that the cluster was assigned to at each time point. The model will include intervention status and time as fixed effects and site and individuals as random effects.

## ETHICS AND DISSEMINATION

Ethics approval has been granted by The University of Melbourne, Human Research Ethics Committee (Approval No.: 1340299.3) and the Federal and State Departments of Health

Committees (Project 20/2014) responsible for routine data collection. Results of the baseline data will be reported in a scientific journal in 2015. Outcomes data will be reported in 2017.

**TRIAL REGISTRATION:** The CORE Study is registered with the Australian and New Zealand Clinical Trials Registry ACTRN12614000457640.

## STRENGTHS

- This study aims to identify the effectiveness of an experienced based co-design methodology for improving individual psychosocial recovery outcomes;
- The stepped wedge design means that all clusters ultimately receive the intervention but those waiting for the intervention to commence act as controls;
- The study is a mixed cohort and cross sectional design to collect data about recovery experience and intervention effects over time but also to replenish the sample size over the course of the study;
- The study design includes a purposeful recruitment strategy to increase reach of people with serious mental illness and their carers through awareness raising and maximising participation options for users.

## LIMITATIONS

- System changes may impact on users' perceptions of service experiences which may affect outcomes and participation;
- Action plans may be formulated as part of the co-design intervention but not implemented at the cluster level;
- Staff may change in participating clusters which may affect outcomes;

- Staff, service users and carers may communicate with other participating teams and contaminate the intervention.
- The study cannot include people who do not speak English well due to translation and resource constraints.

## INTRODCUTION

### Background and rationale

User participation in mental health planning and service design is recognised as an important component of system improvements aligned with user needs and patient-centred care. In the published literature the terms service users, patients, clients and consumers are used interchangeably to refer to recipients of health care services, while the term carer/s refers to family or friends; the term "user" is applied in this article as an umbrella term for these related concepts. User participation has expanded beyond surveying people to gather feedback about services to now include meaningful partnerships facilitated through co-learning, active collaboration, shared power and decision-making in healthcare; all of which are encapsulated in the term "engagement" [1, 2]. Engagement has come to be seen as an integral element to improve quality of care experiences and Experience Based Co-Design (EBCD) has emerged as fitting for this task.

EBCD utilises participatory action research methods and is informed by design thinking to identify users' positive and negative experiences of services.[3, 4] EBCD is more than a survey or satisfaction activity, it is premised on developing deep understanding of how users' perceive and experience the look, feel, processes and structures of services; all the aspects of organisations that touch them ("touch points"). This is followed by a process of sharing these experiences between staff and users, and bringing everyone together to enact and implement change around negative touch points (co-design).[3, 5, 6] EBCD extends the health care system focus on design of processes and practices, to the design of services based on human experience.[5] Engaging users in co-designing organisational changes premised on their

experiences is said to result in better quality of care and system performance, this is achieved through illuminating individual's subjective and personal feelings at different points in the care pathway; in turn, this is said to result in improvements in patient outcomes. At present though there is little evidence from randomised controlled trials (RCTs) of EBCD as to whether better quality of care, system performance and improved user experience does result in changes to individual health outcomes. [7-9] To date, no RCTs have been conducted of EBCD to determine this or explore its potential as method for building user-designed recovery-oriented mental health systems.

EBCD evidence at present is largely from qualitative evaluations of quality of care improvement initiatives in Alzheimer's, breast and lung cancer care in Australia, New Zealand (NZ) and the United Kingdom (UK).[10-13] More recently, an accelerated form of EBCD was tested in intensive care and lung cancer services in the UK.[14-16] EBCD was implemented in Australian New South Wales (NSW) hospital emergency departments in response to quality and safety issues, qualitative evaluation suggested improved consumer experiences and staff work practices.[17-19] There is a current co-design initiative underway in a Victorian Emergency Department in Australia.[20] In the mental health setting however, EBCD appears only been implemented in local, staff driven quality improvement initiatives in the in-patient context. These local initiatives indicate good results, for example, complaints were said to be reduced by 80% over 14 months and staff attitudes to patient experiences of services changed.[21] Rigorous evaluation of the appropriateness and effectiveness of EBCD in the mental health setting for facilitating user-led recovery-oriented services which improve experience and hence recovery outcomes has yet to be conducted.

Other methods of user involvement in the community mental health setting have been tested in RCTs but they have not been co-design and service improvement focused.[22-31] In mental health there is an emphasis on system improvement to be recovery-oriented coupled with the delivery of evidence based mental health services. This is articulated in policies from the United Kingdom (UK), [32, 33] Canada, [34] the United States (US), [35] Australia [36-41] and New Zealand (NZ).[42] Measuring recovery as it contemporarily described is difficult. There is recognition that user defined recovery is different from symptom reduction and functional improvements characteristic of earlier clinical measures.[43] Recovery is articulated as an ongoing, subjective process unique to each individual.[44] EBCD with its focus on capturing individuals' subjective experiences of services may then offer a method to facilitate changes in mental health organisations that are premised on user-driven perspectives of recovery-oriented services.[45-47] Determining if this betterment of experience then translates to improved psychosocial recovery outcomes is critical for informing system design and evidence based mental health care.

The CORE study will be a world first stepped wedge cluster randomised controlled trial to test if a co-design method improves psychosocial recovery outcomes for people affected by mental illness in the community mental health setting.[48-50] The research design is a stepped wedge cluster randomised controlled trial with a nested process evaluation. This article describes the study protocol and adheres to the SPIRIT 2013 explanation and elaboration for drafting of study protocols.[51] Guidelines for the development and reporting of stepped wedge designs are currently in formation and not due for release until 2017.[52] Planning for the CORE study began in June 2013, recruitment of users and carers will commence in 2014, and data collection will be completed April 2017. The study was funded in June 2013 to June 2017.

## OBBJECTIVES

Our hypothesis is that an EBCD based intervention aimed to make services recovery-orientated, will result in improved psychosocial recovery outcomes for people affected by mental illness. In addition it is hypothesised that this will improve carers' mental health and well being, and change staff attitudes to recovery and the recovery orientation of services.

## METHODS AND ANALYSIS

### Design

Figure 1 shows a diagram of the stepped wedge cluster randomised controlled trial with six clusters.

<insert Figure 1 Design for a stepped wedge cluster randomised controlled trial in the community mental health setting about here>.

The duration of the CORE study will be two and a half years (30 months). The first time point corresponds to a baseline measurement (3 months) where none of the clusters receive the intervention ($W_0$ - Wave 0 in figure 1).[53] After that the CORE intervention will be rolled out sequentially to six clusters over three time periods (waves) until all clusters receive the intervention. At each wave, two clusters will receive the intervention over a 9 month period ($W_1$ - Wave 1, $W_2$ – Wave 2, $W_3$ – Wave 3). Clusters that do not receive the intervention at a

particular wave act as a control.[54, 55] The time period to which each cluster is allocated to receive the intervention is assigned randomly.[54] Data will be collected at the cluster and individual level at four time points: baseline and across the subsequent three intervention waves (9, 18 and 27 months).

Cluster randomisation is often adopted when it is difficult to randomise individuals to receive an intervention in routine practice.[56] As the CORE intervention is implemented at the cluster level and involves staff, services users and carers it was not possible to randomise individuals within a cluster to an intervention and a control arm. The stepped wedge design overcomes the issue of not being able to deliver the intervention concurrently to all clusters.[54-56] In addition, a parallel cluster randomised trial for the CORE study, where only half the clusters are randomised to the intervention group, was not feasible with only six clusters.

The CORE study will consist of overlapping samples of individuals that may be measured at one or more subsequent waves.[57]. Individuals (users, carers or staff) will be sampled from each cluster at wave 0 (figure 1) and followed up at each wave (cohort design). New individuals will also be recruited at subsequent waves to capture new users that join the service after the initial baseline recruitment and to allow for attrition of individuals that were recruited at an earlier wave. In using the cohort design for individuals, selection bias may be minimised because individuals are recruited prior to randomisation. However, a cohort design may introduce bias if there is differential loss to follow up at each wave and across clusters. Service users move in and out of the health teams (cluster), and may even move to other teams (who may or may not be part of the trial). Furthermore, with a cohort design there is a

chance that individuals may not attend the health services centre after the intervention has been implemented, hence potentially diluting the intervention effect (contamination).

Due to practical difficulties and high costs it was not possible to recruit successive cross-sectional samples of individuals for this study. One reason is that the population is hard to reach and recruitment of the individuals requires a combination of dedicated research assistants at each site to recruit individuals and staff generating awareness, which is costly and time consuming. A further factor is that the population is unlikely to renew and so incident cases for a cross sectional design are less likely, and given that size of the six teams (clusters) may range between 60 to 300 service users, there is a higher chance that individuals are more likely to be sampled more than once, particularly in the smaller clusters if repeated cross-sectional sampling is adopted.

Informing the trial design is a theoretical model of engagement and translation that has formed the first stage of the study. The first stage of the study involved the recruitment of the service provider organisations so that extensive documentation of the policy and service delivery context could occur (explained later). This data has been used to inform purposefully developed recruitment strategies for users, and implementation and maintenances strategies for the intervention. The theoretical model of engagement and translation is based on a knowledge transfer model that has the ultimate goal of building knowledge and shared understanding of the research question, maintaining partnerships and relationship and getting sites trial ready for implementation.[58] A nested process evaluation of the trial has also been developed.

## PARTICIPANTS AND SETTING

Eligible participants are staff working within the six identified clusters (teams) from three participating Mental Health Community Support Service Providers (MHCSS). The services users receiving care from the participating MHCSS cluster (team) and carers of those service users. To participate, service users and carers will need to speak and understand English well due to fund limitations for the translation of materials or provision of interpreters. Levels of understanding of the requirements for research participation will be determined by the completion of a two stage consent process administered by trained research assistants to check if users have understood their involvement during the enrolment process. Service users and carers who are unable to provide informed consent or are unwell during times of telephone interviews or face to face study days will be placed on a wait-list and re-invited to the study in a fortnight to ensure maximum participation options.

### The setting and target population

MHCSS are located in metropolitan, outer metropolitan and regional areas of Victoria Australia. Services are delivered by community health centres (CHCs) and secular and non-secular non-government organisations (NGOs) by a mix of professionals with training in community nursing, social work, occupational therapy and case work. Teams vary in sizes but typically include 8-12 members who deliver case management and outreach services to anywhere from 60-300 service users in a specified geographical catchment area. The model of service delivery is based on the completion of a comprehensive assessment of client and carer/family needs (housing, social or other support needs). This assessment forms the basis of a user-directed recovery plan which covers an individual's daily living skills, physical

health, housing, relationships, social connections, education, training and employment and parenting or family needs. Carers may be involved in the development of a recovery plan where appropriate.[59]

Service eligibility is set out by the government funding authority responsible for mental health community support services (the Victorian State government). These criteria include age group of 16-65 years, disability attributable to a psychiatric condition (bipolar disorder, schizophrenia, psychosis, major depression, severe anxiety, personality disorders, posttraumatic stress), impairment that is permanent and results in substantially reduced psychosocial functioning for communication, social interaction, learning, self-care, self-management, and impairment that affect the ability for social and economic participation.[59]

**INTERVENTION**

The intervention to be delivered is called Mental Health Experience Based Co-design (MH ECO). MH ECO implements a research methodology that applies the theory and practice of Experience Based Design.[48] It was developed by the Victorian Mental Illness Awareness Council and TANDEM representing Victorian mental health carers (formerly the Victorian Mental Health Carers Network) and piloted in former Psychiatric Disability Rehabilitation Support Services (now called Mental Health Community Support Services). Evaluation of the pilot of MH ECO indicated positive benefits for staff, users and carers.[60] Figure 2 outlines the intervention stages and elements for delivery in the CORE Study. Appendix 1 details the program logic and anticipated outcomes from the intervention.

< insert Figure 2 Flowchart of MH ECO Intervention for CORE about here>

There are two stages to MH ECO. The intervention takes a total of 40 weeks (9 months) to implement as outlined in figure 2. Stage one involves information gathering which is conducted over 21 weeks (5 months) participants are invited to participate in this completion of baseline surveys. A "touch point" computer assisted telephone interview (TP-CATI) is administered with all users and carers in the intervention sites during weeks 1-13. The CATI is termed touch points as it is used to identify the high (positive) experiences and the low (negative) experiences of service users. For CORE the TP-CATI has been modified and adapted to focus on questions that will elicit experiences related to recovery and recovery-orientation of services. The TP-CATI will take approximately 45 minutes with service users and carers. Trained research assistants will administer the TP-CATI with users and carers at The University of Melbourne. CORE study investigators will analyse the open and closed question responses to identify the positive and negative experiences that emerge. . Once the top three positive and negative touch points are determined separate focus groups (FGs) are held with staff (n=8-10), users (n=8-10) and carers (n=8-10) to explore these in-depth. FGs will be administered for 1-2 hours per group. In addition, a series of in-depth, face to face interviews are held with a small number of users (n=3) and carers (n=3) per cluster to hear their service stories between weeks 14 and 21. Interviews will take approximately 1.5-2 hours to complete. Focus groups and interviews will be scheduled by University research staff but facilitated by co-investigators from VMIAC and TANDEM (WW and RC).

Stage two of MH ECO is the co-design process completed over 19 weeks and involves the formation of collaboration and co-design groups; this process is facilitated by RC and WW. Prior to these groups meeting, the facilitators deliver two one day training sessions to staff,

service users and carers to resource and support participation in groups and to outline what to expect from the intervention and group processes. In MH ECO there is one collaboration group and up to three co-design groups (one for each of the negative touch points that may be worked on within a cluster).

Collaboration group membership is ideally comprised of 8 people in total (a 1 manager, 1 quality manager, 2 consumers, 2 carers and 2 staff members) and meets three times (2 hours per meeting). The primary role of the collaboration group is to oversee the project and implement the action plan from the co-design group/s. The collaboration group meet first and discuss the touch points and set objectives for what the co-design groups may work on. Co-design group membership is ideally comprised of 6 people (1 senior staff, 2 consumers, 2 carers and 1 staff). They meet three times (2 hours per meeting): meeting one is a review of existing service processes and the identification of areas for improvement related to the touch point in question; meeting two is a review of good practice examples and discussion of ideas for action plans; meeting three is the development and finalisation of an action plan for implementation to address the touch point. Good practice examples offered in meeting two will be informed by evidence reviews completed by the University research team. The second collaboration group is held in week 39 and to review and implement action plans. A third collaboration group meeting is held 12 weeks later as a monitoring meeting to review the barriers and facilitators to action plan implementation. Fidelity checklists have been developed for WW and RC to complete plus an external research evaluator will cross-check these against audio files of sessions to ensure intervention adherence. Observations of proportions of the intervention (focus groups, interviews, collaboration and co-design groups) have been scheduled as part of a nested process evaluation.

## OUTCOMES

The primary outcome is improvement in psychosocial recovery for individuals measured using the self-rated, validated 24 item Recovery Assessment Scale (Revised) (RAS-R).[61-63] RAS-R was selected because it has been used in mental health outpatient settings, in peer run programs and is one of the few measures available that has been developed from user descriptions of the recovery process.[44] The RAS-R 24 item has also been validated in an Australian population of people with severe mental illness.[62] To determine the most acceptable measures for service users we completed a small pilot of three potential primary outcome measures with 40 service users: RAS-R, MARS (Maryland Assessment Recovery Scale), RSA person in recovery version (Recovery Self Assessment Scale). The pilot identified RAS-R as easy to understand, quick to answer (average completion time was 13-18 minutes), and feasible for telephone administration (an important consideration as data collection is to occur by telephone).

RAS-R uses a five point rating scale from 1="Strongly Disagree" to 5="Strongly Agree". Responses can be calculated as a total score ranging from 24 to 120 with higher scores indicating greater recovery. The RAS-R can also be calculated as five components related to recovery: (i) personal confidence and hope (9 items; range 9 to 45), (ii) willingness to ask for help (5 items; range 5 to 25), (iii) goal and success orientation (3 items; 3 to 15), (iv) reliance on others (4 items; range 4 to 20) and, (v) no domination by symptoms (3 items; range 3 to 15). A higher rating within each individual component indicates recovery progress also. At present there is limited data available on what a clinically significant change is from scales such as RAS-R. Our pilot data indicated the normative mean range for total RAS-R scores

were between 85-95 which follows a similar pattern to baseline data reported in clinical trials that have used this measure; this has been taken account in the sample size calculations.[24]

Consent will also be sought from service users to access routinely collected government data about health services visits (through the Medicare dataset), Pharmaceutical Benefits Scheme, emergency department hospital visits and triage information data (the data available from these datasets is explained in the participant timeline table 1 that follows). The purpose of this data is to reduce the burden of questions being asked of users and the recall errors of self-report about medications and health services uses. This data will be considered in conjunction with outcomes.

Secondary outcomes are service users and carer mental health and wellbeing. These will be assessed using the self-report EUROHIS 8 item Quality of Life (QOL) scale which covers overall QOL, general health, energy, daily life activities, esteem, relationships, finances, and home.[64, 65] Each item has an individualised five point scale and each subscale is scored positively. Staff attitudes to recovery and recovery orientation in services will be measured using the Staff Attitudes to Recovery Scale (STARS) 19 item questionnaire[66] and the Recovery Self Assessment (RSA) provider version 36 item scale.[67] The RSA is a six point scale 1="Strongly Disagree" to 5="Strongly Agree" with a N/A option. It was identified as a strong candidate to measure recovery in Australian settings.[68] Higher scores indicate greater recovery orientation in the identified domains. A detailed description of the psychometric properties of the measures is provided in a Supplementary File Number 1.

## PARTICIPANT TIMELINE

Table 1 Schedule of enrolment, interventions and assessments

| | Wave 0 | Wave 1 | Wave 2 | Wave 3 |
|---|---|---|---|---|
| Time points | 0-3mo | 3-12mo | 12-21mo | 21-30mo |
| ENROLMENT | | | | |
| Eligibility screen | X | | | |
| Informed consent | X | | | |
| Allocation | X | | | |
| STUDY PHASE | | | | |
| Clusters 5 and 6 | Control | Control | Control | Intervention |
| Clusters 3 and 4 | Control | Control | Intervention | Post-intervention monitoring |
| Clusters 1 and 2 | Control | Intervention | Post-intervention monitoring | Post-intervention monitoring |
| ASSESSMENT (in the last THREE MONTHS of each wave) | | | | |
| *Service Users* | | | | |
| Demographics and clinical details | X | X | x | x |
| Recovery Assessment Scale Revised (RAS-R)[61] | X | X | x | x |
| EUROHIS-QOL[64, 65] | X | X | x | x |
| *Carers* | | | | |
| Demographics | X | X | x | x |
| Demographic and clinical details about the person they care for | X | X | x | x |
| EUROHIS-QOL[64, 65] | X | X | x | x |
| *Staff* | | | | |
| Demographic and employment details | X | X | x | x |
| Recovery Self Assessment (RSA)[67] | X | X | x | x |
| Staff Attitudes to Recovery Scale (STARS)[66] | X | X | x | x |
| DATA FROM EXTERNAL SOURCES | | | | |
| Medicare Benefits Scheme (MBS) data[∞] | X | X | x | x |
| Pharmaceutical Benefits Scheme (PBS) data[∞] | X | X | x | x |
| State Government Emergency Minimum Dataset (VEMD) data[β] | X | X | x | x |
| State Government Admitted Episodes Dataset (VAED) data[β] | X | X | x | x |
| State Government Mental Health Triage (CMI/ODS) data[β] | X | X | x | x |

[∞] MBS and PBS information is routinely collection data from the Federal Government in Australia. MBS data provides information about when a medical service was received, the type of service, distance travelled to get to a service and how much out of pocket expenses were incurred for services. PBS data provides information on the type of medications prescribed, when they were prescribed, when they were collected, the distance travelled to collect medications and the costs of medications.

[β] State government emergency (VMED) and admitted episodes data (VAED) provides information about when, were or how an individual was injured or became unwell, how urgent care needs were, the type of care that was received in hospital and length of time in the hospital, how people were cared for once discharged, place of residence, whether the person had a carer, if health insurance was used in hospital, background information about languages spoken and where someone was born. State government mental health triage data (CMI/ODS) provides information on where an individual accessed a mental health service, who referred them and why, how urgent the care was and the type of care that was received, place of residence at the time and background information about the languages someone may speak.

