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Evaluation of a Peer-Led Self-Management Programme (PLSMP) for people with schizophrenia

Submission date
12/09/2013

Recruitment status
No longer recruiting

Registration date
17/09/2013

Overall study status
Completed

Last Edited
18/09/2013

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Self-management programmes have been developed to empower patients with severe mental illness in achieving recovery. Previous research suggested that Peer-Led Self-Management programmes (PLSMP) have been effective in patient recovery. However, the evidence is uncertain. This study aims to find out how well the PLSMP works for people with schizophrenia, in reducing symptom severity, hospital readmission and psychiatric consultation, and in improving mental ability, empowerment, functioning level, medication adherence, recovery, quality of life, and social support. This study also aims to find out about the trainers and participants experience with the PLSMP.

Who can participate?
Clients, aged 21 to 65, coming to the participating centres, who are diagnosed with schizophrenia, in a stable condition and who have not been admitted to hospital due to relapse of schizophrenia symptoms in the past 6 months, can participate in this study.

What does the study involve?
The participants will be randomly assigned to a control group or an intervention group. The control group will receive standard programmes provided by the centre. The intervention group will receive the standard rehabilitation programmes plus a 6-week peer-led self-management programme (PLSMP), which will be provided by peer trainers, who are former patients. The participants will need to meet the researchers for four assessments in the course of the study. Each assessment consists of a same set of self-rating questionnaires on various parameters. The participants will also be invited to an optional individual interview to express their opinion on the programme 12 months after completion. This will take about 30 minutes.

What are the possible benefits and risks of participating?
This study does not provide a direct benefit to the participants. However, the findings obtained from the study may help to improve the management of the condition and treatment in future.

There is no foreseeable possible discomfort and no more than minimum risk to the participants. However, if at any point of time, they dont feel comfortable with the study procedures and assessments, they can stop participating in this study.

Where is the study run from?
This study will be conducted in three community psychiatric rehabilitation centres in Singapore: Simei Care Centre (SCC), Hougang Care Centre (HCC), Community Rehabilitation and Support Services (CRSS); and three psychiatric day centres in Singapore: OcTAVE day centres of Institute of Mental Health.

When is study starting and how long is it expected to run for?
The study will start in October 2013 and is expected to run until September 2016.

Who is funding the study?
This study is funded by the National Medical Research Council, Singapore.

Who is the main contact?
Professor Sally Chan
nurcwcs@nus.edu.sg

Contact information

Type(s)
Scientific

Contact name
Prof Sally Wai Chi Chan

Contact details
Alice Lee Centre for Nursing Studies
Block MD 11
National University of Singapore
10 Medical Drive
Singapore
Singapore
117597

Additional identifiers

Protocol serial number
CIRG12nov043

Study information

Scientific Title
Effectiveness of a Peer-led Self-Management Programme (PLSMP) for people with schizophrenia: a randomized controlled trial

Acronym
PLSMP

Study objectives
Participants who complete the PLSMP will report significantly lower psychotic symptoms, higher scores on cognition level, empowerment, functioning level, medication adherence attitude, perceived recovery, quality of life, perceived social support and fewer number of readmission and psychiatric consultation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institution Review Board (IRB) of National University of Singapore, Singapore; Date: 12 September 2013; Reference number: 11-257

Study design
Stratified randomized controlled two-group pretest and repeated posttest between subjects design

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Psychiatry/schizophrenia/rehabilitation

Interventions
Standard Rehabilitation Programme
Both control and experimental group will receive the standard rehabilitation programme provided at the centres which is conducted by professionals. It consists of psychoeducation, social skills training, employment skill training, life skills training, and academic educational & information technology training.

Intervention Protocol
The experimental group, on top of the standard rehabilitation programme, will receive the PLSMP. The PLSMP was developed with reference from current PLSMP programmes conducting at the in-patient setting in Singapore, the US, literature and previous studies. The four theoretical principles (experiential knowledge, social support, social learning, and empowerment) are the foundation for building the programme. The content of the PLSMP have been reviewed by an expert panel which consisted of two psychiatric nurse educators, one psychiatrist, one psychologist, two social workers and two expert patients. Based on the existing evidence on the length of effective PLSMPs, the PLSMP in the proposed study will have six weekly sessions (two hours each). The group size for the programme is about five to ten participants. The PLSMP is designed to be an interactive educational programme.
Each session will consist of two parts. In the first hour the peer trainers will deliver the self-management knowledge and skills. Training workbook and handouts will be distributed to facilitate learning. In the second hour the peer trainers will share the experiential knowledge in their own successful experiences. The participants will subsequently be encouraged to discuss on their opinions as well as their developed ways of coping. Group therapy ground rules will be laid prior to commencement of each session.

