Community mental health nursing

Submission date 15/01/2016	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 07/03/2016	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 07/03/2016	**Condition category** Mental and Behavioural Disorders	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Most people are affected by a mental health problem in some form during their lives. It is estimated that as many as 1% of the world's population suffer from a serious mental disorder, such as schizophrenia. Schizophrenia is a long-term mental health problem that affects how a person thinks, feels and behaves. It involves a wide range of symptoms, including seeing or hearing things that do not exist (hallucinations), having beliefs that do not reflect reality (delusions) and distinct changes in personality or behaviour. These symptoms can be very difficult for patients to deal with, often affecting the way they live their lives and their ability to work. A study in 2007 found that there is a particularly high amount of people suffering from a serious mental disorder like schizophrenia in Jakarta (capital of Indonesia). It was also found that surprisingly few of these people sought treatment in hospital for their condition. Community mental health nursing (CMHN) is a programme set up to try and help people in the community who are at risk of developing a serious mental health problem by working with families to help build up a support network. The aim of this study is to find out whether the CMHN programme is more effective at helping schizophrenia patients to improve their life skills and how well they are able to work.

Who can participate?
Patients between 18 and 55 years old who have been diagnosed with schizophrenia.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group continue to receive standard care for their condition only. Those in the second groups also continue to receive standard care, but are also given weekly cognitive behavioural therapy sessions (a type of talking therapy aiming to change the way a person thinks and behaves) and weekly home visits from community mental health nurses to talk about their symptoms, for 12 weeks. All participants complete questionnaires in order to measure their life skills and work productivity at the start of the study and then again at 12 and 14 weeks.

What are the possible benefits and risks of participating?
Participants who receive the additional therapy may benefit from being able to better cope with their daily lives and being able to work better. There are no risks to participants taking part in the study.

Where is the study run from?
Twenty health centres in Jakarta (Indonesia)

When is the study starting and how long is it expected to run for?
March 2010 to July 2010

Who is funding the study?
Directorate of university research and community service in Indonesia (Indonesia)

Who is the main contact?
Professor Budi Anna Keliat

Contact information

Type(s)
Scientific

Contact name
Prof Budi Anna Keliat

Contact details
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Indonesia
16151

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of the implementation of Community Mental Health Nursing model to improve life skills and work productivity of patients with mental illness

Acronym
CMHN

Study objectives
The implementation of model of community mental health nursing (CMHN) effective in improving life skills and work productivity of patients with mental disorder.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nursing Faculty of Indonesia University ethics committee, 24/02/2010, ref: 174/H2.F12.D/HKP. 02.04/2010

Study design

Community based randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Schizophrenia

Interventions

Participants are randomly allocated to one of two groups.

Intervention group: Participants receive treatment via the community mental health model which includes standard therapy and nursing care for schizophrenia. Participants also receive 12 weeks of hour-long cognitive behavioural therapy appointments and weekly home-visits from a trained community nurse so that they can talk about any symptoms they have been experiencing.

Control group: Participants standard therapy and nursing care for schizophrenia only.

Participants are visited by a trained community nurse at 12 and 14 weeks, when their life skills and work productivity are assessed using questionnaires.

Intervention Type

Mixed

Primary outcome measure

Life skills are measured using The Life skill Profile (LSP) at baseline, 12 and 14 weeks.

Secondary outcome measures

Work productivity is measured using the Indonesian version of Work Productivity and Activity Impairment (WPAI) Questionnaire at baseline, 12 and 14 weeks.

Overall study start date
01/03/2010

Completion date
30/07/2010

Eligibility

Key inclusion criteria
1. Aged between 17 years to 55 years
2. Capacity to provide informed consent
3. Ability to communicate well
4. Diagnosis of schizophrenia

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
195

Key exclusion criteria
Aged below 18 or above 65.

Date of first enrolment
01/03/2010

Date of final enrolment
09/04/2010

Locations

Countries of recruitment
Indonesia

Study participating centre
Puskesmas Cipayung
Jakarta Selatan. Jl. Monumen Pancasila Sakti
Jakarta Timur
Jakarta
Indonesia
13810

Sponsor information

Organisation
DRPM University of Indonesia

Sponsor details
Jl. Prof. Dr. Bahder Djohan, Kampus UI Depok, West Java
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Sponsor type
University/education

Website
http://fik.ui.ac.id/

ROR
https://ror.org/0116zj450

Funder(s)

Funder type
Research organisation

Funder Name
Directorate of university research and community service in Indonesia (Direktorat riset dan pengabdian masyarakat universitas Indonesia)

Results and Publications

Publication and dissemination plan
Planned publication in the Archives of Neuropsychiatry (Noropsikiyatri Arsivi).

Intention to publish date
30/06/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request