## SAMPLE SIZE

Overall, 1008 measurements from 252 consumers (42 per site) at each of the four waves (one for baseline and at each follow up time) from the six clusters will be sufficient to detect an effect size of 0.35 of 1 standard deviation for psychosocial recovery between the intervention and usual care waves with at least 80% power (Table 1). Sample size was based on the primary outcome of psychosocial recovery score with the following assumptions: intra-cluster correlation for the outcome of 0.1 and significance level of 5% for a two-sided test, probability that each individual will remain at the site at each wave (0, 0.2 and 0.6) and within-subject correlation of individuals that contributed to at least two consecutive waves (0.2 and 0.7).

At the time of determining the sample size, there was no sample size formula available for stepped wedge design with longitudinal follow up of individuals.[69] Thus, to determine the study power for this study we conducted a simulation study using a linear mixed effects model where treatment and time effects were assumed fixed and individual and site effects as random. Whether individuals remained in the cluster at each wave was sampled from a binomial distribution with parameter $p$, the probability that an individual remained. When $p = 0$ this is equivalent having independent sample of subjects at each wave (that is, repeated cross-sectional samples). The study power was calculated as the proportion among all 2000 simulation runs of two-sided p-values for the estimated fixed treatment effect that reached a nominal value of less than 0.05. Two thousand replications for each set of parameter combinations were sufficient to estimate the power with a margin of error of 1.75%, assuming that the true power was 80%. The simulations were run using R version 3.1.1.[70]

Table 2 Power calculations for detecting an effect size=0.35 of 1 standard deviation between the intervention and usual care periods, assuming an intra-cluster correlation of 0.1 and alpha of 5% for a 2-sided test

| Probability of remaining at the centre | Within-subject correlation | Sample cluster size | Power* |
|---|---|---|---|
| 0 | NA | **42** | **0.79** |
| 0.2 | 0.2 | **42** | **0.80** |
| 0.2 | 0.7 | **42** | **0.81** |
| 0.6 | 0.2 | **42** | **0.82** |
| 0.6 | 0.7 | **42** | **0.92** |

*Power calculations based on 2000 simulations;

Table 2 shows that given a fixed sample cluster size, power was the smallest when it was assumed that samples at each time point were independent (that is, probability of remaining at the next wave was zero) and that the study power increased as the probability of remaining at the site and within cluster subject correlation increased.[69] Note the power calculations using the simulation study provided more conservative estimates of the power than the sample size calculations based on the formula provided by Hussey and Hughes.[53] These differences may be due to different derivations of the estimated test statistic. Within the simulation procedure, a t-distribution with Satterthwaite's approximation for degrees of freedom was employed, whereas the analytical approach suggested by Hussey and Hughes[53] assumes a standard normal distribution for the test statistic which yields less conservative results.

**RECRUITMENT**

It is well documented that people experiencing mental illness and their carers are difficult to recruit and to retain in research studies.[71-76] With this in mind and the aim of CORE being a service improvement intervention, the study began with the recruitment of the mental health service provider organisations before identifying clusters (teams) for participation. We sought to establish relationships and understand the service context first to design purposeful recruitment strategies for the users and carers. Service providers were identified according to their geographical catchment area. They were based in metropolitan locations (inner northern, inner eastern and inner south), outer metropolitan areas (north and west, outer east and south east) and regional. Chief Executive Officers or Senior Managers were identified in six providers and approached by telephone by the principal investigator. Face to face 1 hour meetings were held to explain the study and its aims. Three providers declined to participate due to existing research demands and changes to staff. The remaining three agreed to take part with the view that clusters would be selected to participate in the intervention later and staff opt-in via an online survey.

The user recruitment strategy includes an awareness raising phase where purposefully designed posters and postcards will be placed at participating sites and access points in the local community for four weeks. Artwork for the posters and postcards has been designed by users of art support groups for people living with mental illnesses purposefully selected from a regional area not participating in the study. Poster content is purely to generate awareness about the study while postcard content includes information about the two modes of participation that are available: by telephone or coming to a face to face study information and recruitment day. Face to face study information and recruitment days have been designed using a peer support worker (PSWs) model combined with trained research assistants. PSWs

are available to provide information, support and de-briefing to users, while RAs complete the enrolment and baseline survey. The study information and recruitment days include a short comedy routine delivered by WISE Stand Up for Mental Health trained performers (a recovery based program teaching comedy to people with mental illnesses) to disrupt conventional notions of research as tedious and monotonous and demonstrate a recovery practice by people from the same community.[77] The aim is to increase reach and if successful provide face to face study days to complete follow up measures to retain participants. Staff will also be provided with postcards to give out to clients to generate awareness about the study. At the end of four weeks invitation kits will be mailed out to service users and carers from the six participating clusters. Participants will be able to enrol and complete surveys by telephone or face to face.

## METHODS

### Allocation and blinding

Two clusters stratified by service provider will be allocated to each wave. Initially, the 12 possible combinations of the pair-wise clusters from the three different services were created to ensure that clusters from the same service provider are not allocated to the same wave. Using these pairs, the 24 possible sequence allocation combinations of the paired clusters to the three waves are listed in Table 3 which is provided in Appendix 2 (8 combinations of three sets of paired clusters by three different possible starting times). One of the 24 possible sequence allocation combinations will be randomly selected by allocating a random number from the uniform distribution using Stata[78] to each of the 24 sequence allocation

combinations and selecting the sequence allocation with the smallest random number. The random selection of the sequence allocation will be conducted by a statistician blinded to the identity of the clusters and not involved in the assessment or intervention delivery (PC). The pair of clusters and order in which they receive the intervention will be communicated to the trial coordinators (MP and KG). The two clusters allocated to the first wave will be notified of intervention commencement after the initial baseline period is completed. The remaining four clusters will be notified of the intervention commencement at the start of their allocated step/wave. Staff, service users and carers are not blinded to the intervention but they are blinded to the wave during which they receive it. Research interviewers collecting outcome data will remain blinded to who is in receipt of the intervention.

## DATA COLLECTION

Service users and carer quantitative outcome data will be collected at regular 9 monthly intervals following baseline and the intervention period (baseline, 9, 18 and 27 months) as illustrated in figure 3. The enrolment and baseline survey has been tested with ten users of mental health services and takes a maximum of 30 minutes for completion by telephone or face to face. Enrolment of participants will always be completed by research assistants trained in working with people with mental illness and their carers and the purpose designed database. The 9 month follow-up period was based on the intervention length being nine months and being able to measure for any effects close to intervention completion.

<insert Figure 3 Trial data collection time points about here>

Services users can complete surveys by telephone or face to face, carers complete surveys by telephone only. Telephone interviews are administered by a trained research assistant with answers entered into a purposefully designed database with an allocated code for participants to conceal personal information when data is aggregated and analysed. Face to face surveys are completed through study information and recruitment days for service users by trained researchers or individually if a person prefers. Individuals can only see their individual survey and no other aspects of the data base to ensure confidentiality of all participants is maintained.

Demographic questions are completed by users and carers at each time point. Information includes age, gender, education, employment, and sources of income. Service users are asked specific questions related to the name given for their condition, length of time experiencing this condition, who gave them the name, visits to hospitals and why they access the mental health support service. Service users are also asked to give consent to access routinely collected data about health care visits, medication prescriptions, distance travelled to access services and obtain medication and hospitalisation information (reason for attending, length of stay, place of residence at the time). Carers are asked about their length of time caring for the person and whether they have been engaged by the mental health support service who cares for the consumer. Staff, service users and carers are all asked the Family and Friend Test (FFT) single question to measure quality of service experience.[79] Service users complete the RAS-R and EUROHIS-QOL and carers complete the EUROHIS-QOL.[61, 64, 65] Staff complete an online survey with open ended questions using Qualtrics survey software (version 2013)[80], to collect information every nine months about training, recovery

programs occurring at services and engagement of service users and carers in services including the STARS and RSA.[66, 67] All three participant groups are invited to the next stage of the intervention at the completion of surveys.

The concurrent nested process evaluation will use quantitative and qualitative data collected to identify contextual (organisational and environmental) factors that affect the intervention. The process evaluation has been organised using the RE-AIM framework as a guide.[81, 82] The evaluation will examine the reach (representativeness of participants in the study and the intervention), effectiveness (the impact of the intervention on the study outcomes), adoption (proportion and representative of those who participated in each component of the intervention), implementation (fidelity to the implementation of the intervention) and maintenance of the intervention (the extent to which co-design becomes embedded in sites).[81-84] The detail of the framework and questions are to be provided in a separate published protocol for the nested process evaluation. Data management protocols can be provided from the University Ethics Approval applications if requested.

## STATISTICAL ANALYSIS

Descriptive statistics will be used to summarise the characteristics of staff, service users and carers. The participants will be analysed in the group that the cluster was assigned to at each time point. A linear mixed effects model will be used to compare the intervention and usual care periods for continuous outcomes and generalised linear mixed effects model for binary outcomes. The model will include intervention status and time as fixed effects and site and individuals as random effects. Organisational and individual factors strongly correlated with

the outcome will also be included as fixed effects in the model. These will include: recovery orientation of services and staff attitudes to recovery at baseline, age, gender, education level, work status, quality of life, medication and hospitalisation. The estimated intervention effect will be reported as mean outcome difference for continuous outcomes and odds ratio for binary outcomes between study groups, with respective 95% confidence intervals and p-values. A secondary analysis will investigate an interaction effect between intervention and time.[54, 55] Costs of the delivery of the intervention will be recorded but no economic evaluation will be undertaken. An intention-to-treat (ITT) analysis strategy will be used.[85] Every effort will be made to minimise missing outcome data at each wave and reasons individuals are lost to follow-up will be recorded. Sensitivity analyses will be conducted to assess the robustness of the missing data assumption made in the primary analysis. Analysis will be conducted using Stata software 13.[78]

## DATA MONITORING

An advisory and data monitoring committee has been established for the study and a Charter prepared following guidance from the Data Monitoring and Outcomes Study Group (DAMACOLES).[86] The role of the ADMC is to advise investigators regarding the implementation, maintenance and monitoring of overall conduct of the trial; safeguard the interests of trial participants, assess the safety of the interventions during the trial and address any adverse events; provide advice and feedback on qualitative elements and the nested process evaluation for the trial (the ADMC Charter has been provided as a supplementary file number 2). Membership consists of nine international and national experts engaged in research across EBCD, recovery, psychiatry and serious mental illness, complex interventions, randomised controlled trials and statistics. The ADMC meet twice per year to

discuss progress and any adverse events, they are responsible for annual audits of trial conduct. In CORE the ADMC will not apply the stopping rules and interim analysis as per a clinical trial because (a) the intervention is not therapeutic and (b) the stepped wedge design does not allow for mid-way analysis since all clusters will not have received the intervention. It is expected that the ADMC will monitor the trial for any serious adverse events related to the intervention and make recommendations to the team on actions related to these which will be reported as required to the Human Research Ethics Committee of the University. Since the intervention has been developed by lead service user and carer agency it is believed that the likelihood for need to discontinue the intervention will be extremely minimal. Membership for the committee is provided in Appendix 3.

## ETHICS AND DISSEMINATION

The CORE study involves working with vulnerable participants who experience mental illness and their carers. To ensure the needs of these communities are met, the research team has lead investigators from service user and carer agencies who actively contribute to the design, development and implementation of intervention. Contextual data collected through stage one application of a theoretical model of engagement and translation has been used to inform particular strategies for recruitment, retention and ensuring implementation of the intervention is as successful as possible. Ethics approval has been granted by The University of Melbourne Human Research Ethics Committee (HREC NO. 1340299.3) and the Federal and State government departments (Project 20/2014) responsible for routine data collection on health service use, pharmaceutical use, hospital admissions and triage. Baseline data will be presented in 2015 and trial outcomes in 2017 and published in scientific journals. Only investigators and approved researchers added by ethics approval will have access to the final

trial dataset. Dissemination will include delivery of conference papers, study updates for staff, users and carers and knowledge transfer to government and the wider community through presentations, policy briefs and media releases where appropriate. Any protocol amendments will be reported to the responsible University and government ethics committee as trial sponsor and provided to the journal in which this protocol is to be published. Ethics procedures includes measures for addressing any unintended harms for intervention participants post-trial by coordination of access to support services and follow-up by professional care workers.

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**Competing Interests** None.

**Ethics Approval**

The University of Melbourne Human Research Ethics Committee (HREC No.: 1340299.3) has approved this study. The Federal Government Department of Health has approved the collected of Medicare and Pharmaceutical Benefits Scheme data and the State Government of Victoria has approved the collection of hospital admission and triage data.

**Contributors** VP conceived the study in conjunction with staff located in community mental health services. LR contributed the theoretical model for engagement and translation. PC and TS led the calculation of the sample size and quantitative components of the protocol. All authors participated in the preparation of the manuscript providing written comments on drafts and approving the final version. The trial sponsor is The University of Melbourne. The trial sponsor has not been directly involved in the design, collection, management or analysis and interpretation of the data but is responsible for ethical conduct and ensuring data storage and management procedures are adhered to. They have not been involved in the decision to submit the protocol for publication.

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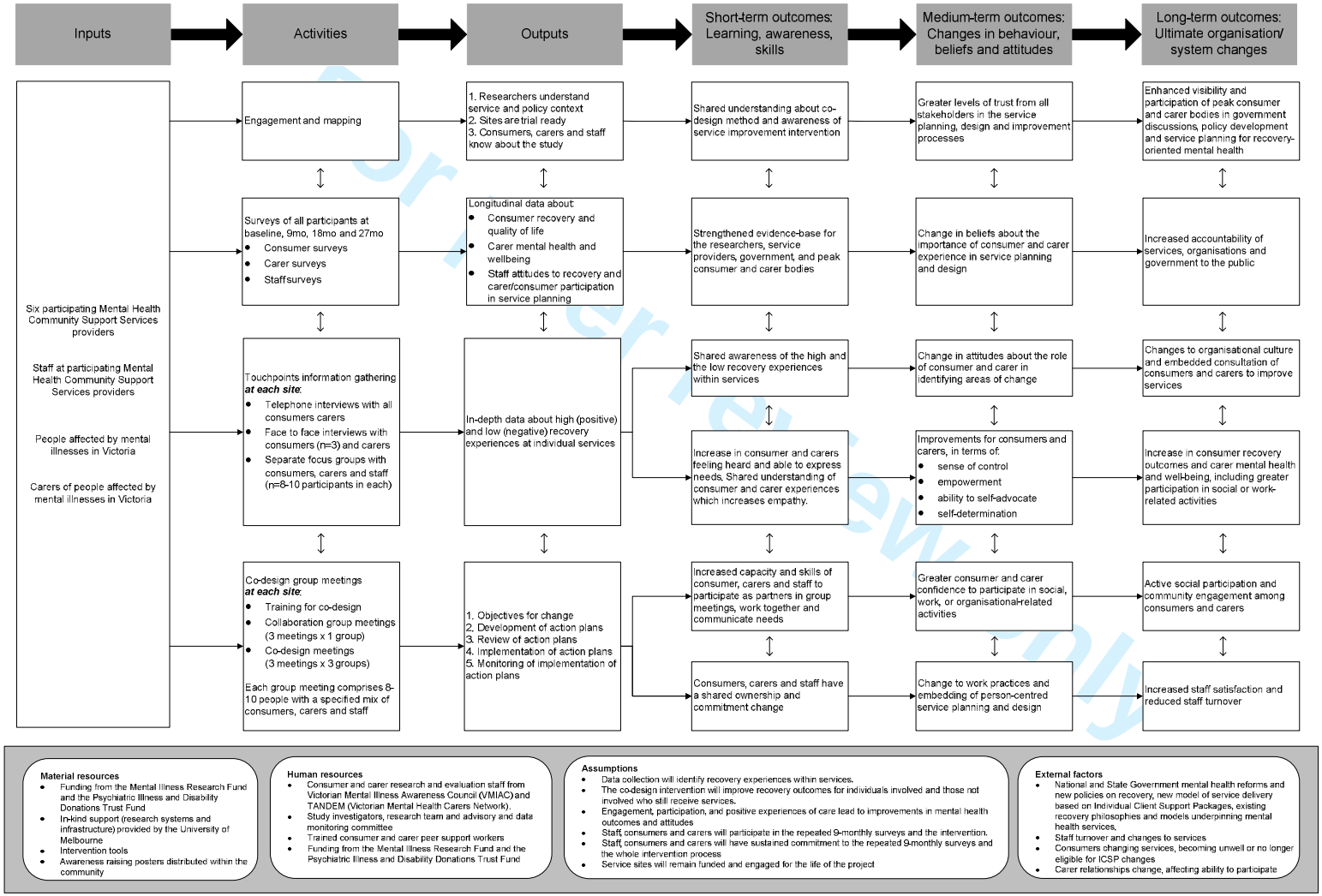
Appendix 1. Logic model for the MH ECO intervention in the CORE Study



Appendix 2

Table 3: All possible sequence allocation combinations for a cluster randomised trial with a stepped wedge design with three steps and six clusters from three service providers, stratified by service provider

| Number | Wave 1 | | Wave 2 | | Wave 3 | |
|---|---|---|---|---|---|---|
| 1 | A1 | B1 | B2 | C1 | C2 | A2 |
| 2 | B2 | C1 | C2 | A2 | A1 | B1 |
| 3 | C2 | A2 | A1 | B1 | B2 | C1 |
| 4 | A1 | B1 | B2 | C2 | C1 | A2 |
| 5 | B2 | C2 | C1 | A2 | A1 | B1 |
| 6 | C1 | A2 | A1 | B1 | B2 | C2 |
| 7 | A2 | B1 | B2 | C1 | C2 | A1 |
| 8 | B2 | C1 | C2 | A1 | A2 | B1 |
| 9 | C2 | A1 | A2 | B1 | B2 | C1 |
| 10 | A2 | B1 | B2 | C2 | C1 | A1 |
| 11 | B2 | C2 | C1 | A1 | A2 | B1 |
| 12 | C1 | A1 | A2 | B1 | B2 | C2 |
| 13 | A1 | B2 | B1 | C1 | C2 | A2 |
| 14 | B1 | C1 | C2 | A2 | A1 | B2 |
| 15 | C2 | A2 | A1 | B2 | B1 | C1 |
| 16 | A1 | B2 | B1 | C2 | C1 | A2 |
| 17 | B1 | C2 | C1 | A2 | A1 | B2 |
| 18 | C1 | A2 | A1 | B2 | B1 | C2 |
| 19 | A2 | B2 | B1 | C1 | C2 | A1 |
| 20 | B1 | C1 | C2 | A1 | A2 | B2 |
| 21 | C2 | A1 | A2 | B2 | B1 | C1 |
| 22 | A2 | B2 | B1 | C2 | C1 | A1 |
| 23 | B1 | C2 | C1 | A1 | A2 | B2 |
| 24 | C1 | A1 | A2 | B2 | B1 | C2 |

Note: Clusters A1 and A2 are the sites from Service provider 1, B1 and B2 belong to the 2nd Service provider and C1 and C2 belong to the 3rd service provider

Appendix 3: Membership of the CORE Study Advisory and Data Monitoring Committee:

Ms Hilary Boyd (Experience Based Co-Design, New Zealand), Professor John Carlin (Biostatistics, Australia), Professor Judith Cook (Psychiatry and RCTs, United States of America), Ms Karen Fairhurst (Carer Representative, Australia), Ms Jane Gray (Experience Based Co-Design, Australia), Dr Lynn Maher (Experience Based Co-Design, New Zealand), Professor Glenn Robert (Experience Based Co-Design, United Kingdom), Assistant Professor Robert Whitely (Recovery from Serious Mental Illness, Canada), Professor Sally Wyke (Complex Interventions and RCTs, Scotland).