Peer trainers are expert patients who have been selected and recommended by the study centres health care professionals including centre in-charge (a collaborator of the study), clinician, psychologist occupational therapist and social worker. Expert patients are defined as people with schizophrenia who are currently managing their condition and treatment with confidence and in collaboration with psychiatric healthcare professionals. They should also possess effectively communication skills and English language proficiency of secondary school or above. Nine expert patients have been trained by the principal investigator (PI) and two chief investigators (CI) for this study. They have been trained on the use of standard materials for training the participants, presentation skills and group facilitation skills. Training guide was provided to them for learning and reference. They have been assessed by the research team through a simulated group session before they are appointed qualified peer trainer to ensure they have the required knowledge and skills. All trained peer trainers passed the assessment. Each PLSMP session will have one peer trainer presented. One CI is presented at each session as observer to ensure the programme is delivered in standard way as described by the programme manual and to provide feedback to the peer trainers. Besides assessing peer trainers performance at each session, the CI will observe the group interaction, intervene and de-escalate disruptive or stressful situation, and debrief peer trainers after each session.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Compared to the control group, participants who complete the peer-led self-management program will report significantly lower psychotic symptom scores at 12 months follow up. Outcome will be assessed at baseline, immediate after the intervention (posttest 1), six months (posttest 2) and 12 months (posttest3) after the intervention. Individual interviews will be conducted for trainers and participants 12 months after the intervention.

Primary Outcome Measure: Clinician-Rated Scale
Positive And Negative Syndrome Scale (PANSS). It is a 30-item rating scale that is specifically developed to assess individuals with schizophrenia. It is based upon the premises that schizophrenia has two distinct syndromes: positive and negative. The positive syndrome includes those productive features such as delusions and hallucinations, while the negative syndrome includes those features which are lacking/poorly developed in individuals with schizophrenia, such as social withdrawal and flattened or blunted affect. The Inter-class correlation coefficiency is r=0.88-0.98 in the subscales.

Key secondary outcome(s))
Outcome will be assessed at baseline, immediate after the intervention (posttest 1), six months (posttest 2) and 12 months (posttest3) after the intervention. Individual interviews will be conducted for trainers and participants 12 months after the intervention.

Clinician-Rated Scales
1. Specific level of Functioning Scale (SLOF). It will be used to assess social functioning and daily living skills of participants. It is a 43-item behavioural rating scale designed for use in people mentally ill in the community. The internal consistency reliability of the subscales ranged from á=0.68-0.92.
2. Schizophrenia Cognition Rating Scale (SCoRS), which is a 20-item interview-based assessment.

It aims to assess cognitive processes that are commonly affected in schizophrenia patients which include attention, memory, reasoning and problem solving, working memory, language production and motor skills. All items are rated on a 4-point scale. Validation in Singapore found good intra-class correlation coefficient: r=0.984. Ratings from three sources (subject, informant and interviewer) correlated significantly with each other (r = 0.6840.846, df = 143, P < 0.001). The convergent validity of SCoRs was assessed by comparing with the Brief Assessment of Cognition in Schizophrenia (BACS) The SCoRS global rating score was significantly correlated with Brief Assessment of Cognition in Schizophrenia BACS composite score and scores on majority of the BACS sub-tests.
3. Cogstate Schizophrenia Battery will be used to assess participants cognition level through its computerized task based assessment. It was specifically designed to assess people with schizophrenia in the domains of speed of processing, attention/vigilance, working memory, visual learning, verbal learning, reasoning/problem solving and social cognition. It was well validated with Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS) (r=0.83). An introduction brochure for Cogstate Schizophrenia Battery is attached.