Figure 1 Design for a stepped wedge cluster randomised controlled trial in the community mental health setting about here

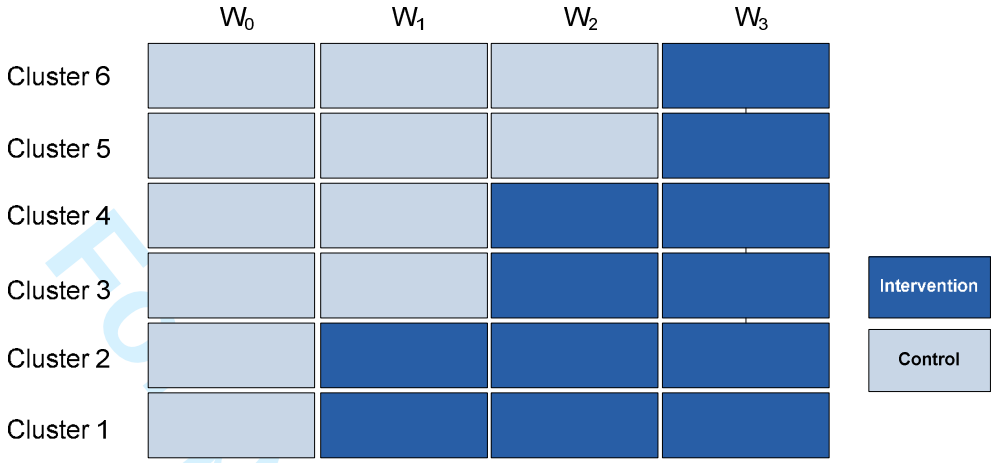


Figure 2 Flowchart of MH ECO Intervention for CORE

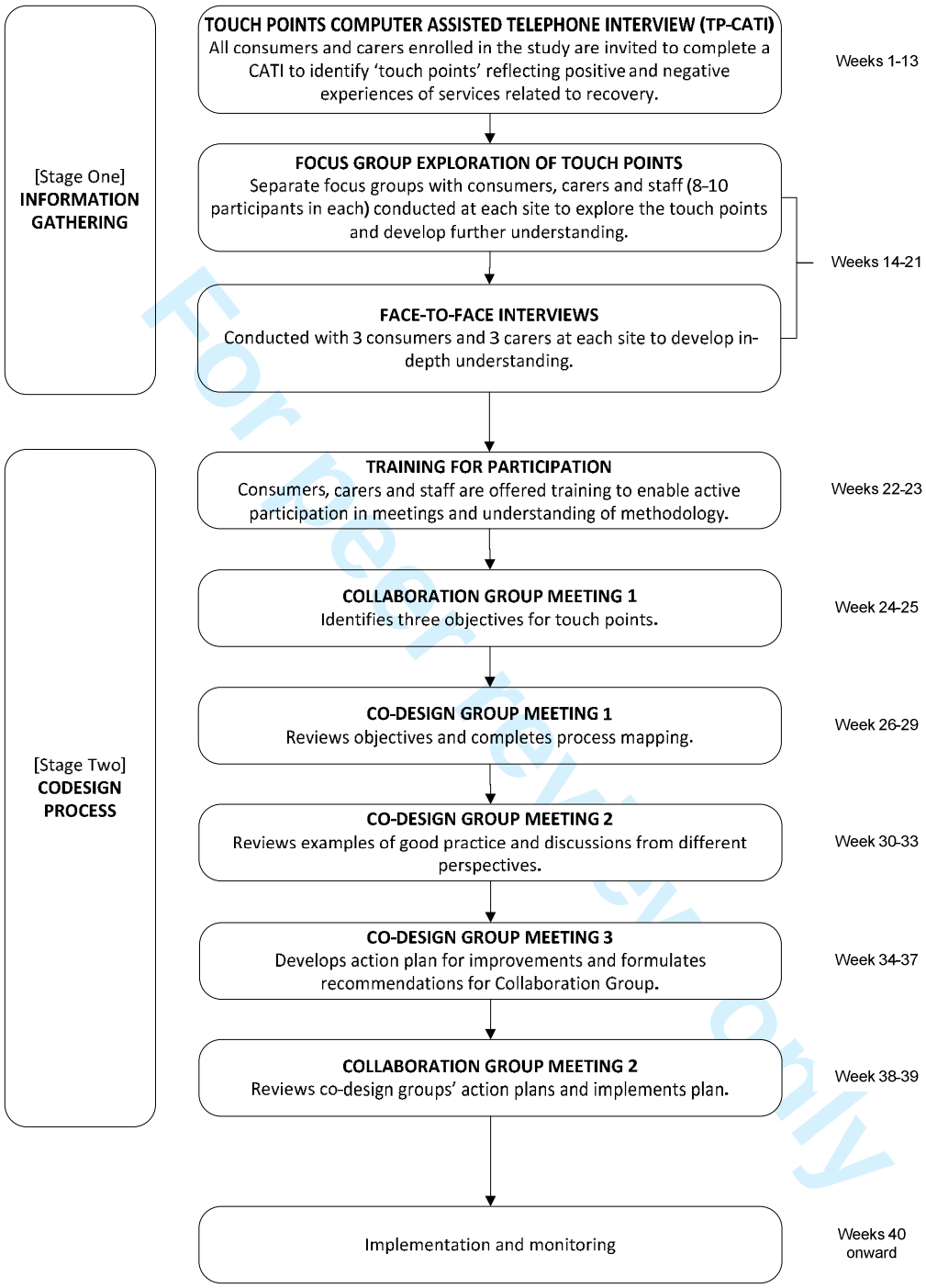


Table 1 Schedule of enrolment, interventions and assessments

| | Wave 0 | Wave 1 | Wave 2 | Wave 3 |
|---|---|---|---|---|
| Time points | 0-3mo | 3-12mo | 12-21mo | 21-30mo |
| ENROLMENT | | | | |
| Eligibility screen | X | | | |
| Informed consent | X | | | |
| Allocation | X | | | |
| STUDY PHASE | | | | |
| Clusters 5 and 6 | Control | Control | Control | Intervention |
| Clusters 3 and 4 | Control | Control | Intervention | Post-intervention monitoring |
| Clusters 1 and 2 | Control | Intervention | Post-intervention monitoring | Post-intervention monitoring |
| ASSESSMENT (in the last THREE MONTHS of each wave) | | | | |
| *Service Users* | | | | |
| Demographics and clinical details | X | X | x | x |
| Recovery Assessment Scale Revised (RAS-R)[61] | X | X | x | x |
| EUROHIS-QOL[64, 65] | X | X | x | x |
| *Carers* | | | | |
| Demographics | X | X | x | x |
| Demographic and clinical details about the person they care for | X | X | x | x |
| EUROHIS-QOL[64, 65] | X | X | x | x |
| *Staff* | | | | |
| Demographic and employment details | X | X | x | x |
| Recovery Self Assessment (RSA)[67] | X | X | x | x |
| Staff Attitudes to Recovery Scale (STARS)[66] | X | X | x | x |
| DATA FROM EXTERNAL SOURCES | | | | |
| Medicare Benefits Scheme (MBS) data[∞] | X | X | x | x |
| Pharmaceutical Benefits Scheme (PBS) data[∞] | X | X | x | x |
| State Government Emergency Minimum Dataset (VEMD) data[β] | X | X | x | x |
| State Government Admitted Episodes Dataset (VAED) data[β] | X | X | x | x |
| State Government Mental Health Triage (CMI/ODS) data[β] | X | X | x | x |

[∞] MBS and PBS information is routinely collection data from the Federal Government in Australia. MBS data provides information about when a medical service was received, the type of service, distance travelled to get to a service and how much out of pocket expenses were incurred for services. PBS data provides information on the type of medications prescribed, when they were prescribed, when they were collected, the distance travelled to collect medications and the costs of medications.

[β] State government emergency (VMED) and admitted episodes data (VAED) provides information about when, were or how an individual was injured or became unwell, how urgent care needs were, the type of care that was received in hospital and length of time in the hospital, how people were cared for once discharged, place of residence, whether the person had a carer, if health insurance was used in hospital, background information about languages spoken and where someone was born. State government mental health triage data (CMI/ODS) provides information on where an individual accessed a mental health service, who referred them and why, how urgent the care was and the type of care that was received, place of residence at the time and background information about the languages someone may speak.

Figure 3 Trial data collection timepoints

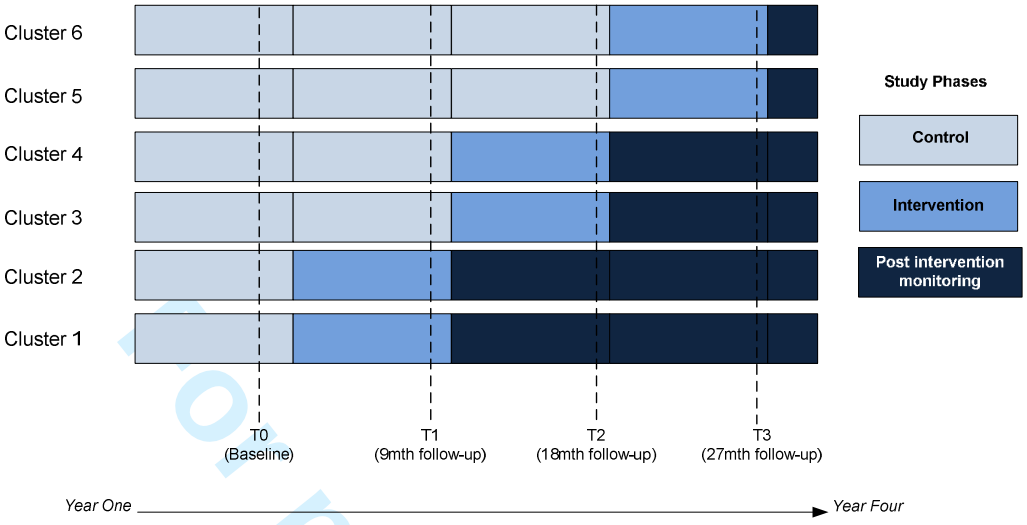


Table 2 Power calculations for detecting an effect size=0.35 of 1 standard deviation between the intervention and usual care periods, assuming an intra-cluster correlation of 0.1 and alpha of 5% for a 2-sided test

| Probability of remaining at the centre | Within-subject correlation | Sample cluster size | Power* |
|---|---|---|---|
| 0 | NA | **42** | **0.79** |
| 0.2 | 0.2 | **42** | **0.80** |
| 0.2 | 0.7 | **42** | **0.81** |
| 0.6 | 0.2 | **42** | **0.82** |
| 0.6 | 0.7 | **42** | **0.92** |

*Power calculations based on 2000 simulations;

Table 3: All possible sequence allocation combinations for a cluster randomised trial with a stepped wedge design with three steps and six clusters from three service providers, stratified by service provider

| Number | Wave 1 | | Wave 2 | | Wave 3 | |
|---|---|---|---|---|---|---|
| 1 | A1 | B1 | B2 | C1 | C2 | A2 |
| 2 | B2 | C1 | C2 | A2 | A1 | B1 |
| 3 | C2 | A2 | A1 | B1 | B2 | C1 |
| 4 | A1 | B1 | B2 | C2 | C1 | A2 |
| 5 | B2 | C2 | C1 | A2 | A1 | B1 |
| 6 | C1 | A2 | A1 | B1 | B2 | C2 |
| 7 | A2 | B1 | B2 | C1 | C2 | A1 |
| 8 | B2 | C1 | C2 | A1 | A2 | B1 |
| 9 | C2 | A1 | A2 | B1 | B2 | C1 |
| 10 | A2 | B1 | B2 | C2 | C1 | A1 |
| 11 | B2 | C2 | C1 | A1 | A2 | B1 |
| 12 | C1 | A1 | A2 | B1 | B2 | C2 |
| 13 | A1 | B2 | B1 | C1 | C2 | A2 |
| 14 | B1 | C1 | C2 | A2 | A1 | B2 |
| 15 | C2 | A2 | A1 | B2 | B1 | C1 |
| 16 | A1 | B2 | B1 | C2 | C1 | A2 |
| 17 | B1 | C2 | C1 | A2 | A1 | B2 |
| 18 | C1 | A2 | A1 | B2 | B1 | C2 |
| 19 | A2 | B2 | B1 | C1 | C2 | A1 |
| 20 | B1 | C1 | C2 | A1 | A2 | B2 |
| 21 | C2 | A1 | A2 | B2 | B1 | C1 |
| 22 | A2 | B2 | B1 | C2 | C1 | A1 |
| 23 | B1 | C2 | C1 | A1 | A2 | B2 |
| 24 | C1 | A1 | A2 | B2 | B1 | C2 |

Note: Clusters A1 and A2 are the sites from Service provider 1, B1 and B2 belong to the 2nd Service provider and C1 and C2 belong to the 3rd service provider

Supplementary File 1 Instruments used for the CORE Study and Psychometric Information

| Instrument and relevant published references | Psychometric information |
|---|---|
| **Recovery Assessment Scale (RAS)**<br>**1995 United States**<br><br>Giffort D , Schmook A, Woody C, Vollendorf C & Gervain M (1995)<br><br>**Administration Time:**<br>Individual interview takes approximately 20 minutes.<br><br>**Qualification/Training Requirement:**<br>RAS interviewers must be able to reliably read and score items.<br><br>**Scoring:**<br>There are explicit guidelines indicating how to score responses.<br><br>**Supporting Material:**<br>Available materials include administration and scoring guidelines.<br><br>Developed by analysing four consumer stories of recovery. This yielded 39 items that were reviewed by 12 consumers. Feedback resulted in 41-item scale. The RAS was developed as an evaluation measure, and has been used to assess the impact of a range of programs. It is designed to assess various aspects of recovery from the perspective of the consumer, with a particular emphasis on hope and self- determination. The original instrument comprised 41 items, and a shorter version containing 24 items is available. In both versions, each item is rated on a 5-point Likert scale in which 5 =Strongly Agree.<br><br>It covers five domains: personal confidence and hope; willingness to ask for help; goal and success orientation; reliance on others; and no domination by symptoms. A 24-item Japanese version of the RAS has recently been developed (Chiba, 2010).<br><br>**References and Suggested Readings**<br>Andresen R, Oades L, Caputi P. (2003). The experience of recovery From schizophrenia: towards an empirically validated stage model. Aust N Z J Psychiatry, 37:586594. | *Factor analysis:*<br>Corrigan, Salzer, Ralph, and Sangster (2004) used exploratory and confirmatory factor analysis (CFA) to establish the factor structure of the RAS. Exploratory factor analysis was performed using principal component analysis and Varimax rotation on a random subset of half of the sample. This analysis yielded eight factors. With the remainder of the sample, structural equation models that corresponded with the item factor loadings were used to cross-validate the factors. Three factors were removed due to an unsatisfactory fit. A second CFA validated the five factor structure. The alphas for the five factors ranged from .74 to .87: personal confidence and hope (alpha=.87); willingness to ask for help (alpha=.84); goal and success orientation (alpha=.82); reliance on others (alpha=.74); no domination by symptoms (alpha =.74).<br><br>*Internal Consistency*:<br>RAS responses in initial testing yielded a Cronbach's alpha =.93 (Corrigan et al.,1999).<br><br>*Field testing:*<br>The RAS has been field tested four times.<br><br>First it was administered by reading the items to 35 consumers in the University of Chicago partial hospitalisation program in an interview format (Corrigan et al., 1999). Participants had a diagnosis of serious mental illness, at least three hospitalisations within the past two years and an inability to work as a result of their mental illness. The ethnic/racial make-up of the sample was 57.1% African American, 37.1% European American, and 5.8% other. Females made up 35.1% of the sample and the mean age was 33.1 (SD 9.2).<br><br>Second field testing of RAS (factor structure and validity) used responses from the baseline assessment of consumers participating in the Consumer Operated Services Program (COSP) Multi-site Research Initiative (Corrigan et al., 2004). The sample size was originally 1,824 (missing items possibly lowered the sample to 1,750). Participants had a DSM-IV, Axis I diagnosis consistent with serious mental illness and a significant functional disability as a result from the mental illness. The sample included individuals from diverse ethnic/racial backgrounds: 23.8% African American, 74.5% European American, 3.4% Latino or Hispanic, 18.1% Native American, and 1.4% Asian or Pacific Islander. 60.1% of the sample was female and the mean age was 41.8<br>(SD 10.4). |

Supplementary File 1 Instruments used for the CORE Study and Psychometric Information

Battista, J., and Almond, R. (1973). The development of meaning in life. *Psychiatry*, *36*(4):409-427.

Bullock WA, Young SL. Mental Health Recovery Measure (MHRM) (2005). In: Bullock WA, Campbell-Orde T, Garrett E, Leff S, eds. Measuring the promise of recovery: a compendium of recovery and recovery-related instruments, Part II. Cambridge, MA: Evaluation Center@HSRI. Retrieved 10 September 2005 from http://psychology.utoledo.edu/ images/users/3/MHRM% 20compendium% 20entry%20%209-5-05.doc.

Chiba R, Miyamoto Y, Kawakami N. (2010). Reliability and validity of the Japanese version of the Recovery Assessment Scale (RAS) for people with chronic mental illness: Scale development. *International Journal of Nursing Studies*, *47*: 314-322.

Debats, D.L. (1990). The Life Regard Index: Reliability and validity. *Psychological Reports*, *67*(1):27-34.

Derogatis, L.R., Lipman, R.S., Rickels, K., Uhlenhuth, E.H., & Covi, L. (1974). The Hopkins Symptom Checklist (HSCL): A self-report symptom inventory. *Behavioral Science*, *19*(1):1-15.

Corrigan P.W., Giffort D., Rashid F., Leary, M., & Okeke, I. (1999). Recovery as a psychological construct. *Community Mental Health Journal*, 35(3), 231-239.

Corrigan PW, Phelan SM. (2004). Social support and recovery in people with serious mental illnesses. *Community Mental Health Journal,* 40(6):513-523. [b]

Corrigan, P.W., Salzer, M., Ralph, R., & Sangster, Y. (2004). Examining the factor structure of the Recovery Assessment Scale. *Schizophrenia Bulletin*, *30*(4), 1034-1041.

Corrigan, P., McCorkle, B., Schell, B., & Kidder, K. (2003). Religion and spirituality in the lives of people with serious mental illness. *Community Mental Health Journal*, *39*(6), 487-499.

The third testing data from this study were obtained during baseline assessment of participants (N=176) in the Consumer Operated Services Project. This CMHS-funded multi-site study examined the impact of consumer services on people with serious mental illness; criteria for the definition of consumers included a DSM-IV, Axis I diagnosis consistent with serious mental illnesses like schizophrenia, bipolar disorder, or major depression AND a significant functional disability that resulted from the mental illness (Corrigan et al., 2004)[b].

Archival data from168 patient-participants (98 men and 58 women) who completed baseline measures were used in the further validation. This constituted 83% of the total sample who had agreed to participate in the AIMhi study at the time data were extracted. Ages ranged from19 to 68 years (mean38.98 years, SD 12.1 years). Of the participants 84% were single, 9% were married or in a de-facto relationship and 7% were divorced or widowed. Most had been diagnosed with mental illness for at least 5 years (84%), with 12% receiving a diagnosis between 1 and 4 years prior and only four people indicating they had been diagnosed for <1 year (McNaught, Caputi, Oades, Deane, 2007).

*Test-Retest Reliability:*
Test-retest reliability between two administrations fourteen days apart yielded a Pearson Product Moment Correlation r=.88 (Corrigan et al.,1999).

*Validity:*
Validity of the RAS was further explored by running a series of regressions in which each of the five RAS factors was regressed on a set of five recovery-related measures.

The RAS total score was found to be correlated with five psychosocial variables (Corrigan et al.,1999): positively associated with the Rosenberg Self-Esteem Scale (Rosenberg, 1965) = .55, Empowerment Scale: Self-orientation (Rogers, Chamberlin, Ellison, & Crean, 1997) = -.71, short version of the Social Support Questionnaire (Sarason, Levine, Basham, & Sarason, 1983) = .48, and subjective component of the Quality of Life Interview (Lehman, 1983) = .62. Stepwise multiple regression indicated that the Rosenberg Self- Esteem Scale and the Empowerment Scale scores are significant predictors of the total Recovery Scale Score (Corrigan et al., 1999).

Validity was explored further by conducting series of regressions of RAS components with set of five recovery measurements: Empowerment Scale (Rogers et al., 1997); Short Version Lehman's Quality of Life Interview (Lehman, 1983); Herth Hope Index (Herth, 1991); Life Regard Index's Meaning of Life Subscale (Battista and Almond, 1973; Debats, 1990); and Hopkins Symptom Checklist (Derogatis, Lipman, Rickels, Uhlenhuth, & Covi,

Supplementary File 1 Instruments used for the CORE Study and Psychometric Information

Giffort, D., Schmook, A., Woody, C., Vollendorf, C., & Gervain, M. (1995). *Construction of a scale to measure consumer recovery*. Springfield, IL: Illinois Office of Mental Health.

Herth, K. (1991). Development and refinement of an instrument to measure hope. *Scholarly Inquiry for Nursing Practice*, 5(1): 36-51.

Kessler RC, Andrews G, Colpe LJ, et al (2002). Short screening scales to monitor population prevalences and trends in non-specific psychological distress. *Psychological Medicine,* 32(6):959-976.

Lehman, A.F. (1983). The effects of psychiatric symptoms on quality of life assessments among the chronic mentally ill. *Evaluation and Program Planning*, 6, 143-151.

Lukoff, D., Liberman, R.P., & Nuechterlein, K.H. (1986). Manual for the expanded Brief Psychiatric Rating Scale (BPRS). *Schizophrenia Bulletin*, *12*, 594-602.

McNaught M, Caputi P, Oades L, Deane FP (2007). Testing the validity of the Recovery Assessment Scale using an Australian sample. *Australian and New Zealand Journal of Psychiatry* 2, *41*(5):450-457.

Rogers, E.S., Chamberlin, J., Ellision, M. L., & Crean, T. (1997). A consumer-constructed scale to measure empowerment among users of mental health services. *Psychiatric Services*, *48*(8), 1042-1047.

Rosenberg, M. (1965). *Society and the adolescent self-image*. Princeton, NJ: Princeton University Press.

Sarason, I.G., Levine, H.M., Basham, R.B., & Sarason, B.R. (1983). Assessing social support: The Social Support Questionnaire. *Journal of Personality and Social Psychology*, *44*, 127-139.

Stein, C. H., Rappaport, J., & Seidman, E. (1995). Assessing the social networks of people with psychiatric disability from multiple perspectives. Community Mental Health Journal, 31(4), 351–367.

1974). The RAS has been shown to have good concurrent validity.

Herth Hope Index scores were found to positively predict scores on each of the five RAS factors; the remaining four measures each predicted two or more RAS factors, suggesting a complex inter-relationship between the RAS factors and the constructs measured by the five established instruments. The overall r for each of the five regressions ranged from .83 for the Personal Confidence and Hope factor to .52 for the Willingness to Ask for Help factor (Corrigan et al., 2004).

It has also demonstrated significant correlation in the expected direction with, the Social Networks Scale (Stein et al., 1995), and it was inversely associated with the expanded version of the Brief Psychiatric Rating Scale (Lukoff, Liberman, & Nuechterlein, 1986) = -.44, however this correlation coefficient did not meet the Bonferroni Criterion for significance (Corrigan et al., 2004)[b].

RAS factors displayed convergent validity with positive and significant correlations with Mental Health Recovery Measure (Bullock WA, Young, 2005) and the Self-Identified Stage of Recovery (Andresen, Oades, Caputi, 2003).Concurrent validity was demonstrated with significant but lower correlations with clinician-rated Nation Outcome Scales (Wing, Beevor, Curtis, Park, Hadden ,Burns, 1998) and the consumer-rated Kessler-10 (Kessler, Andrews, Colpe, 2002) (McNaugh et al., 2007).

*Sensitivity to change:*
The sensitivity to change of the RAS has not been tested.

Supplementary File 1 Instruments used for the CORE Study and Psychometric Information

Wing JK, Beevor AS, Curtis RH, Park SBG, Hadden S, Burns A. (1998). Health of the Nation Outcome Scales(HoNOS): research and development. Br J Psychiatry, 172:1118.

**Recovery Self Assessment (RSA)**
**2005 United States**

O'Connell M, Tondora J, Croog G, Evans AL, Davidson L. (2005). From rhetoric to routine: Assessing perceptions of recovery-oriented practices in a state mental health and addiction system. *Psychiatric Rehabilitation Journal,* 28(4):378-386.

**Administration Time:** Less than 10 minutes.
**Qualification/Training Requirement:** None, the instrument is self-administered.
**Scoring:** There are explicit guidelines indicating how to score responses.
**Supporting Material Available:** Information on administering the instrument, interviewer/administration training, guidelines to scoring responses, guidelines to interpreting data scores, technical assistance.

The RSA is designed to measure the extent to which recovery-supporting practices are evident in mental health services. It contains 36 items and each item is rated on a 5-point Likert scale. There are four versions, one for each of the following stakeholder groups: consumers (person in recovery version); family members or carers (family/significant others/advocates version); providers (provider version); and managers (CEO/Agency director version).

It covers 5 domains: Life Goals; Involvement;
Diversity of treatment options; Choice, & Individually tailored services.

Originally RSA was developed by the authors to assess the degree to which recovery-supporting practices are evident in the Connecticut Department of Mental Health and Addiction Services agencies. The RSA items are associated with nine principles of recovery identified

*Factor analysis and Internal Consistency:*

O'Connell, Tondora, Croog, Evans, Davidson, (2005) used exploratory to establish the factor structure of the RSA. 36 RSA items were entered into a principal components factor analysis and subjected to Varimax rotation (N=967). Analysis revealed five primary factors, all with good to excellent levels of internal consistency: Life Goals, Involvement, Diversity of Treatment Options, Choice, Individually Tailored Services with five components accounted for 53.8% of the total variance in the sample. A first factor, "Life Goals" accounted for 13.7% of the total variance in the sample. The internal consistency estimate for this factor was .90. A second factor, "Involvement" accounted for 13.3% of the total variance in the sample. The internal consistency estimate for this factor was .87.
A third factor, "Diversity of Treatment Options" accounted for 9.8%of the total variance in the sample. The internal consistency estimate for this factor was .83. A fourth factor, "Choice" accounted for 8.9%of the total variance in the sample. The internal consistency estimate for this factor was .76. The final factor, "Individually-Tailored Services," accounted for 8% of the total variance and had an internal consistency estimate of .76.

*Field Testing:*
An initial pilot of the survey was conducted in 2002 with 148 individuals at 10 mental health and addiction agencies receiving funding from the Connecticut Department of Mental Health and Addiction Services. Revisions were made following the initial pilot (Davidson et al. 2003).

A second study was conducted with all state funded agencies providing mental health services (N=208). Each agency was sent 16 copies of the survey (one Agency Director version, five Provider versions, five Persons in Recovery versions, and five Family Member/Significant Other/Advocate versions). A total of 3,328 surveys were mailed to agency directors across the state. Completed surveys were received from 974 individuals in 82 (agency response rate of 39%) facilities. Included in the analysis were 967 (individual response rate of 29%) surveys of which 68 were from the CEO/Agency Director Version, 344 from the Provider Version, 326 from the Person in Recovery Version, and 229 from the Family/Significant Others/Advocate Version (O'Connell, et al., 2005).

Supplementary File 1 Instruments used for the CORE Study and Psychometric Information

through extensive literature: renewing hope and commitment; redefining self; incorporating illness; being involved in meaningful activities; overcoming stigma; assuming control; becoming empowered and exercising citizenship; managing symptoms; and being supported by others (Davidson et al. 2003).
These principles were used to generate the initial 80-items. Experts in clinical and community psychology, consumers and direct service providers of mental health and addiction services, and family members provided feedback and suggestions for the revision and/or addition of new items. The items were then edited, balanced with regard to conceptual domain, and selectively eliminated to generate the current, 36-item version of the RSA (O'Connell et al. 2005).

*Validity:*
The face validity of the instrument is supported. Items were derived from extensive literature reviews and discussions with persons in recovery, mental health and addiction service providers, family members, and administrators. Quantitative indicators of validity are pending (Davidson et al. 2003).

**References and Suggested Readings**

Connecticut Department of Mental Health and Addiction Services (undated). Recovery self-assessment. *Executive Summary*. New Haven, CT.

Davidson, L., O'Connell, M., Sells, D., & Staeheli, M. (2003). Is there an outside to mental illness? In L. Davidson, *Living outside mental illness. Qualitative studies of recovery in schizophrenia*.(pp. 31-60).New York: New York University Press.

O'Connell, M., Tondora, J., Croog, G., Evans, A., & Davidson, L. (2005). From rhetoric to routine: Assessing perceptions of recovery-oriented practices in a state mental health and addiction system. *Psychiatric Rehabilitation Journal*, *28* (4), 378-386.

**Staff Attitudes to Recovery Scale (STARS)**
**2006 Australia**

Crowe TP, Deane FP, Oades L, Caputi P, Morland KG. (2006). Effectiveness of a collaborative recovery training program in Australia in promoting positive views about recovery. *Psychiatric Services,* 57(10):1497-1500.

**Administration Time:** Less than 10 minutes.
**Qualification/Training Requirement:** None, the instrument is self-

*Field Testing:*

Two hundred and forty eight community mental health workers showed improvements in recovery attitudes and hopefulness as measured by the STARS following the 'Collaborative Recovery Training Program' (CRTP) (Oades et al., 2005), with medium effect sizes reported (Government $\eta 2$ = .48; non-Government $\eta 2$ = .38). Specifically, trainees showed greater hopefulness regarding the ability of individuals with serious mental illness to set and achieve goals (Crowe et al. 2006).

One hundred and three providers attended formal recovery training and completed

Supplementary File 1 Instruments used for the CORE Study and Psychometric Information

administered.
**Scoring:** There are explicit guidelines indicating how to score responses.
**Supporting Material Available:** Information on administering the instrument, interviewer/administration training, guidelines to scoring responses.

STARS was developed as an evaluation tool to assess the impact of a recovery-based training program on staff attitudes towards recovery. It measures attitudes and hopefulness related to consumers' goal striving and recovery possibilities. It comprises 19 items, each of which is rated on a 5-point Likert scale.

Crowe et al. (2006) adapted items from the dispositional Hope Scale (Snyder et al., 1991) to construct a situationally-specific measure of hope, reflecting providers' hopefulness regarding consumer recovery prospects. This measure was integrated as a subscale within the Staff Attitudes to Recovery Scale (STARS), which also included items measuring more general recovery attitudes.

**References and Suggested Readings**

Copic, V., Deane, F. P., Crowe, T. P. & Oades, L. G. (2011). Hope, meaning and responsibility across stages of recovery for individuals living with an enduring mental illness. The Australian Journal of Rehabilitation Counselling, 17 (2), 61-73.

Crowe TP, Deane FP, Oades L, Caputi P, Morland KG. (2006). Effectiveness of a collaborative recovery training program in Australia in promoting positive views about recovery. *Psychiatric Services,* 57(10):1497-1500.

Oades, L., Deane, F., Crowe, T., Lambert, W.G., Kavanagh, D. & Lloyd, C. (2005). Collaborative recovery: An integrative model for working with individuals who experience chronic and recurring mental illness. *Australasian Psychiatry, 13,* 279- 284.

Oades, L.G., Crowe, T.P. & Nguyen, M. (2009). Leadership coaching transforming mental health systems from the inside out: The Collaborative Recovery Model as personcentred strengths based

measures of recovery knowledge, attitudes, hopefulness and optimism. A 2 (pre/post training) x 2 (high/low hope) within and between groups MANOVA was used to investigate whether participants with higher dispositional hope showed comparably greater improvement on the STARS following training. The MANOVA indicated a main effect across STARS showing that recovery attitudes and optimism significantly improved over the course of training, $F(2, 72) = 58.10$, $p < .001$, $\eta 2 = .617$. No interaction with dispositional hope was observed, $F(2, 72) = .41$, $p > .05$. Both univariate ANOVAs showed main effects, at $p < .001$ ($d = .872$). Results: Training improved providers' recovery knowledge, attitudes, hopefulness and optimism. Providers with both high and low dispositional hope achieved similar gains (Copic et al. 2011).

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coaching psychology. *International Coaching Psychology Review, 4,* 25-36.

Snyder, C.R., Harris, C., Anderson, J.R., Holleran, S.A., Irving, L.M., Sigmon, S.T., Yoshinobu, L., Gibb, J., Langelle, C. & Harney, P. (1991). The will and the ways: Development and validation of an individual-differences measure of hope. *Journal of Personality and Social Psychology, 60,* 570-585.

**EUROHIS-QoL 8-item index**
**UK 2003**

Schmidt, S., et al. (2006). The EUROHIS-QOL 8-item index: psychometric results of a cross-cultural field study. *The European Journal of Public Health 16*(4): 420-428.

**Administration Time:** Less than 5 minutes.
**Qualification/Training Requirement:** None, the instrument is self-administered.
**Scoring:** There are explicit guidelines indicating how to score responses.
**Supporting Material Available:** Information on administering the instrument, interviewer/administration training, guidelines to scoring responses.

Developed in the UK as a part of the European EUROHIS minimum dataset of measures project (Power 2003). The EUROHIS-QOL 8-item index is composed of eight empirically derived from the WHOQOL-Bref using structural equation and Rasch modelling . The WHO8 EUROHIS questions are primarily about personal satisfaction with different life aspects items (overall QOL, general health, energy, daily life activities, esteem, relationships, finances, and home). Scoring of the WHO8 is through simple summation of item scores (Schmidt, Muhlan et al. 2005). However, conceptually the psychological, physical, social and environmental domains are each represented by two items. All answer scales have a 5-point response format on a Likert scale, ranging for instance from 'not at all' to 'completely'.

*Field Testing:*

The two major international studies are reported:

1. In 2005 conducted by Schmidt, Muhlan, and Power (Schmidt, Muhlan et al. 2005).
2. In 2012 conducted by Rocha, Power, Bushnell and Fleck (Rocha et al. 2012).

Study 1
The EUROHIS-QOL 8-item index was assessed across 10 countries, with equal samples adjusted for selected socio-demographic data. The total number of respondents from the 10 countries was 4849, with 1203 individuals from the UK, France and Germany, A combined total of 1876 from Croatia, the Czech Republic, Romania and Slovakia, 778 from the Baltic States Lithuania and Latvia and 992 from Israel. Participants were also investigated with a chronic condition checklist, measures on general health perception, mental health, health-care utilization and social support (Schmidt, Muhlan et al. 2005).

*Factor analysis:*
A universal one-factor structure with a good fit in structural equation modelling analyses (SEM) was identified with, however, limitations in model fit for specific countries.

*Internal Consistency:*
Findings indicated good internal consistencies across a range of countries (Internal consistency was Cronbach $\alpha = 0.83$).

*Validity:*
*Convergent validity*
Analysis showed acceptable convergent validity showing moderate correlations with measures of mental health (Mental Health Index measured by SF-36, Rumpf et al. 2001), general health ('How is your health in general'), and social support Oslo Social Support

Supplementary File 1 Instruments used for the CORE Study and Psychometric Information

The items are all from the WHOQOL-Bref, the WHO8 EUROHIS is available in many languages and population norms are available from a number of European and other countries (Schmidt, Muhlan et al. 2005). Because copyright over the WHOQOL-Bref items is vested in the WHOGroup and the WHO, the WHO8 may not be reproduced without permission of the WHOQOL Group.

**References and Suggested Readings**

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Schmidt S, Muhlan H & Power M. (2005). The EUROHIS-QOL 8-item index: psychometric results of a cross-cultural field study. European Journal of Public Health. doi:10.1093/eurpub/ckil155. The WHOQOL Group. (1998). Development of the World Health Organization WHOQOL-BREF quality of life assessment. Psychol Med, 28:551–8.

Ware JE Jr, Sherbourne CD. (1992). The MOS 36-item short-form Scale, Brevik et al. 1996).

In the total sample, the zero-order correlation between the EUROHIS-QOL and the mental health index (MHI5) was r = 0.49, between QOL and the general health variable r = 0.53 and between QOL and social support (OSLO measure) r= 0.36. Comparing the interrelationship between these three measures across the four country groups the correlations between the QOL and general health showed correlations higher than r = 0.50 for all of these countries. In the Baltic states and southern/eastern European countries the correlation between the QOL and the MHI5 was r = 0.40 and r = 0.39, respectively.

*Discriminant validity*

Measure discriminates well between individuals that report having a longstanding condition and healthy individuals across all countries. A significant discriminative potential for the overall score can be shown across all countries except for the Israel (P = 0.090) and Slovakian (P = 0.111).

Study 2.

Cross-cultural evaluation of the WHOQOL-BREF domains in primary care depressed patients using Rasch analysis was conducted in 2012. The sample consisted of 2359 subjects identified from primary care settings, with 1193 having a confirmed diagnosis of depression. Data came from six countries (Australia, Brazil, Israel, Russia, Spain, and the United States) involved in a large international study, the Longitudinal Investigation of Depression Outcomes (Rocha et al. 2012).

*Factor analysis:*

A confirmatory factor analysis was performed by using structural equation modelling analyses, for testing the one-factor model of the EUROHIS-QOL 8-item index. The analyses were performed across all countries, as well as in each country sample.

A common one-factor structure with acceptable fit was identified in three out of six countries. The model fitted the data acceptably (comparative fit index CFI = 0.85, root mean square error of approximation RMSEA = 0.11) with adequate contribution of the latent factor on each item. The model fit varied across counties, with a better fit in the United States (CFI = 0.93, RMSEA = 0.08) and Australia (CFI = 0.88, RMSEA = 0.10) and a poorer fit in Spain (CFI = 0.78, RMSEA = 0.13) and Russia (CFI = 0.70, RMSEA = 0.15).

*Internal consistency:*

The index showed good total internal consistency measured by Cronbach's alpha within

Supplementary File 1 Instruments used for the CORE Study and Psychometric Information

health survey (SF-36), I: conceptual framework and item selection. Med Care, 30:473–83.

Weiller E, Lecrubier Y, Maier W, et al. (1994). The relevance of recurrent brief depression in primary care: a report from the WHO project on Psychological Problems in General Health Care conducted in 14 countries. Eur Arch Psychiatry Clin Neurosci, 244:182–9.

each country, Israel 0.81, Spain, 0.75, Australia 0.79, Brazil 0.72, the United States 0.80, and Russia 0.72. The alpha for the total EUROHIS-QOL 8-item index was 0.78. The index discriminated well between depression (t = 6.31–20.33; P < 0.001) across all countries.

*Validity:*

*Convergent validity*

Assessed by using Pearson correlations with different measures for mental health (Symptom Checklist 90), physical health (self-evaluation), and quality of life (WHOQOL-BREF and short form 36 health survey – SF-12). Correlations between the EUROHIS-QOL 8-item index and different measures - Symptom Checklist 90 (Derogatis et al. 1974) (r = -0.42), physical health ('How is your health in general') (r = -0.42), and short form SF-36 health survey (Ware et al. 1992) (r = 0.58) - were all significant (P < 0.001). The strongest correlations were between the EUROHIS-QOL 8-item index and WHOQOL- BREF (The WHOQOL Group, 1998) domains (rphysical = 0.73; rpsychological = 0.77; rsocial = 0.61; renvironment = 0.72; P's < 0.001).

*Discriminant validity*

It was assessed using diagnosed depressed and non-depressed patients. The EUROHIS-QOL 8-item index significantly discriminated (t = 6.31–20.33; P < 0.001) between patients with and without major depression disorder (CES-D (Radloff, 1977) score =>16 and positive CIDI (Weiller et al. 1994) for major depression - Diagnostic and Statistical Manual of Mental Disorders,Fourth Edition criteria).

*Sensitivity to change:*

A sample of patients (n = 975) was assessed at baseline and after 9 months of follow-up at the EUROHIS-QOL 8-item index. The EUROHIS-QOL 8-item index total score mean significantly improved (2.88 vs. 3.17; t = 14.03; P < 0.001; effect size = -0.21).

*THE ADVISORY AND DATA MONITORING COMMITTEE CHARTER*[1]


# The CORE Study: a stepped wedge cluster randomised controlled trial to test a co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness in the community mental health setting

**PROTOCOL NUMBER:** Version 1

**SPONSOR OF PROTOCOL:** The University of Melbourne

**DATE:** 25 May 2014

[1] This Charter has been prepared using Ellenberg et al's 2002 Template for the DMC Charter, the DAMACOLES Study Group (DAta, MOnitoring COmmittees: Lessons, Ethics, Statistics guidance. DAMACOLES 'A Proposed charter for clinical trial data monitoring: helping them to do their job well' Lancet 2005; 365; 711-22 and Chan et al's 'SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials' BMJ Research Methods and Reporting 2013; 346: e7586.

*Introduction*

This Charter is for the Advisory and Data Monitoring Committee (ADMC) for **CORE Protocol Version 1.** CORE is registered with the Australia and New Zealand Clinical Trials Registry (ACTRN 12614000457640) and has received ethics approval from The University of Melbourne Health Sciences Ethics Sub-Committee No: (1340299.3).

CORE is a stepped wedge cluster randomised controlled trial (SWCRCT) to test a co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness. It is a world first trial of a structured co-design method in the community mental health setting. The trial design means that the intervention will be rolled out sequentially to participating mental health community support services (two clusters at a time). By the end of the trial all clusters (and participants) will have received the intervention. Figure 1 shows the trial design from the original **CORE** protocol.

*Scope of this Charter*

This Charter details the aim and terms of reference of the ADMC for **CORE**. It describes roles and responsibilities, membership and size, the frequency and format meetings, methods of providing information to and reporting from the ADMC in the context of the **CORE** trial.

*Trial Design*

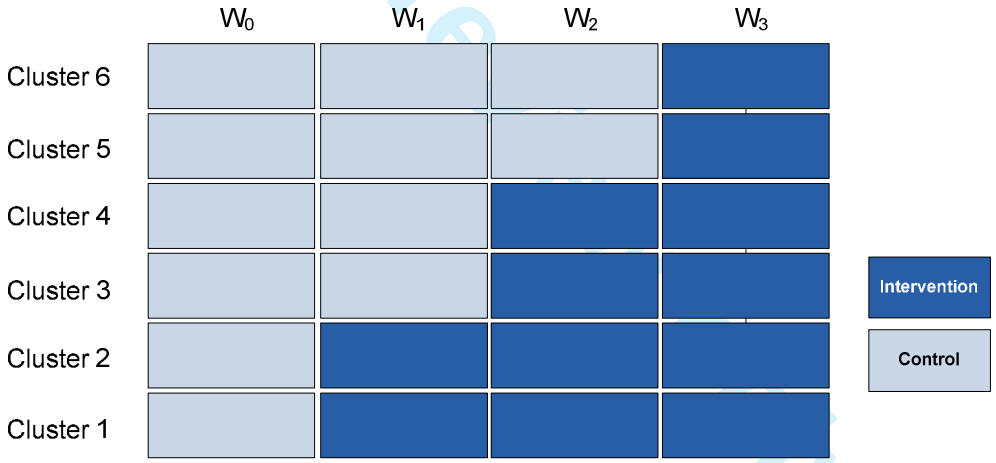



Figure 1 Design of a stepped wedge cluster randomised controlled trial in the community mental health setting.

*Funding and Sponsor*

CORE (2013-2017) is funded by the Victorian State Government's Mental Illness Research Fund (MIRF) and the Psychiatric Illness & Intellectual Disability Donations Trust Fund (PIIDDTF). The University of Melbourne, Australia is the sponsor organisation and the study is coordinated by the Primary Care Research Unit located in the General Practice and Primary Health Care Academic Centre, Faculty of Medicine, Dentistry and Health Sciences.

*Aims and Terms of Reference*

The aim of the **CORE** ADMC is to:

1) advise investigators regarding the implementation, maintenance and monitoring of overall conduct of the trial;

2) safeguard the interests of trial participants, assess the safety of the interventions during the trial and address any adverse events;

3) provide advice and feedback on qualitative elements and the nested process evaluation for the trial.

*Responsibility of ADMC*

The ADMC is responsible for safeguarding the interests of trial participants by assessing the safety of the interventions and monitoring the overall conduct of the trial. The ADMC will provide advice to enhance trial integrity, recruitment and retention, procedures for data management and quality control, and give feedback on qualitative aspects and the process evaluation. The ADMC is advisory to the investigator and trial management group.

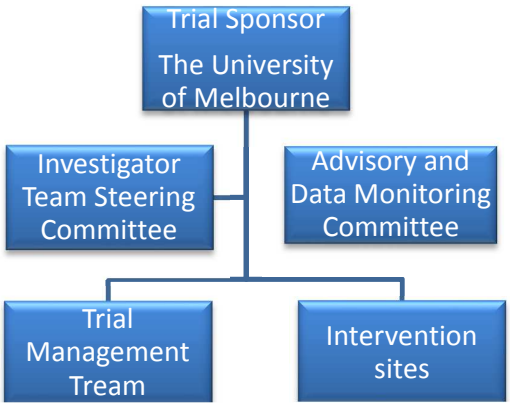
*Roles of the ADMC*

- monitor implementation of trial protocol;
- advise on protocol modifications suggested by investigators (e.g. to inclusion criteria, trial endpoints or sample size);
- advise on recruitment, retention and follow up issues;
- monitor sample size assumptions;
- advise on statistical analysis plan;
- advise on qualitative data collection and analysis plan;
- advise and feedback on the nested process evaluation framework, data collection and analysis;
- consider adverse events and possible harms to study participants[2].

*Governance of CORE*

The following diagram shows the relationship between the ADMC and other functional areas involved in the CORE trial.

[2] *A note on "stopping rules" in CORE – in clinical trials interim statistical analyses of the primary outcome are conducted to determine the effectiveness of a therapeutic intervention mid-way, if harm is determined a stopping rule may apply. CORE does not employ the stopping rule in the same way as a clinical trial because (a) the intervention is not therapeutic and (b) the stepped wedge design does not allow for mid-way analysis since all clusters will not have received the intervention. It is expected that the ADMC will monitor the trial for any serious adverse events related to the intervention and make recommendations to the team on actions related to these.*




*Membership, Composition and Size*

There are nine committee members for the ADMC (See Appendix A). Members represent a multidisciplinary mix with research expertise across the study disciplines: psychosocial recovery, randomized controlled trials and complex interventions, experience based co-design, biostatistics and clinical psychiatry, consumer and carer representation. The role of the Chair is to summarise discussions and encourage consensus. It may be best for the Chair to provide their opinion last.

*Confidentiality and Conflicts of Interest*

Members of the ADMC have been identified and selected because they do not have financial, scientific or regulatory conflicts. Members should declare any consulting agreements or financial interests they may have with the funder or sponsor organisation or trial sites. ADMC members will declare any competing interests; members agree that if this changes they will notify the Chair. If significant conflicts of interest emerge during the course of the trial the member should consider resignation from the ADMC and the investigator team will reappoint a replacement.

*Relationship with investigator team*

The ADMC functions in an advisory capacity only. Members are independent of the sponsor, funding body and investigators.

*Frequency, location and duration of meetings*

The CORE ADMC will meet bi-annually (circa February and November) for up to two hours on each occasion. Where ADMC members are located in Victoria, Australia they will participate in face-to-face to meetings to be held at the General Practice & Primary Health Care Academic Centre, The University of Melbourne. Where ADMC members are located interstate within Australia or internationally, they will be provided with videoconference call details to join meetings. Local members of the ADMC will be reimbursed for travel and a nominal reimbursement for other member's time will be provided in the form of a voucher as a small acknowledgement of time commitment and time taken away from other duties.

*Organisation of the ADMC meetings*

Meetings will consist of open and closed sessions. Open sessions are appropriate for investigators to attend while closed sessions may contain confidential data and results that should not be reviewed by investigators. Open sessions will be audio recorded and summaries presented back to the Committee and investigator team.

The first meeting of the ADMC for 2014 members will be introduced to the study protocol[3] and discuss the Terms of Reference as stipulated within this Charter. The first session provides an opportunity for ADMC members to give feedback and advice on the study protocol to ensure trial integrity. The second meeting for 2014 will involve discussion and feedback on protocol implementation and recruitment and overall study progress.

Meetings for 2015 and 2016 will focus on updates about intervention implementation and maintenance, follow up, retention and attrition. 2017 meetings will examine progress in the context of outcomes. All meetings will consider any qualitative data collection and process evaluation issues that are relevant.

*Reports to the ADMC - trial documentation and procedures to ensure confidentiality and proper communication*

At least 2 weeks before each meeting, the investigators and trial management team will send ADMC members a report for the open meetings with details on the trial progress, including recruitment, baseline characteristics of participants, available pooled data, eligibility violations, withdrawals, completeness of follow up, and compliance. The trial coordinator is responsible for preparing these reports and open reports will be overseen by Principal Investigator (PI) Palmer. The trial biostatistician will attend open sessions in conjunction with the statistical advisory member.

Closed reports will be provided for closed sessions that address any adverse events or harms including any relevant data analyses. Closed reports will be prepared by trial coordinator. Effectiveness and safety data by study group will especially be made available. The ADMC will be blinded to the intervention allocation; blinding can be removed at the request of the Committee.

The ADMC members do not have the right to share confidential information with anyone outside the ADMC, including the PI. The PI/trial management team will be responsible for circulating any external evidence from other trials/systematic reviews to the ADMC members.

*Decision-making*

The ADMC is independent to the investigator group and functions in an advisory capacity. The ADMC is asked to make decisions about the ethical, practical, statistical and financial implications of reports for the trial and make recommendations to the investigators. There should be a minimum number of five attendees at each ADMC for decision-making. An odd number is preferred if a decision must be voted on. If at short notice someone cannot attend, then the meeting should go ahead once the Chair, one clinician representative and the trial

[3] DAMOCOLES guidance outlines that the committee members should be in agreement with the trial protocol so an early meeting to introduce members and consider the protocol in more detail is important. Following this first meeting, CORE ADMC members have the opportunity to withdraw their membership if they do not agree with trial protocol.

statistician are present. Comments on reports circulated prior to committee meetings for those who cannot attend should be passed to the Chair.

*Reporting from ADMC*

The ADMC will make its recommendations verbally to the PI and other investigators at the end of every open meeting. Minutes of the open sessions will be recorded and circulated to the ADMC and investigators. The ADMC will report to or meet the funding body, the Victorian State Government, should the need arise. Closed reports will be provided back to the trial coordinator.

*After the trial*

ADMC members' names and affiliations will be listed in the protocol and main report and outcomes paper, unless they explicitly request otherwise. A brief summary of the timing and conclusions of ADMC meetings will be included in the body of the outcomes paper. The ADMC will be given the opportunity to read and comment on any publications prior to submission, any feedback provided will be acknowledged within the acknowledgements section of published works. To maintain independence from the trial, ADMC members external to the investigator group will not participate as authors in publications arising directly from the trial data.

Membership of the ADMC for the CORE Trial

| |
|---|
| **Professor Judith Cook** (Randomised Controlled Trials and Recovery)<br>Director, Center on Mental Health Services Research and Policy<br>Department of Psychiatry<br>University of Illinois at Chicago, USA<br>Email: cook@ripco.com |
| **Hilary Boyd** (Experience Based Co-design)<br>Performance Improvement Specialist \| Concord Team<br>Auckland District Health Board, New Zealand<br>Email: hboyd@adhb.govt.nz |
| **Karen Fairhurst** (Carer / quality and safety representative)<br>Victorian Mental Health Carers Network, Australia<br>Email: karen.fairhurst@carersnetwork.org.au |
| **Professor Sally Wyke** (Complex interventions and Health Services Research)<br>Deputy Director<br>Institute of Health and Wellbeing<br>University of Glasgow, Scotland<br>Email: Sally.Wyke@glasgow.ac.uk |
| **Professor John Carlin** (Biostatistics)<br>Director, Clinical Epidemiology & Biostatistics Unit<br>Murdoch Children's Research Institute<br>Royal Children's Hospital, Australia<br>Professor, Department of Paediatrics, and<br>Centre for Molecular, Environmental<br>Genetic & Analytic (MEGA) Epidemiology<br>School of Population Health<br>University of Melbourne<br>Email: john.carlin@mcri.edu.au |
| **Dr Lynne Maher** (Expertise in Experience Based Co-design)<br>Director for Innovation<br>Ko Awatea, the Centre for Health System Innovation and Improvement for Counties Manukau Health<br>Auckland, New Zealand<br>Email: lynne.maher@middlemore.co.nz |
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| **Assistant Professor Robert Whitely** (Expertise in psychosocial recovery)<br>Social Science Researcher<br>Douglas Hospital Research Centre<br>Assistant Professor, Department of Psychiatry<br>McGill University, Canada<br>Email: robert.whitley@mcgill.ca |

BMJ Open

# The CORE Study Protocol: a stepped wedge cluster randomised controlled trial to test a co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness in the community mental health setting



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## Title Page

# The CORE Study Protocol: a stepped wedge cluster randomised controlled trial to test a co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness in the community mental health setting.

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**Key Words**

Quality of Health Care, Community Mental Health Services, Intervention Studies, Patient Centred Outcomes Research, Psychosocial Recovery

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## INTRODUCTION

User engagement in mental health service design is heralded as integral to health systems quality and performance, but does engagement improve health outcomes? This article describes the CORE study protocol; a novel stepped wedge cluster randomised controlled trial (SWCRCT) to improve psychosocial recovery outcomes for people with severe mental illness.

## METHODS

A SWCRCT with a nested process evaluation will be conducted over nearly four years in Victoria, Australia. 11 teams from four mental health service providers will be randomly allocated to one of three dates 9 months apart to start the intervention. The intervention, a modified version of Mental Health Experience Co-Design (MH ECO), will be delivered to 30 service users, 30 carers and 10 staff in each cluster. Outcome data will be collected at baseline (6 months) and at completion of each intervention wave. The primary outcome is improvement in recovery score using the 24-item Revised Recovery Assessment Scale for service users. Secondary outcomes are improvements to user and carer mental health and well being using the shortened 8-item version of the WHOQOL Quality of Life scale (EUROHIS), changes to staff attitudes using the 19-item Staff Attitudes to Recovery Scale and recovery orientation of services using the 36-item Recovery Self Assessment Scale (provider version). Intervention and usual care periods will be compared using a linear mixed effects model for continuous outcomes and a generalized linear mixed effects model for binary outcomes. Participants will be analysed in the group that the cluster was assigned to at each time point.

## ETHICS AND DISSEMINATION

The University of Melbourne, Human Research Ethics Committee (1340299.3) and the Federal and State Departments of Health Committees (Project 20/2014) granted ethics approval. Baseline data results will be reported in 2015 and outcomes data in 2017.

**TRIAL REGISTRATION:** Australian and New Zealand Clinical Trials Registry ACTRN12614000457640.

## STRENGTHS

- This study is the first to implement a stepped-wedged cluster randomised controlled trial design to identify if an EBCD intervention designed to change recovery-orientation of services improves psychosocial recovery outcomes in people with serious mental illnesses;
- With the stepped wedge design all clusters will ultimately receive the intervention while those waiting for the intervention to commence act as controls;
- The study collects data on a cohort of service users from the community mental health setting about recovery experience and intervention effects over time;
- The design incorporates flexible participation options for people experiencing mental illness and their carers through multiple modes of completion of measures (telephone, face to face with research assistance, or self-complete);
- The trial design includes an engagement model to increase reach and retention of people with serious mental illness and their carers.

## LIMITATIONS

- System changes due to a major reform of service delivery models may impact on staff continuity, users' perceptions of service experiences which may affect outcomes and participation;
- The stepped wedge design means that some clusters wait for a long period before commencing the intervention which may increase dropout rates and decrease motivation for participation;
- The study cannot include people who do not speak English well due to translation, lack of appropriate culturally-specific recovery measures and resource constraints.

## INTRODUCTION

### Background and rationale

User participation in mental health planning and service design is recognised as an important component of system improvements aligned with user needs and patient-centred care. In the published literature the terms service users, patients, clients and consumers are used interchangeably to refer to recipients of health care services, while the term carer/s refers to family or friends; the term "user" is applied in this article as an umbrella term for these related concepts. User participation has expanded beyond surveying people to gather feedback about services to now include meaningful partnerships facilitated through co-learning, active collaboration, shared power and decision-making in healthcare; all of which are encapsulated in the term "engagement". [1, 2] Engagement has come to be seen as an integral element to improve quality of care experiences and Experience Based Co-Design (EBCD) has emerged as fitting for this task.

EBCD utilises participatory action research methods and is informed by design thinking to identify users' positive and negative experiences of services.[3, 4] Design thinking centres on the principles of good design: the functionality (fit for purpose performance); the safety (good engineering and reliability) and the usability (the interaction with the aesthetics) of a system or service.[3] EBCD is premised on developing deep understanding of how users' perceive and experience the look, feel, processes and structures of services; all the aspects of organisations that users' interact with. These interaction points are termed "touch points". This is followed by a process of sharing commonly identified touch points with staff and users, and through a participatory action method bringing everyone together to co-design

solutions especially around the negative touch points. This is followed by the implementation of the changes; a phase called co-design.[3, 5, 6]

EBCD extends the current health care system focus on design of procedures and structured practices, to the design of services based on human experience.[5] Engaging users in co-designing organisational changes premised on their experiences is said to result in better quality of care and system performance, this is achieved through illuminating individual's subjective and personal feelings at different points in the care pathway which in turn is said to result in improvements to health outcomes.[7] At present though there is little evidence from completed EBCD studies as to whether better quality of care, system performance and improved user experience does result in changes to individual health outcomes.[8-10] To date, no randomised controlled trials (RCTs) have been conducted of EBCD to determine this or explore its potential as method for building user-designed recovery-oriented mental health systems.

EBCD evidence at present is largely from qualitative evaluations of quality of care improvement initiatives in Alzheimer's, breast and lung cancer care in Australia, New Zealand (NZ) and the United Kingdom (UK).[11-14] More recently, an accelerated form of EBCD was tested in intensive care and lung cancer services in the UK.[15-17] EBCD was implemented in Australian New South Wales (NSW) hospital emergency departments in response to quality and safety issues. Qualitative evaluation of the NSW program suggested improved patient/user experiences and staff work practices.[18-20] There is a current co-design initiative underway in a Victorian Hospital Emergency Department in Australia.[21] In the mental health setting however, EBCD appears only to have been implemented in local, staff driven quality improvement initiatives in the in-patient setting. These local initiatives

indicate good results, for example, complaints were said to be reduced by 80% over 14 months and staff attitudes to how patients experience services changed.[22] Rigorous evaluation of the appropriateness and effectiveness of EBCD in the mental health setting for improving user experience with a focus on improving recovery outcomes has yet to be conducted.

Other methods of user involvement in the community mental health setting have been tested in RCTs but they have not been co-design nor service improvement focused.[23-32] In mental health there is an emphasis on system improvement which is recovery-oriented and coupled with the delivery of evidence based mental health services. This focus is articulated in policies from the United Kingdom (UK), [33, 34] Canada, [35] the United States (US), [36] Australia [37-42] and New Zealand (NZ).[43] Yet, clearly articulating the components of recovery-oriented service and how these result in health outcomes is difficult. Part of this challenge is linked with how recovery is contemporarily described. There is recognition that user defined recovery is different from symptom reduction and functional improvements characteristic of earlier concepts of clinical recovery.[44] Recovery is articulated as an ongoing, subjective process unique to each individual which encompasses social, psychological, cultural and spiritual dimensions.[45] EBCD with its focus on capturing individuals' subjective experiences of services may then offer a method to facilitate changes in mental health services that are premised on user-driven perspectives of recovery-oriented services.[46-48] Determining if this betterment of experience then translates to improved psychosocial recovery outcomes is critical for informing system design and evidence based mental health care. The CORE study will be a world first stepped wedge cluster randomised controlled trial (SWCRCT) to test if an EBCD method improves psychosocial recovery outcomes for people affected by mental illness in the community mental health setting.[49-51]

This article describes the CORE study protocol. The protocol adheres to the SPIRIT 2013 guidelines.[52] Guidelines for the development and reporting of stepped wedge designs are currently in formation and not due for release until 2017.[53] Planning for the CORE study began in June 2013, services were recruited in early 2014 and recruitment of users and carers was initiated later in 2014. Data collection of outcome measures will be completed in June 2017. The study was funded in June 2013 to June 2017.

## OBJECTIVES

Our hypothesis is that an EBCD intervention aimed to make community mental health services recovery-orientated will result in improved psychosocial recovery outcomes for people affected by mental illness. In addition it is hypothesised that this will improve carers' mental health and well being, and change staff attitudes to recovery and the recovery orientation of services.

## METHODS

### Design

The CORE study is a stepped wedge cluster randomised trial with a nested process evaluation. The nested process evaluation will be explained in a separate publication. A cluster randomised design was selected because the EBCD intervention (explained later) is an organisational/service level intervention which requires a high proportion of staff, users and carers in community mental health services to participate in all the elements, therefore it was not possible to randomise individuals within a cluster to the different starting dates for the EDCB intervention.[54] The stepped wedge design overcomes the logistical constraint of not being able to deliver the intervention concurrently to all clusters. Using a stepped wedge

design also enables all participating clusters to ultimately receive the EBCD intervention which is an advantage when working with a vulnerable population group where it is not ethical to withhold an intervention that is perceived to be beneficial.[54-56] Other designs such as a parallel cluster randomised trial were not feasible because sufficient study power could not be achieved to detect the desired effect size with the proposed number of clusters. It was not possible to increase the number of clusters because of practical, cost and logistical constraints.

The CORE trial will take almost four years to complete. The EBCD intervention will be delivered in three waves to 11 clusters (teams) from four community mental health services in Victoria Australia as shown in Figure 1. Recruitment of individuals and baseline data collection will occur in wave 0. When baseline data is collected, four teams will be randomly allocated to start the intervention at beginning of the wave 1, four in wave 2 and three in wave 3. The clusters not in receipt of the intervention at each wave act as a control.[55, 56] Data will be collected at the cluster and individual level at four time points: baseline (6 months) and at the end of the three waves following the completion of the EBCD intervention (see Figure 1). Duration of each wave will be nine months, seven months for the delivery and implementation of the EBCD intervention and two months to collect the data.

Soon after recruitment of individuals was initiated and study research staff met with service teams on site there were a few practical and feasibility issues identified that led to the following modifications to the study protocol. These modifications were made before randomly allocating the clusters to the three waves.

1) At the beginning recruitment of users and carers was slow, thus the time frame for recruitment of participants and baseline measurement was extended from an originally proposed three months to six months to ensure that we reach our target sample size.
2) The intervention has been modified so that the information gathering stage takes 12 weeks instead of 20 weeks as per the original protocol (the justifications for this are explained in the intervention section).
3) In the original proposal we proposed randomising six clusters from three mental health service providers. Some clusters were formed by combining teams that serviced the same geographical catchment areas to avoid contamination and ensure a sufficient number of users were available in each cluster for recruitment. However, after visiting the teams on site we identified teams were located some 20-100 kilometres apart functioning as discrete teams. This raised a logistical issue around the feasibility of delivering the intervention in vast geographical areas. In particular widely dispersed service users and carers would be unlikely to actually attend face to face meetings linked with the intervention. Thus, three clusters that consisted of two geographically diverse service teams (one from each of the three service providers) were split to form two clusters. Thus, the number of clusters increased from six to nine, that is, three for each service provider.
4) In addition, to allow for drop out of clusters, we recruited a fourth community mental health service provider with two service teams to supplement the three community

mental health service providers. During the recruitment process of individuals it became apparent that there was a risk that some teams may drop out of the study, particularly those that were struggling to identify and recruit sufficient individuals to meet sample size targets.

The remainder of the protocol has been updated to reflect the modifications made to the stepped wedge design where the number of clusters was increased from 6 to 11 clusters and recruitment period was extended from 3 to 6 months.

**Accounting for service user characteristics in the design**

The service user groups at community mental health services are characterised as having enduring psychosocial disabilities and long term impairments from mental illnesses. Conditions range from bipolar disorder, schizophrenia, psychosis, chronic depression and anxiety to obsessive compulsive disorders and other personality disorders. The fluctuating nature of mental illnesses means that the majority of service users are likely to be in contact with service teams for long periods of time and this will result in CORE participants being present as service users at multiple follow up time points. However, it is also anticipated that some users may recover and may be discharged from services as they no longer meet eligibility criteria to receive services or they move away from the area or join a new service.

To address the issue of mobility of users in and out of the services and attrition over duration study, the CORE study will consist of overlapping samples of individuals that may be measured at one or more subsequent waves.[57, 58] Individuals (users, carers or staff) will be sampled from each cluster and followed up at each time point (cohort design). Individuals will also be recruited at the beginning of subsequent waves and followed up to refresh the

sample and offset attrition over time, particularly as the study duration of nearly three years.[57, 59]

In using the cohort design for individuals, selection bias may be minimised because individuals are recruited prior to randomisation and we can gather richer information than cross-sectional samples. However, a cohort design may introduce bias if there is differential loss to follow up at each wave and across clusters. Service users may move in and out of the community mental health teams (cluster), and may even move to other teams (who may or may not be enrolled in the trial). Furthermore, with a cohort design there is a chance that individuals may not attend the mental health service after the intervention has been implemented, hence potentially diluting intervention effect.

Due to practical difficulties and high costs it will not be possible to recruit successive cross-sectional samples of individuals for this study. One reason is that the population is extremely difficult to reach. The recruitment of the individuals requires a combination of dedicated research assistants visiting the mental health community support services to directly offer information and face to face recruitment for individuals. In addition, recruitment is dependent on staff in the team clusters generating awareness about the study by giving service users a purposefully designed study postcard. Both methods are costly and time consuming. Given that size of the 11 teams (clusters) may range between 60 to 350 service users, there is also a higher chance that individuals are more likely to be sampled more than once, particularly in the smaller clusters if repeated cross-sectional sampling is adopted.

**Engagement model underpinning trial design**

Informing the trial design is a model of engagement and translation based on the combination of a knowledge transfer model and relational ethical theories. The model has the ultimate goal of building knowledge and shared understanding of the research question, maintaining partnerships and relationships and preparing sites for trial implementation through translation of research systems and structures into practice.[60] In addition such a model incorporates some of the strategies that have been identified as important in addressing mobility issues in trials.[58] Engagement activities will include study posters being distributed to access points in local communities near to mental health services, regular scheduled phone calls to key contacts within teams to provide study updates, meetings with service provider organisations to document the policy and service delivery context, conversations with staff about recruitment strategies for service users to increase reach and participation in all clusters, a purposefully designed study blog with fortnightly updates to keep staff engaged, newsletters to user and carer participants three times a year and implementation and maintenances strategies for the intervention with staff.[61]

**Study setting and target population**

Mental Health Community Support Service Providers (MHCSS) are located in metropolitan, outer metropolitan and regional areas across Victoria, Australia. In 2010-2011 it was estimated that some 14 000 people in Victoria received services from mental health community support agencies.[62] Since the government implemented a new model of delivery there are now 14 main providers of services in distinct geographical catchments that cross over 2-3 and up to 7 local municipal boundaries. It is well documented that people experiencing mental illness and their carers are difficult to recruit and to retain in research studies.[63-68] With this in mind and the aim of CORE to improve service recovery-

orientation, the study began with the recruitment of the mental health service provider organisations in early 2014 before identifying clusters (teams) within the service providers for participation (explained in the recruitment section).

The primary focus of MHCSS's is to provide daily living, social and community support to people living with mental illnesses. Data from 2010 indicated that most people who receive services have between one and four complex factors which include: social isolation, activities of daily living, issues related to unresolved trauma, treatment resistant symptoms, extensive time to maintain levels of functionality with little improvement in functionality over time, chronic physical health problems, difficulty complying with medications, problems with intellectual disability/cognition, alcohol use, illicit drug use.[62] MHCSS services provide support across these complex areas however staff do not provide clinical assessments and clinical care of individuals.

Services are delivered by community health centres (CHCs) and secular and non-secular non-government community organisations (NGOs). Services are staffed by a mix of professionals with training in community nursing, social work, occupational therapy and case work. Teams vary in sizes but typically include 8-15 members (part-time or full-time equivalent) who deliver case management and outreach services to anywhere from 60-350 service users in a specified geographical catchment area. The model of service delivery is based on the completion of a comprehensive assessment of service user and carer/family needs (housing, social or other support needs). This assessment forms the basis of a user-directed recovery plan which covers an individual's daily living skills, physical health, housing, relationships, social connections, education, training and employment and parenting or family needs. Carers may be involved in the development of a recovery plan where appropriate.[62]

Eligibility for using the services is set out by the Victorian State government in Australia funding authority responsible for mental health community support services. These criteria include age group of 16-65 years, disability attributable to a psychiatric condition (bipolar disorder, schizophrenia, psychosis, major depression, severe anxiety, personality disorders, posttraumatic stress), impairment that is permanent and results in substantially reduced psychosocial functioning for communication, social interaction, learning, self-care, self-management, and impairment that affects the ability for social and economic participation.[62]

**Participant eligibility criteria**

Eligible participants for the study are service users receiving care from the participating MHCSS teams including carers of those service users and staff members of those teams. Carers are defined as family members or other persons identified as being in a caring relationship with a person experiencing serious mental illness. To be eligible to participate all service users and carers will need to understand spoken English as there is limited funding for translation of materials or provision of interpreters including the issue of measures not being validated in languages other than English. Levels of understanding of the requirements for research participation will be determined by the completion of a two stage consent process. Testing and re-testing for understanding is recommended in literature discussing the issues of informed consent for people with mental illness (explained further in the recruitment section).[69]

**Intervention**

The intervention to be delivered is a modified version of Mental Health Experience Based Co-design (MH ECO). MH ECO implements a complex research methodology that applies the theory and practice of EBCD in the mental health setting.[49] MH ECO was developed by the Victorian Mental Illness Awareness Council (VMIAC) and TANDEM representing Victorian mental health carers (formerly the Victorian Mental Health Carers Network) and piloted in former Psychiatric Disability Rehabilitation Support Services (now called Mental Health Community Support Services).

The evaluation of the pilot of MH ECO with young people and adults experiencing serious mental illness indicated positive benefits for staff, users and carers.[70] Figure 2 shows the two stages to MH ECO: the information gathering (12 weeks) and the co-design (14 weeks) as modified for delivery in the CORE trial. All 30 users and 30 carers will be invited to participate in all elements of the intervention but it is not compulsory that everyone participate in every component. The main modification in MH ECO for CORE was shortening the length of the intervention to 26 weeks instead of the original 40 weeks in the earlier MH ECO work (this is explained below). Appendix 1 details the program logic and anticipated outcomes from the intervention.

*Stage one: information gathering*

Information gathering is about developing understanding of how users' experience services and identifying the positive and negative touch-points for co-design. In MH ECO this is achieved by all recruited users and carers, who are in the clusters allocated to the intervention wave, being invited to complete a 30 minute Computer Assisted Telephone Interview about service experiences, this is called the Touch Points CATI (TP-CATI). The TP-CATI occurs in weeks 1-6 and is comprised of no more than fifteen closed and no more than five closed questions. The closed question responses will be counted to determine the top three positive and top three negatively shared experiences and open ended responses will be analysed by two members of the investigator team reading responses and identifying the common themes to emerge.

The touch points will be explored further in face to face interviews with three users and three with carers (1-2hrs in length) from each cluster. Interview data will be used to compile service stories which will be used in focus groups held separately with 8-10 staff, 8-10 users and 8-10 carers (up to 2 hours in length) in each cluster to explore the touch points in more depth. Sampling for the interviews and the focus groups will take account of gender and illnesses represented to ensure a wide range of views are collected. The interviews and focus groups occur weeks 7-14.

*Modifications of the information gathering phase of MH ECO for CORE*

For CORE, the TP-CATI has been modified from the original telephone interview conducted in the MH ECO pilot from 40 questions that took participants between 45 minutes and 1.5 hrs to 20 that will take 30 minutes. It will be shortened from a 5 month to 3 month phase for two

reasons. First the sample will already be recruited and users and carers will be expecting contact from the study to complete the service experience questions. Second, international trends within the published literature indicate the importance of accelerated forms of EBCD so that change issues can be identified and solutions can be co-designed and implemented more efficiently.[15] This is an important consideration in the context of people with serious mental illness and their carers where motivation to stay in the intervention may be impacted on by a lengthy intervention phase.

Another modification from the MH ECO pilot is that trained research assistants working from the CATI room facilities at The University of Melbourne will administer the TP-CATI with users and carers rather than an external telephone consulting company. The TP-CATI responses will be entered verbatim into a purpose built data management system for analysis. Focus groups and interviews will be scheduled by University research staff and facilitated by co-investigators from VMIAC and TANDEM (WW and RC) including two additionally trained intervention facilitators. Interviews and focus groups will be audio recorded and transcribed by a professional transcription company ready for analysis.

*Stage two: co-design phase*

The co-design phase will be led by RC and WW with additionally trained facilitators. Facilitation will always include one lead facilitator accompanied by a newly trained facilitator. The facilitators will use techniques from the design sciences to facilitate the co-development of solutions. These techniques include journey mapping through storyboarding and co-designed solutions using prototype development.

Co-design commences with the establishment of a collaboration (one group) and co-design group/s (up to three if three clear touch points are identified). Prior to these groups meeting, the lead facilitators (RC and WW) deliver two one-day training sessions to staff, service users and carers to resource and support participation in groups and to outline what to expect from participation in group processes; training occurs weeks 15-16. This is followed by the first meeting of the collaboration group (weeks 17-18) and then subsequent co-design group meetings (weeks 19 to 24). The collaboration group will meet again in weeks 25-26 to review and implement action plans.

The collaboration and co-design group membership will be different. Collaboration group membership will ideally comprise of 8 people in total (1 senior manager, 1 quality manager, 2 consumers, 2 carers and 2 staff members from service teams) and will meet two times (2 hours per meeting). The primary role of the collaboration group is to set out some preliminary objectives for co-design groups and to implement the action plan from the co-design group/s.

Each co-design group will ideally comprise of 6 people (1 service manager, 2 consumers, 2 carers and 1 service team member). They meet three times (2 hours per meeting): meeting one is a review of existing service processes and the identification of areas for improvement related to the touch point in question; meeting two is a review of good practice examples and discussion of ideas for action plans; meeting three is the development and finalisation of an action plan for implementation to address the touch point. Good practice examples offered in meeting two will be informed by evidence reviews completed by the University research team.

*Modifications to MH ECO co-design stage*

In the original MH ECO model a third collaboration group meeting was held 12 weeks later as a monitoring meeting to review the barriers and facilitators to action plan implementation. The CORE study will not include a third collaboration group due to the time constraints and need to complete follow up measures. In addition, the existing nested process evaluation is designed to capture information about emerging barriers and facilitators to change implementation.

Fidelity checklists for ensuring all elements of the co-design processes have been created for WW and RC to complete plus an external research evaluator (independent of the intervention) will cross-check these against audio files of sessions to check for fidelity. Independent observations of a random selection of the intervention components (focus groups, interviews, collaboration and co-design groups) across clusters and waves have been scheduled as part of the nested process evaluation.

**Outcomes**

The primary outcome is improvement in psychosocial recovery for individuals measured within 9 months from the beginning of each intervention wave. To determine the most acceptable measures for service users a small pilot of three potential primary outcome measures was completed with 40 people identified through a consumer organisation supporting people with mental illness. Service users completed combinations of either the 24-item Recovery Assessment Scale Revised (RAS-R) [71-73] and the 26-item Maryland Assessment of Recovery in People With Serious Mental Illness (MARS)[74] (17 people in total), or the RAS-R and person in recovery version of the 36-item Recovery Self Assessment Scale (RSA)[75] (13 people in total). Measures were completed in written form for one group

and telephone for another to ensure both completion modes were acceptable and feasible for people. The pilot identified the 24-item RAS-R as easy to understand, quick to answer, the average completion time was 13-18 minutes, and it was feasible for written or telephone administration.[76] RAS-R was also determined to be a good measure because it has been used in mental health outpatient settings, in peer run programs and is one of the few measures available that has been developed from user descriptions of the recovery process.[45] The RAS-R has been validated in an Australian population of people with severe mental illness.[72]

RAS-R uses a five point rating scale from 1="Strongly Disagree" to 5="Strongly Agree". Responses can be calculated as a total score ranging from 24 to 120 with higher scores indicating greater recovery. The RAS-R has five domains related to recovery: (i) personal confidence and hope (9 items; range 9 to 45), (ii) willingness to ask for help (3 items; range 3 to 15), (iii) goal and success orientation (5 items; 5 to 25), (iv) reliance on others (4 items; range 4 to 20) and, (v) no domination by symptoms (3 items; range 3 to 15). A higher rating within each domain indicates recovery progress. At present there are limited data available on what a clinically significant change is from scales such as RAS-R. Our pilot data indicated the mean for total RAS-R scores from 17 service users of this measure was 88 (standard deviation=13; range 58 to 104) which followed a similar pattern to baseline data reported in clinical trials that have used this measure; this has been taken into account in the sample size calculations.[25]

Secondary outcomes are changes to service users and carers mental health and wellbeing and changes to staff attitudes to recovery and recovery orientation of services. User and carer mental health and well being will be assessed using the EUROHIS-QOL 8-Item Index

derived from the WHOQOL-BREF Quality of Life scale. [71, 77, 78] The index is composed of 8 items which covers overall quality of life , general health, energy, daily life activities, esteem, relationships, finances, and home.[77, 78] Each item has a five point Likert scale and the overall quality of life is calculated by summing the 8 items, with higher scores indicating better quality of life. Staff attitudes to recovery and recovery orientation in services will be measured using the Staff Attitudes to Recovery Scale (STARS) 19 item questionnaire[79] and the provider version of the 36-item Recovery Self Assessment (RSA).[75] Higher scores on the STARS and RSA scales indicate improved staff attitudes to recovery and greater recovery orientation of the mental health services, respectively.

## Participant timeline

Table 1 Schedule of enrolment, interventions and assessments

| | Wave 0 | Wave 1 | Wave 2 | Wave 3 |
|---|---|---|---|---|
| Time points | 0-6mo | 7-15mo | 16-24mo | 25-33mo |
| ENROLMENT | | | | |
| Eligibility screen | X | | | |
| Informed consent | X | | | |
| Baseline | X | | | |
| Allocation | X | | | |
| STUDY PHASE | | | | |
| Clusters 9-11 | Control | Control | Control | Intervention |
| Clusters 5-8 | Control | Control | Intervention | Post-intervention |
| Clusters 1-4 | Control | Intervention | Post-intervention | Post-intervention |
| ASSESSMENT | | | | |
| *Service Users* | | | | |
| Demographics and clinical details | X | X | X | X |
| Recovery Assessment Scale Revised (RAS-R)(71) | X | X | X | X |
| EUROHIS-QOL[77, 78] | X | X | X | X |
| *Carers* | | | | |
| Demographics | X | X | X | X |
| Demographic and clinical details about the person they care for | X | X | X | X |
| EUROHIS-QOL[77, 78] | X | X | X | X |
| *Staff* | | | | |
| Demographic and employment details | X | X | X | X |
| Recovery Self Assessment (RSA)[75] | X | X | X | X |
| Staff Attitudes to Recovery Scale (STARS)[79] | X | X | X | X |
| DATA FROM EXTERNAL SOURCES | | | | |
| Medicare Benefits Scheme (MBS) data[∞] | X | X | X | X |
| Pharmaceutical Benefits Scheme (PBS) data[∞] | X | X | X | X |
| Victorian Emergency Minimum Dataset (VEMD)[β] | X | X | X | X |
| Victorian Admitted Episodes Dataset (VAED)[β] | X | X | X | X |
| Victorian Mental Health Triage Dataset (using CMI/ODS information system)[β] | X | X | X | X |

[∞] MBS and PBS information is routinely collection data from the Federal Government in Australia. MBS data provides information about when a medical service was received, the type of service, distance travelled to get to a service and how much out of pocket expenses were incurred for services. PBS data provides information on the type of medications prescribed, when they were prescribed, when they were collected, the distance travelled to collect medications and the costs of medications.

[β] State government emergency (VEMD) and admitted episodes (VAED) datasets provide information about when, were or how an individual was injured or became unwell, how urgent care needs were, the type of care that was received in hospital and length of time in the hospital, how people were cared for once discharged, place of residence, whether the person had a carer, if health insurance was used in hospital, background information about languages spoken and where someone was born. State government mental health triage dataset provides information on where an individual accessed a mental health service, who referred them and why, how urgent the care was and the type of care that was received, place of residence at the time and background information about the languages someone may speak.

**Sample size**

Thirty individuals from nine clusters at each of the four waves (one for baseline and at each follow up time),will be sufficient to detect an effect size of 0.35 of 1 standard deviation for psychosocial recovery measured at 9 monthly intervals between the intervention and usual care waves with at least 80% power (Table 1). Sample size was based on the primary outcome of psychosocial recovery score with the following assumptions: intra-cluster correlation for the outcome of 0.1 and significance level of 5% for a two-sided test, probability that each individual will remain at the site at each wave (0, 0.2 and 0.6) and within-subject correlation of individuals that contributed to at least two consecutive waves (0.2 and 0.7). The sample size was further inflated by including an additional two clusters from a fourth service to allow for loss of clusters (teams) over the duration of the study.

At the time of determining the sample size, there was no sample size formula available for stepped wedge design with longitudinal follow up of individuals.[80] Thus, to determine the power for this study a simulation study was conducted using a linear mixed effects model where treatment and time effects were assumed fixed and individual and site effects as random. Whether individuals remained in the cluster at each wave was sampled from a binomial distribution with parameter $p$ , the probability that an individual remained. When $p = 0$ this is equivalent having independent sample of subjects at each wave (that is, repeated cross-sectional samples). The study power was calculated as the proportion among all 2000 simulation runs of two-sided p-values for the estimated fixed treatment effect that reached a nominal value of less than 0.05. Two thousand replications for each set of parameter combinations were sufficient to estimate the power with a margin of error of 1.75%, assuming that the true power was 80%. The simulations were run using R version 3.1.2.[81]

Table 2 Power calculations to detect an effect size=0.35 of 1 standard deviation between the intervention and usual care periods, assuming an intra-cluster correlation of 0.1 and alpha of 5% for a 2-sided test for a stepped edge cluster randomised trials with nine clusters and three steps

| Probability of remaining at the centre | Within-subject correlation | Sample cluster size | Power* |
|---|---|---|---|
| 0 | NA | **30** | **0.81** |
| 0.2 | 0.2 | **30** | **0.82** |
| 0.2 | 0.7 | **30** | **0.86** |
| 0.6 | 0.2 | **30** | **0.86** |
| 0.6 | 0.7 | **30** | **0.94** |

*Power calculations based on 2000 simulations;

Table 2 shows that given a fixed sample cluster size, power was the smallest when it was assumed that samples at each time point were independent (that is, probability of remaining at the next wave was zero) and that the study power increased as the probability of remaining at the site and within cluster subject correlation increased.[80] Note the power calculations using the simulation study provided more conservative estimates of the power than the sample size calculations based on the formula provided by Hussey and Hughes.[82] These differences may be due to different derivations of the estimated test statistic.

## Recruitment

### *The mental health community support service providers*

Service providers were identified in early 2014 according to the geographical catchment area they serviced to aim for a spread across metropolitan, outer metropolitan and regional locations. Originally seven providers were approached by the principal investigator (VP). 1 hour face to face meetings were held with Chief Executive Officers or Senior Managers to present the study and its aims. Four of the seven providers invited to the study declined to

participate. Reasons included existing research demands, changes to staff, dealing with the implementation of a new model of service delivery at the service and user level and inability to provide a mail out option for recruitment to service users. The remaining three agreed to take part with the view that clusters would be selected to participate in the intervention at a later date and staff would opt-in to co-design intervention via an online survey. To accommodate for the potential loss of any clusters during the trial a fourth service provider was approached in December 2014 and agreed to participate. The same approach to recruitment of the service provider was used with a face to face meeting to explain the study purpose and aims. Two clusters were added from this service to allow for cluster drop out in the trial.

***User and carer recruitment***

The user and carer recruitment strategy will include an awareness raising phase where purposefully designed posters and postcards will be placed at participating sites and access points in the local community for four weeks prior to a service level mail out. Artwork for the posters and postcards has been designed by users of art support groups for people living with mental illnesses purposefully selected from a regional area not participating in the study. Poster content is purely to generate awareness about the study while postcard content includes information about the two modes of participation that are available: by telephone or attending a face to face study information and recruitment day. As a way of increasing reach and to identify if recruitment rates increase, the study has incorporated face to face study information days.[83] These information days are based on a peer support worker (PSWs) model combined with trained research assistants so that PSWs are available to provide information, support and de-briefing to users, while RAs complete the enrolment and baseline survey. The study information and recruitment days include the provision of lunch and a

short comedy routine delivered by WISE Stand Up for Mental Health trained performers (a recovery based program teaching comedy to people with mental illnesses) to disrupt conventional notions of research as tedious and monotonous and demonstrate a recovery practice by people from the same community.[84] The aim is to increase reach and if successful provide face to face study days to complete follow up measures to retain participants given issues of retention with people living with serious mental illness in research studies.[68] At the end of four weeks invitation kits will be mailed out to service users and carers from participating clusters.

*Enrolment and informed consent*

Enrolment of participants will be completed by research assistants trained in working with people with mental illness and their carers using the purpose designed database. Enrolment processes for users and carers will include entering participant contact details, carer information where available, and completion of the consent process by agreeing or disagreeing with ten statements read out by research assistant interviewers. The ten statements will explain study requirements, privacy and ethical obligations of the research team. This will be followed by a second stage consent process (explained earlier) which asks participants to answer three true/false statements to demonstrate their understanding of the nature and requirements of the research. These include: understanding that the study is about recovery and is not for treatment; understanding that being in the study will involve all staff, users and carers working together for the service improvement project (the intervention), understanding that participation is voluntary and that information is kept private. Users who are unable to provide information consent or who are unwell during times of telephone interview and/or face to face study day meetings will be placed on a wait-list and re-invited to the study in a fortnight to ensure maximum participation options. Staff will be eligible to

participate if they work within a participating mental health community support services team. Staff consent to participation during face to face meetings and via the online staff survey.

**Allocation and blinding**

Eleven teams (clusters) from four services will be randomly allocated to three starting dates for the intervention (waves), four teams will be allocated to the first two waves and three teams to the last wave. The allocation sequence stratified by service provider will be generated in Stata 13.0[85] by a statistician blinded to the identity of the clusters and not involved in the assessment or intervention delivery (PC). The clusters (teams) and order in which they receive the intervention will be communicated to the trial coordinators (MP and KG). The four clusters allocated to the first wave will be notified of intervention commencement after the initial baseline period is completed. The remaining clusters will be notified of their intervention commencement at the start of their allocated wave.

Thus, study participants and research staff will be blinded to the random allocation sequence during baseline recruitment and data collection. Due to the nature of the intervention it will not be possible to blind staff, service users and carers to the study arm status at each wave when the clusters have been allocated to the intervention arm. However, participants in the control arm at wave 1 will be blinded to whether they will receive the intervention at the second or third wave. Research interviewers collecting outcome data will remain blinded to who is in receipt of the intervention during the entire study period.

**Data collection**

Table 1 outlines the data collected at each time point for service users, carers and staff. Data collection in waves 1-3 will occur between the end of the intervention implementation and prior to the start date of the next intervention wave as depicted earlier in Figure 1.

The enrolment and baseline survey has been tested with ten users of mental health services and takes on average 30 minutes to complete by telephone or face to face. Services users and carers will be able to complete surveys by telephone or face to face; both modes of completion were provided as a way to offer maximum and flexible participation options to people and both the RAS-R and EUROHIS scales have been previously administered in both modes in research studies.[76, 78] The database allocates a code to participants to conceal personal information when data are aggregated and analysed.

Demographic questions will be completed by service users and carers at each data collection time point, there are completed by a research assistant and directly entered into the purpose built database. Information will include age, gender, education, employment, and sources of income. Service users will be asked specific questions related to if they have ever been given a name for their condition, length of time experiencing this condition, who gave them the name, visits to hospitals and why they access the mental health support service. The research team purposefully included the wording "name" of a condition rather than a diagnosis to identify the ways that users and carers describe the mental health conditions. Carers will be asked about their length of time caring for the person and whether they have been engaged by the mental health support service who cares for the consumer. Staff, service users and carers

will all be asked the Family and Friend Test (FFT) single question to measure quality of service experience.[86]

Consent will also be sought from service users to access routinely collected government data about health services visits (Medicare Benefits Scheme), medication prescriptions (Pharmaceutical Benefits Scheme), emergency department (Victorian Emergency Minimum Dataset) and hospital visits (Victorian Admitted Episodes Dataset), distance travelled to access services and obtain medication and hospitalisation information (reason for attending, length of stay, place of residence at the time) and triage information data (Mental health triage minimum dataset). The data available from these routinely collected datasets is explained in the footnote of table 1. The purpose of this data is to reduce the burden of questions being asked of users and the recall errors of self-report about medications and health services use. This data will be considered in conjunction with outcomes data to develop detailed understanding of health service and medication use over time including understanding if intervention participation or survey completion is affected by rates of hospitalisation.

Staff will complete an online survey with open ended questions using Qualtrics survey software (version 2013)[87], to collect information at each data collection point about training, recovery programs occurring at services and engagement of service users and carers in services including the STARS and RSA.[75, 79]

The concurrent nested process evaluation will use quantitative and qualitative data collected to identify contextual (organisational and environmental) factors that affect the intervention. The process evaluation has been organised using the RE-AIM framework as a guide.[88, 89]

The evaluation will examine the reach (representativeness of participants in the study and the intervention), effectiveness (the impact of the intervention on the study outcomes), adoption (proportion and representative of those who participated in each component of the intervention), implementation (fidelity to the implementation of the intervention) and maintenance of the intervention (the extent to which co-design becomes embedded in sites).[88-91] The detail of the framework and questions are to be provided in a separate published protocol for the nested process evaluation. Data management protocols can be provided from the University Ethics Approval applications if requested.

**Statistical Analysis**

Descriptive statistics will be used to summarise the characteristics of staff, service users and carers. The participants will be analysed in the group that the cluster was assigned to at each time point. A linear mixed effects model will be used to compare the intervention and usual care periods for continuous outcomes and generalised linear mixed effects model for binary outcomes. The model will include intervention status and time as fixed effects and site and individuals as random effects. Where appropriate, organisational and individual factors strongly correlated with the outcome will also be included as fixed effects in the model. These may include: recovery orientation of services and staff attitudes to recovery at baseline, age, gender, education level, work status, quality of life, medication and hospitalisation. The estimated intervention effect will be reported as mean outcome difference for continuous outcomes and odds ratio for binary outcomes between intervention and control periods, assuming a constant treatment effect over time. The estimated intervention effects will be reported with 95% confidence intervals and p-values. A secondary analysis will investigate

an interaction effect between intervention and time.[55, 56] Costs of the delivery of the intervention will be recorded but no economic evaluation will be undertaken. An intention-to-treat (ITT) analysis strategy will be used.[92] Every effort will be made to minimise missing outcome data at each wave and reasons individuals are lost to follow-up will be recorded. Sensitivity analyses will be conducted to assess the robustness of the missing data assumption made in the primary analysis. A detailed analysis plan will be developed for secondary and sensitivity analyses. Analysis will be conducted using Stata statistical software 13.[85]

**Data Monitoring**

An advisory and data monitoring committee has been established for the study and a Charter prepared following guidance from the Data Monitoring and Outcomes Study Group (DAMCOLES).[93] The role of the ADMC is to advise investigators regarding the implementation, maintenance and monitoring of overall conduct of the trial; safeguard the interests of trial participants, assess the safety of the interventions during the trial and address any adverse events in particular harmful events; provide advice and feedback on qualitative elements and the nested process evaluation for the trial (the ADMC Charter has been provided as supplementary file number 1). Membership consists of nine international and national experts engaged in research across EBCD, recovery, psychiatry and serious mental illness, complex interventions, randomised controlled trials and statistics. The ADMC meet twice per year to discuss progress and any adverse events, they are responsible for annual audits of trial conduct. In CORE the ADMC will not apply the stopping rules and interim analysis as per a clinical trial because (a) the intervention is not therapeutic and (b) the stepped wedge design does not allow for interim analysis since all clusters will not have received the intervention. It is expected that the ADMC will monitor the trial for any serious

adverse events related to the intervention and make recommendations to the team on actions related to these which will be reported as required to the Human Research Ethics Committee of the University. Definitions of serious or other adverse events are provided within the ADMC Charter (Supplementary File 1). Since the intervention has been developed by lead service user and carer agency it is believed that the likelihood for need to discontinue the intervention will be extremely minimal. Membership for the committee is provided in the Supplementary File 1.

**Ethics and Dissemination**

The CORE study involves working with vulnerable participants who experience serious mental illness and their carers. To ensure the needs of these communities are met, the research team has lead investigators from service user and carer agencies who actively contribute to the design, development and implementation of intervention. Contextual data collected through the model of engagement and translation in earlier parts of the study planning and recruitment of mental health community support service providers has been used to inform particular strategies for recruitment, retention and ensuring implementation of the intervention is as successful as possible. Ethics approval has been granted by The University of Melbourne Human Research Ethics Committee (HREC NO. 1340299.3) and the Federal and State government departments (Project 20/2014) responsible for routine data collection on health service use, pharmaceutical use, hospital admissions and triage. Baseline data will be presented in 2015 and trial outcomes in 2017 and published in scientific journals. Only investigators and approved researchers added by ethics approval will have access to the final trial dataset. Dissemination will include delivery of conference papers, study updates for staff and the research community via an online blog site, newsletters for users and carers

three times per year and knowledge transfer to government and the wider community through presentations, policy briefs and media releases where appropriate. Any protocol amendments will be reported to the responsible University and government ethics committee as trial sponsor and provided to the journal in which this protocol is to be published. Ethics procedures include measures for addressing any unintended harms for intervention participants post-trial by coordination of access to support services and follow-up by professional care workers.

**Discussion/Conclusion**

A stepped wedge design has some advantages and limitations for implementing this kind of trial in such a complex setting. The advantages are that all participants will ultimately receive the intervention and the delivery of the intervention can be staggered to manage the practical and logistical constraints that would come with the delivery of the intervention concurrently in 11 clusters. The staggered implementation of the intervention also allows for time effects to be taken into account on the outcome measures, this provides much greater depth of analysis than a pre-post design. The limitation of the stepped wedge design is that some clusters will wait a long time to receive the intervention and in populations such as those experiencing severe mental illness this could result in reduced motivation to continue participation and make contact difficult because of hospitalization or people moving in and out of services.[58] For this reason the CORE study team has developed and implemented the model of engagement to underpin the trial. The engagement model serves multiple purposes. It seeks to: build enduring relationships with all staff, service users and carers to last the length of the trial; communicate trial requirements to staff to encourage stronger implementation and hence embedding of the intervention into the setting; and, to keep services users and carers engaged during the wait periods for the intervention.

The longitudinal design offers a major strength for developing better insights into recovery outcomes over time for people affected by serious mental illness in the community mental health setting. With the current emphasis in mental health policy on developing recovery orientation in services, it is critical to understanding the components from user perspectives that are important in facilitating recovery experiences and how these may result in individual recovery outcomes.

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**Competing Interests** None.

**Ethics Approval**

The University of Melbourne Human Research Ethics Committee (HREC No.: 1340299.3) has approved this study. The Federal Government Department of Health has approved the collected of Medicare and Pharmaceutical Benefits Scheme data and the State Government of Victoria has approved the collection of hospital admission and triage data.

**Contributors** VP conceived the study in conjunction with staff located in community mental health services. LR contributed the theoretical model for engagement and translation. PC and TS led the calculation of the sample size and quantitative components of the protocol. All authors participated in the preparation of the manuscript providing written comments on drafts and approving the final version. The trial sponsor is The University of Melbourne. The trial sponsor has not been directly involved in the design, collection, management or analysis and interpretation of the data but is responsible for ethical conduct and ensuring data storage and management procedures are adhered to. They have not been involved in the decision to submit the protocol for publication.

**Provinance and peer review** Not commissioned; externally peer reviewed.

**Figure legends**

Figure 1 A stepped wedge cluster randomised controlled trial in the community mental health setting

Figure 2 Modified MH ECO intervention for the CORE trial

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Figure 1 Trial data collection timepoints

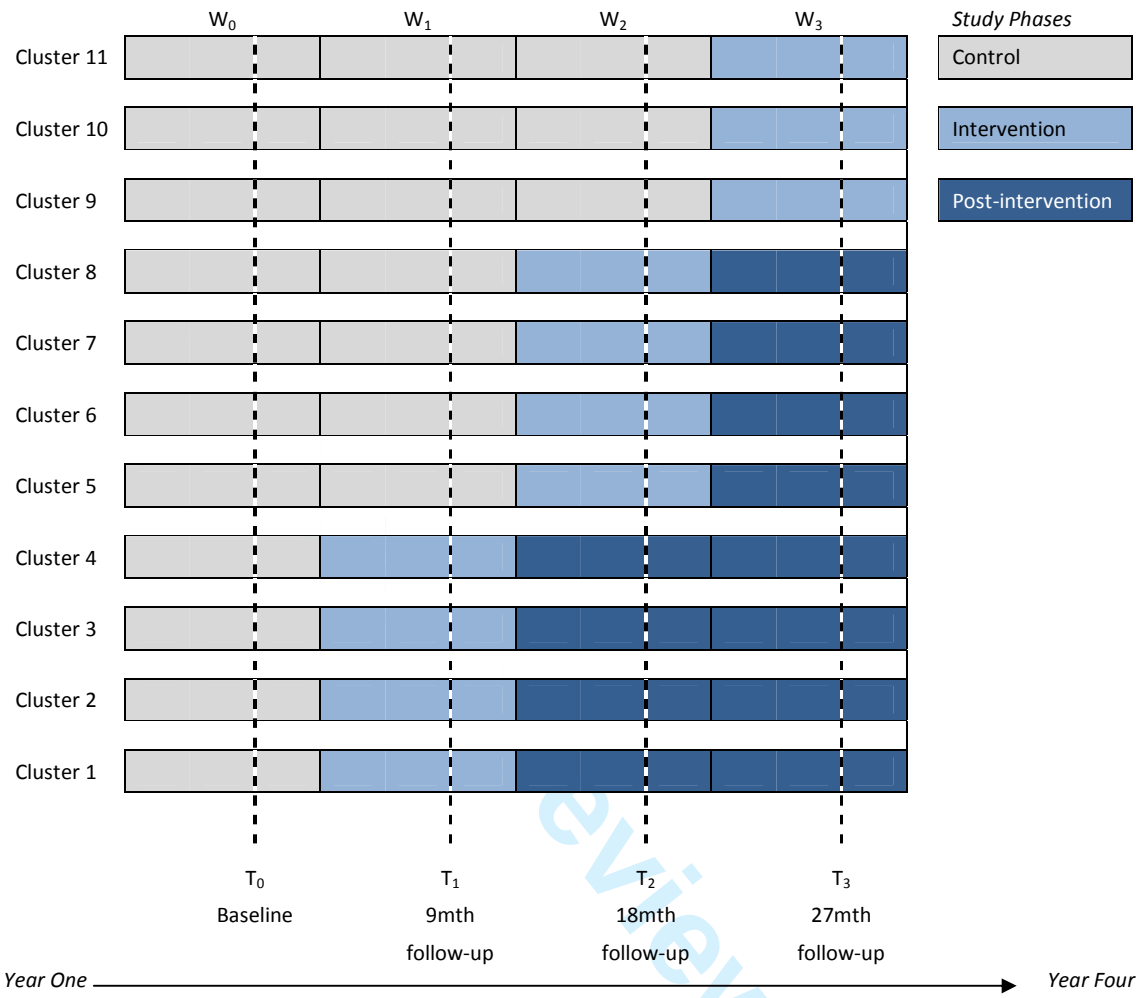
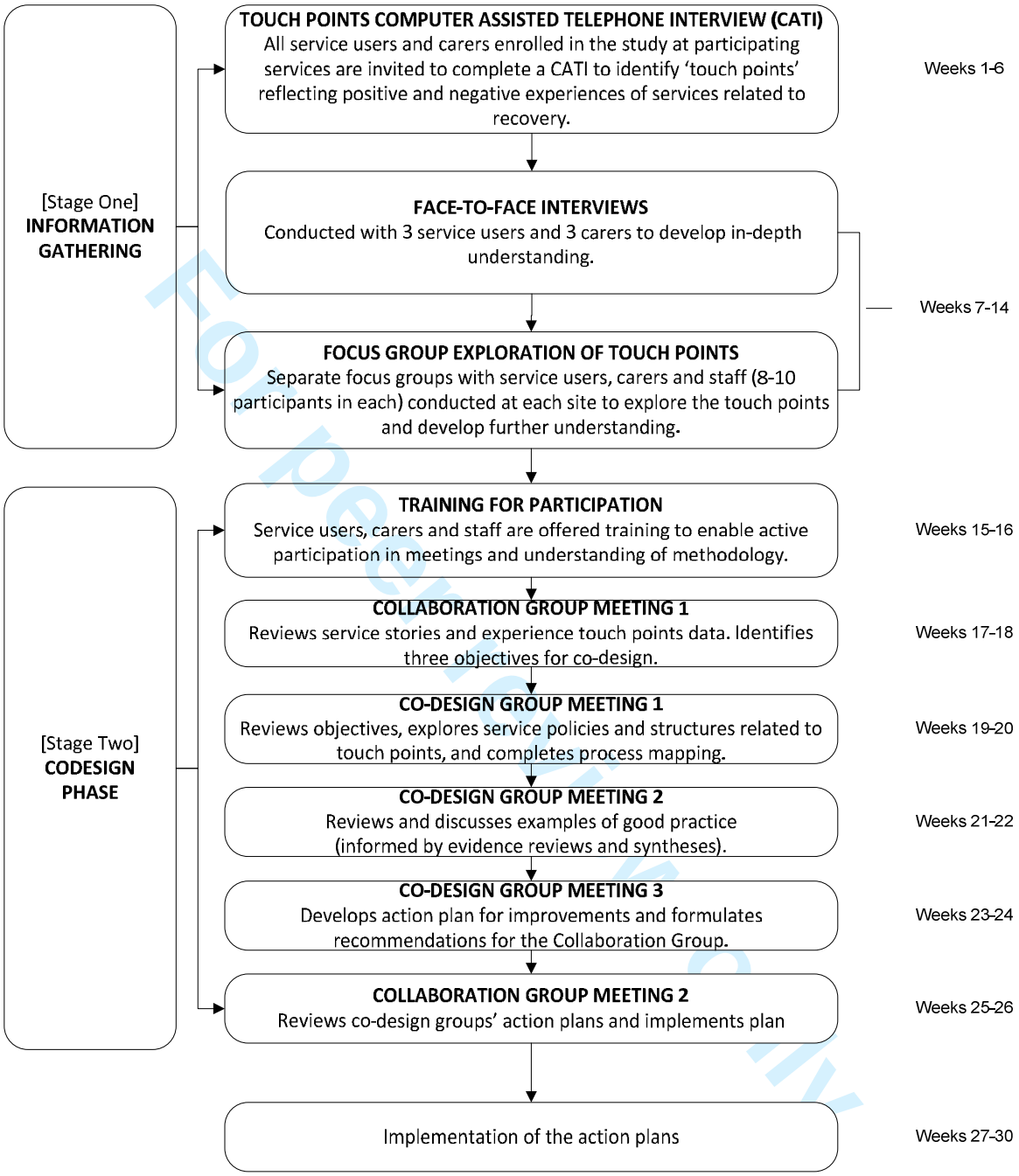


Figure 2 Flowchart of modified MH ECO Intervention for CORE



*THE ADVISORY AND DATA MONITORING COMMITTEE CHARTER*[1]


# The CORE Study: a stepped wedge cluster randomised controlled trial to test a co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness in the community mental health setting

**PROTOCOL NUMBER:** Version 2

**SPONSOR OF PROTOCOL:** The University of Melbourne

**DATE:** 13 February 2015

[1] This Charter has been prepared using Ellenberg et al's 2002 Template for the DMC Charter, the DAMOCLES Study Group (DAta, MOnitoring COmmittees: Lessons, Ethics, Statistics guidance. DAMOCLES 'A Proposed charter for clinical trial data monitoring: helping them to do their job well' Lancet 2005; 365; 711-22 and Chan et al's 'SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials' BMJ Research Methods and Reporting 2013; 346: e7586.

*Introduction*

This Charter is for the Advisory and Data Monitoring Committee (ADMC) for **CORE Protocol Version 2.** CORE is registered with the Australia and New Zealand Clinical Trials Registry (ACTRN 12614000457640) and has received ethics approval from The University of Melbourne Health Sciences Ethics Sub-Committee No: (1340299.3).

CORE is a stepped wedge cluster randomised controlled trial (SWCRCT) to test a co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness. It is a world first trial of a structured Experience Based Co-design (EBCD) method to improve recovery orientation in the community mental health setting and test for individual improvements in recovery outcomes (see Study Protocol for full explanation). The stepped wedge design means that the intervention will be rolled out sequentially to participating mental health community support service teams (11 clusters). Clusters are randomised by time to one of three start dates (waves) to receive the intervention. By the end of the trial all clusters (and participants) will have received the intervention. Figure 1 shows the trial design for the **CORE** study.

*Scope of this Charter*

This Charter details the aim and terms of reference of the ADMC for **CORE**. It describes roles and responsibilities, membership and size, the frequency and format meetings, methods of providing information to and reporting from the ADMC in the context of the **CORE** trial.

*Trial Design*

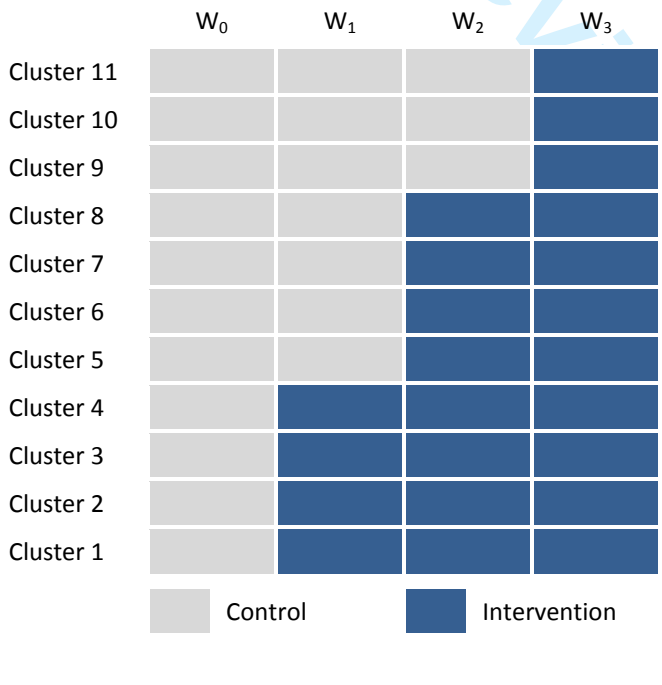



Figure 1 Design of a stepped wedge cluster randomised controlled trial in the community mental health setting.

*Funding and Sponsor*

CORE (2013-2017) is funded by the Victorian State Government's Mental Illness Research Fund (MIRF) and the Psychiatric Illness & Intellectual Disability Donations Trust Fund (PIIDDTF). The University of Melbourne, Australia is the sponsor organisation and the study is coordinated by the Primary Care Research Unit located in the Department of General Practice, Melbourne Medical School, The University of Melbourne.

*Aims and Terms of Reference*

The aim of the **CORE** ADMC is to:

1) advise investigators regarding the implementation, maintenance and monitoring of overall conduct of the trial;

2) safeguard the interests of trial participants, assess the safety of the interventions during the trial and address any adverse events (particularly the reporting of harms for the duration of the trial);

3) provide advice and feedback on qualitative elements and the nested process evaluation for the trial.

*Responsibility of ADMC*

The ADMC is responsible for safeguarding the interests of trial participants by assessing the safety of the intervention and monitoring the overall conduct of the trial. The ADMC will provide advice to enhance trial integrity, recruitment and retention, procedures for data management and quality control, and give feedback on qualitative aspects and the process evaluation. The ADMC is advisory to the investigator and trial implementation group and entails the following functions.

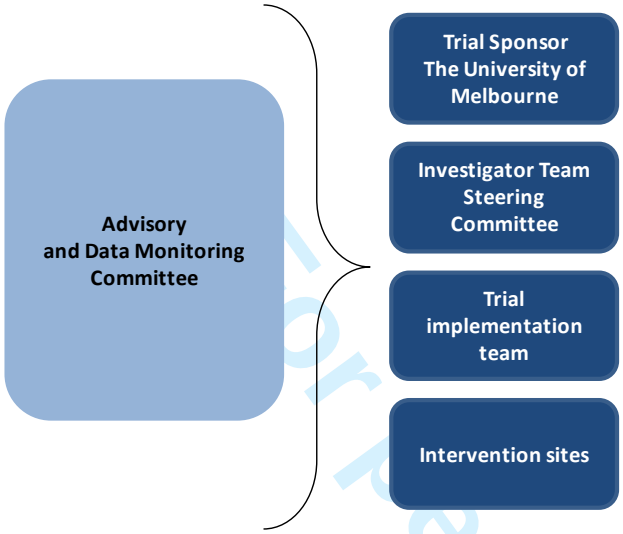
*Roles of the ADMC*

- monitor implementation of trial protocol;
- advise on protocol modifications suggested by investigators (e.g. to inclusion criteria, trial endpoints or sample size);
- advise on recruitment, retention and follow up issues;
- monitor sample size assumptions;
- advise on statistical analysis plan;
- advise on qualitative data collection and analysis plan;
- advise and feedback on the nested process evaluation framework, data collection and analysis;
- consider adverse events and possible harms to study participants[2].

[2] *A note on "stopping rules" in CORE – in clinical trials interim statistical analyses of the primary outcome are conducted to determine the effectiveness of a therapeutic intervention, if harm is determined a stopping rule may apply. CORE does not employ the stopping rule in the same way as a clinical trial because (a) the intervention is not therapeutic and (b) the stepped wedge design does not allow for interim analysis since all clusters will not have received the intervention. It is expected that the ADMC will monitor the trial for any serious adverse events related to the intervention and make recommendations to the team on actions related to these.*

*Governance of CORE*

The following diagram shows the relationship between the ADMC and other functional areas involved in the CORE trial.




*Membership, Composition and Size*

There are nine committee members for the ADMC (member details are provided in Appendix 1 of this Charter). Members represent a multidisciplinary mix of research expertise across the study disciplines: psychosocial recovery, randomized controlled trials and complex interventions, experience based co-design, biostatistics and clinical psychiatry, consumer and carer representation. The ADMC is chaired by the Principal Investigator (Victoria Palmer) to enable a summary of the trial developments in the context of the ADMC report, facilitate discussion and encourage consensus. It may be best for the Chair to provide their opinion last.

*Confidentiality and Conflicts of Interest*

Members of the ADMC have been identified and selected because they do not have financial, scientific or regulatory conflicts. Members should declare any consulting agreements or financial interests they may have with the funder or sponsor organisation or trial sites. ADMC members will declare any competing interests; members agree that if this changes they will notify the Chair. If significant conflicts of interest emerge during the course of the trial the member should consider resignation from the ADMC and the investigator team will reappoint a replacement.

*Relationship with investigator team*

The ADMC functions in an advisory capacity to provide expert input into design and implementation issues and be an independent safeguard for trial participants. Members are independent of the sponsor, funding body and investigators.

*Frequency, location and duration of meetings*

The CORE ADMC will meet bi-annually (circa February and November) for up to two hours on each occasion via teleconference.

*Organisation of the ADMC meetings*

Each meeting will be an open session that other investigators can attend if they wish. No closed sessions for the ADMC are likely to be required as there is unlikely to be any confidential data and results that should not be reviewed by investigators presented to the ADMC, particularly since no interim analysis will occur. Open sessions will be audio recorded and summaries presented back to the Committee and investigator team.

The first meeting of the ADMC for 2014 members will be introduced to the study protocol[3] and discuss the Terms of Reference as stipulated within this Charter. The first session provides an opportunity for ADMC members to give feedback and advice on the study protocol to ensure trial integrity. The second meeting for 2014 will involve discussion and feedback on protocol implementation and recruitment and overall study progress.

Meetings for 2015 and 2016 will focus on updates about recruitment, intervention implementation and maintenance, follow up, retention and attrition. 2017 meetings will examine progress in the context of outcomes. All meetings will consider any qualitative data collection and process evaluation issues that are relevant including the need to report any adverse or harmful events.

*Reports to the ADMC - trial documentation and procedures to ensure confidentiality and proper communication*

At least 2 weeks before each meeting, the trial implementation team will send ADMC members a report for the open meetings with details on the trial progress, including recruitment, baseline characteristics of participants, available pooled data, eligibility violations, withdrawals, completeness of follow up, and compliance.

The trial coordinator is responsible for preparing these reports and open reports will be overseen by Principal Investigator (PI) Palmer. The trial biostatistician will attend open sessions in conjunction with the statistical advisory member.

All reports will include any reporting of adverse events or "harmful events that occurring during a trial" including any relevant data analyses. Table 1 documents the definitions of adverse events and harms as they apply to the CORE intervention and a form for documentation of adverse events is available on request.

[3] DAMOCLES guidance outlines that the committee members should be in agreement with the trial protocol so an early meeting to introduce members and consider the protocol in more detail is important. Following this first meeting, CORE ADMC members have the opportunity to withdraw their membership if they do not agree with trial protocol.

Table 1 Definitions of adverse and harmful events in the CORE trial

| | |
|---|---|
| **Adverse Event**<br><br>Adverse events may be serious (resulting in death, hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions) with the causal link with the intervention difficult to determine. | Serious adverse events as a result of the experience based co-design method intervention are highly unlikely but given the population group there is a small risk that hospitalization may occur and coincide with the intervention. |
| **Harms**<br><br>The total opposite of adverse consequences of an intervention or therapy; they are the direct opposite of benefits, against which they must be compared. | An individual participating in the focus groups or face to face meetings for the co-design phase of the intervention may experience heightened anxiety, reduced functioning and harm may result instead of the anticipated improvements to recovery.<br>An individual who completes an in-depth interview to collect their story about service experience may re-experience negative emotions and experiences and feel distressed as a result of re-telling negative aspects of service experiences. |

Effectiveness and safety data by study group will especially be made available where appropriate. The ADMC will be blinded to the intervention allocation; blinding can be removed at the request of the Committee.

The ADMC members do not have the right to share confidential information with anyone outside the ADMC. The PI/trial implementation team will be responsible for circulating any external evidence from other trials/systematic reviews to the ADMC members that assist in the interpretation of the report or data within the report.

*Decision-making*

The ADMC is independent to the investigator group and functions in an advisory capacity. The ADMC is asked to make decisions about the ethical, practical, statistical and financial implications of reports for the trial and make recommendations to the investigators. ADMC members will provide advice on the actions taken regarding adverse and harmful events and review the procedures followed by the trial implementation team. There should be a minimum number of five attendees at each ADMC for decision-making. An odd number is preferred if a decision must be voted on. If at short notice someone cannot attend, then the meeting should go ahead once the Chair, one clinician representative and the trial statistician are present. Comments on reports circulated prior to committee meetings for those who cannot attend should be passed to the Chair.

*Reporting from ADMC*

The ADMC will make its recommendations verbally to the PI and other investigators at the end of every open meeting. Minutes of the open sessions will be recorded and circulated to the ADMC and investigators.

*After the trial*

ADMC members' names and affiliations will be listed in the protocol and main report and outcomes paper, unless they explicitly request otherwise. A brief summary of the timing and conclusions of ADMC meetings will be included in the body of the outcomes paper. The ADMC will be given the opportunity to read and comment on any publications prior to submission, any feedback provided will be acknowledged within the acknowledgements section of published works. To maintain independence from the trial, ADMC members external to the investigator group will not participate as authors in publications arising directly from the trial data.

Appendix 1

Membership of the ADMC for the CORE Trial

| |
|---|
| **Professor Judith Cook** (Randomised Controlled Trials and Recovery)<br>Director, Center on Mental Health Services Research and Policy<br>Department of Psychiatry<br>University of Illinois at Chicago, USA<br>Email: cook@ripco.com |
| **Hilary Boyd** (Experience Based Co-design)<br>Performance Improvement Specialist \| Concord Team<br>Auckland District Health Board, New Zealand<br>Email: hboyd@adhb.govt.nz |
| **Karen Fairhurst** (Carer / quality and safety representative)<br>Victorian Mental Health Carers Network, Australia<br>Email: karen.fairhurst@carersnetwork.org.au |
| **Professor Sally Wyke** (Complex interventions and Health Services Research)<br>Deputy Director<br>Institute of Health and Wellbeing<br>University of Glasgow, Scotland<br>Email: Sally.Wyke@glasgow.ac.uk |
| **Professor John Carlin** (Biostatistics)<br>Director, Clinical Epidemiology & Biostatistics Unit<br>Murdoch Children's Research Institute<br>Royal Children's Hospital, Australia<br>Professor, Department of Paediatrics, and<br>Centre for Molecular, Environmental<br>Genetic & Analytic (MEGA) Epidemiology<br>School of Population Health<br>University of Melbourne<br>Email: john.carlin@mcri.edu.au |
| **Dr Lynne Maher** (Expertise in Experience Based Co-design)<br>Director for Innovation<br>Ko Awatea, the Centre for Health System Innovation and Improvement for Counties Manukau Health<br>Auckland, New Zealand<br>Email: lynne.maher@middlemore.co.nz |
| **Jane Gray** (Expertise in Experience Based Co-design)<br>Director of Innovation for Hunter New England Health District, Australia<br>Email: jane.gray@hnehealth.nsw.gov.au |
| **Professor Glenn Robert** (Expertise in Experience Based Co-design)<br>Chair in Healthcare Quality and Innovation<br>King's College London, UK<br>E-mail: glenn.robert@kcl.ac.uk |
| **Assistant Professor Robert Whitely** (Expertise in psychosocial recovery)<br>Social Science Researcher<br>Douglas Hospital Research Centre<br>Assistant Professor, Department of Psychiatry<br>McGill University, Canada<br>Email: robert.whitley@mcgill.ca |


SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 4 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | NA |
| Protocol version | 3 | Date and version identifier | NA |
| Funding | 4 | Sources and types of financial, material, and other support | 28 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1,2, 29 |
| | 5b | Name and contact information for the trial sponsor | 29 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 29 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | 26 |

| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 6-8 |
| | 6b | Explanation for choice of comparators | |
| Objectives | 7 | Specific objectives or hypotheses | 9 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 9-11 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 12-13 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 12-13 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 13-15 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | 27 |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 15 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | NA |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 16-17 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 18 |

| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | ____18-19_____ |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | ____21-22___ |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | ____22-23, 36 _ |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | ___22-23_____ |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | ____22-23____ |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | __22-23_____ |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | ___22-23__ |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | __23-25, Supplementary File No. 1__ |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | __22, 23-25_ |

| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | ____25__ |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | ___25-26_____ |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | ___25-26_____ |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | ___26_____ |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 26-27, Supplementary File 2____ |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | 26-27 Supplementary File 2__ |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | _26-27_____ |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | __26_____ |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | _____27_____ |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | _____27_____ |

| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | _12,_23-24___ |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | ___NA_____ |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | ___23-25_____ |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | ____29_____ |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | _27-28_____ |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | ____28_____ |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | _____27_____ |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | _____NA_____ |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | _____NA____ |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Available on request |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | _NA_____ |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

# Correction

Palmer VJ, Chondros P, Piper D, *et al*. The CORE study protocol: a stepped wedge cluster randomised controlled trial to test a co-design technique to optimise psychosocial recovery outcomes for people affected by mental illness in the community mental health setting. *BMJ Open* 2015;5:e006688. One of the authors' names in this paper was misspelt. Konstancja Densely should be Konstancja Densley.


*BMJ Open* 2015;**5**:e006688. doi:10.1136/bmjopen-2014-006688corr1