SelfRated Questionnaires
1. Modified Empowerment Scale (ES) which contains 28 items of 5-point Likert scales. The higher the score, the better the empowerment level is. It is a consumer-constructed scale to measure personal empowerment among mental health consumers (Cronbachs á=0.86).
2. Modified Recovery Assessment Scale-Revised (RAS-R). This will be used to measure perceived recovery and hopefulness. The RAS-R is a 24-item instrument with 5-point Likert scale designed to measure recovery from mental illness. The items on the scale categorized into five subscales: personal confidence and hope, willingness to ask for help, goal and success orientation, reliance on others and no domination by symptoms . In addition to subscales, a total score can be calculated as a measure of overall recovery. The higher the scores, the better perceived recovery and hopefulness are. Psychometric evaluation have reported Cronbachs á=0.93(64).
3. Modified Multidimensional Scale of Perceived Social Support scale (MSPSS). It consists of 12 5-Likert scales. It measures participants perceived social support with family (Cronbachs á=0.9), friends (Cronbachs á=0.9), and significant others (Cronbachs á=0.91). The higher the scores the better the social support is.
4. Drug Attitude Inventory (DAI). It is a 10-item self-report scale that predicts drug adherence. The DAI contains two subscales: subjective positive and subjective negative. The scale is equally balanced for items to be scored true and false. "Positive" answers will be as follows and score as plus one: "Negative" answers score as minus one. The final score for each person at each time is the positive score minus the negative score. A positive total final score means a positive subjective response (adherent). A negative total score means a negative subjective response (non-adherent). This instrument has been used in the study venue to measure patient drug adherence and demonstrated good validity and a test-retest reliability of r=0.82.
Apart from DAI, the pill count record will be documented. It is a routine procedure carried out by the Centre staff. Information will be retrieved from the residences casenotes.
5. World Health Organization Quality of Life Scale-Brief Version (WHOQoL-BREF, which aims to assess participants quality of life. This is a 28-item transcultural research tools with an aim to allow valid international comparisons of the nature of mental disorders and their management. Though it is not a disease-specific instrument, it has been used in studies of persons with schizophrenia in Singapore and Hong Kong and found it as a valid and reliable tool. This WHOQoL-BREF is structured in four domains: Physical health, psychological, social relationship and environment. Subjects were asked to comment on their satisfactory level of each item during the past month on a 5-point Likert scale (1=very dissatisfied to 5=very satisfied).

Hospital Readmission Rate and Psychiatric Consultation Number
They will be tracked through the centres record on psychiatric treatment. For participants who

will be discharged to their own homes, the researchers will monitor the number of admission to psychiatric hospital and psychiatric consultation numbers through participants and families self-reported history during the study period. The 12-month readmission rates and psychiatric consultation numbers will be compared between control and intervention groups.

Semi-structured Interviews
Semi-structured interviews for peer trainers will explore their perception on the effect of delivery peer-led programme on their own psycho-social wellbeing and development, and how they perceive their effort in helping the peers in their recovery. Semi-structured interview questions are:
1. Please tell me about your experience in conducting PLSMP to peers.
2. Please tell me how you think the delivery of the peer session have an effect on you. Please use examples to illustrate.
3. Please tell me how you think your participation as peer trainer has an effect on your peer participants.

Semi-structured interviews for participant will aim to explore participants perspective on the programme and to seek opinion for improvement. The interviews will be guided by an interview schedule and will be audio-recorded. Examples of the interview questions are:
1. Please tell me your experience in the programme.
2. Please tell me what was most helpful about the programme.
3. Please tell me what was least helpful about the programme.
4. Please tell me what is like working with a consumer provider.
5. Please tell me what has been the biggest change for you.
6. Please tell me what other aspects you would like this programme to improve.

Completion date
30/09/2016

Eligibility

Key inclusion criteria
This study aims to sample the whole population at the six centres (Simei Care Centre (SCC), Hougang Care Centre (HCC), Community Rehabilitation Support & Service (CRSS) and three Occupational Therapy: Activities, Vocation and Empowerment (OcTAVE) day centres) who meets the sample inclusion criteria during one-year recruitment period. This study will include participants who are:
1. Diagnosed with schizophrenia or schizoaffective disorders by a clinical psychiatrist according to DSM-IV or ICD-10
2. In a stable condition, not in acute mental health crisis or psychotic episode, and not been admitted to hospital due to relapse of schizophrenia symptom in the past 6 months, and no change in antipsychotic dosage in the past 6 months
3. Global Assessment of Functioning score more than 50
4. English speaking
5. 21-65 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Potential participants will be excluded if they have:
1. Non-related diagnosis, or having co-morbidity of personality disorders or mental retardation
2. Exposed to other PLSMP previously
3. Incompetent to sign informed consent as assessed by psychiatrist
In the event that participants are readmitted into a psychiatric hospital during the intervention period, their participation in the study will cease. If participants are readmitted to psychiatric hospital during the 12-month follow up period and be discharged before the 12-month follow up assessment, they will need re-assessment by their attending psychiatrist using Global Assessment of Functioning (GAF) to determine their competency in continuing with this study (GAF score of 50 and above). If participants are readmitted at 12-month assessment time, their participation will cease.

Date of first enrolment
01/10/2013

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
Singapore

Study participating centre
Alice Lee Centre for Nursing Studies
Singapore
Singapore
117597

Sponsor information

Organisation
National University of Singapore (Singapore)

ROR
https://ror.org/01tgyzw49

Funder(s)

Funder type
Research council

Funder Name
National Medical Research Council (Singapore) - Clinician-Scientist Individual Investigators Grant (CIRG12nov043)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes