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The efficacy of cognitive remediation on processing speed in patients with first episode psychosis

Submission date
10/08/2017

Recruitment status
No longer recruiting

Registration date
17/08/2017

Overall study status
Completed

Last Edited
23/09/2022

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Psychosis is a mental health problem that causes people to perceive or interpret things differently from those around them, and might involve hallucinations or delusions. Schizophrenia is a type of psychosis. Functional and recovery outcomes are poor in patients with schizophrenia in terms of work, their self-care and their relationships. Cognitive remediation therapy (CRT) is a type of rehabilitation treatment that aims to improve abilities such as attention and memory. Most findings on CRT challenge the assumption that simply improving cognitive functioning in schizophrenia will spontaneously lead to better outcomes. The aim of this study is to find out whether targeted CRT (ReMind) is better than conventional CRT at improving functional outcomes in first-episode psychosis patients.

Who can participate?
First-episode psychosis patients aged 18 to 40

What does the study involve?
During the first visit, participants answer a set of questionnaires and attempt a cognitive test. Participants are randomly allocated to targeted CRT (ReMind) or conventional CRT for 15 sessions over 8 weeks. The questionnaires are repeated after the treatment sessions to measure the difference in cognitive functioning. Participation in this study takes about two months with three months follow-up.

What are the possible benefits of participating?
Participants gain knowledge about cognition and schizophrenia, recovery and cognitive skills. There are no known risks and/or discomforts associated with the treatment in this study.

Where is the study run from?
Hospital Putrajaya, Hospital Kajang, Hospital Kuala Lumpur and UKM Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
February 2016 to October 2019

Who is funding the study?
Public Service Department of Malaysia and Universiti Kebangsaan Malaysia

Who is the main contact?
1. Mrs Naniyati Shuib (scientific and public)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The efficacy of cognitive remediation on processing speed in patients with first episode psychosis: a randomized controlled trial

Acronym
ReMind

Study objectives
Current hypothesis as of 09/12/2020:
To evaluate whether the targeted CRT (ReMind) is superior to conventional CRT in improving global cognitive functioning in first-episode psychosis (FEP) patients.

Previous hypothesis:
To evaluate whether the adjunct CRT (A-NEAR) is superior to conventional CRT in improving global cognitive functioning in first episode psychosis (FEP) patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Malaysia ethics board (NMRR) through Medical Research Ethics Committee (MREC), Ministry of Health, Malaysia, 01/06/2016, ref: NMRR-16-598-29797 (IIR)
2. Ethics Committee of Universiti Kebangsaan Malaysia, ref: (UKM)NN-2016-037

Study design
Single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Psychosis

Interventions
This single-blinded randomised controlled trial will address the efficacy of CR therapy using NEAR model by targeting processing speed in first episode psychosis. Participants' cognition, functioning and clinical symptoms will be assessed at baseline and then randomised to treatment arm (adjunct CRT (A-NEAR)) or standard care of conventional CRT as active control for 15 sessions over 8 weeks. All participants will be assessed again at post-randomisation assessment with 3 months follow-up. A sequential mixed methods design will be used, in which the intervention will be executed in sequence followed by in-depth interview before the data could be embedded. There will be a primary outcome of improvement in global cognition and psychosocial functioning as a secondary outcome. All procedures and reporting of primary and secondary outcomes will follow Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines.

The primary purpose of ReMind study will be to execute intervention of CR with the use of quantitative instruments to test the eclectic theories of neuropsychological, learning, educational psychology and rehabilitation psychology that predict the treatment effect between independent variables of A-NEAR treatment that will influence positively the performance of cognitive domains and functional outcomes as dependent variables in patients with first episode psychosis with processing speed as mediator.

Randomisation and allocation concealment
Signed informed consent will be obtained prior to randomisation. The single blinded (masked) assessors will recruit the participants through demographic data and assessments. After a comprehensive baseline assessment, those meeting the eligibility will be randomized.

Thereafter, a randomisation is performed, the potential participants will be informed of the result of the randomisation. The patients and treatment providers will not be blinded. The blinding applies to ReMind training team involved in assessments, data management, data analysis, and drawing outcome conclusions.

Successful randomisation in practice depends on two interrelated aspects which adequate generation of an unpredictable allocation sequence and concealment of that sequence until assignment occurs. The treatment allocation system will be set up so that the person enrolling participants does not know in advance which treatment the next person will get, a process termed allocation concealment. Although there are many approaches to randomization that are known to effectively conceal the randomization sequence, the use of sequentially numbered, opaque sealed envelopes (SNOSE) will be adopted in the study as it is the most accessible and straightforward method of maintaining allocation concealment and does not require the use of specialized technology. Moreover, the method is both cheap and effective in ensuring source of bias can be eliminated by concealing the upcoming allocation sequence from researchers and participants.

For primary and secondary outcomes, the assessments will be conducted at baseline, prior to randomisation, as information from the baseline assessment is used to perform randomisation and validate inclusion and exclusion criteria. The post assessment will also be administered after 8 weeks of intervention.

Intervention Type
Other

Primary outcome measure
Cognitive functioning, assessed by neurocognitive assessment through The Brief Assessment of Cognition in Schizophrenia (BACS) at baseline and 8 weeks

Secondary outcome measures
Functional outcomes, assessed using functional measures including Schizophrenia Cognition Rating Scale (SCoRS), Social Functioning Scale (SFS), Social and Occupational Functioning Assessment Scale (SOFAS) and Schizophrenia Quality of Life Scale Revision 4 (SQLS-R4) at baseline and 8 weeks

Overall study start date
08/02/2016

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. First-episode psychosis patients with schizophrenia, schizophreniform disorder or schizoaffective disorder at diagnosis and presenting with cognitive deficits
2. Young adults aged 18 to 40
3. Able to read and write in Malay and/or English
4. Written informed consent
5. Fulfil the criteria of cognitive measures, symptomatology and other functioning
6. The symptoms must have been present during the past year including other criteria

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
104

Total final enrolment
92

Key exclusion criteria
1. Previous diagnosis of mental retardation, psychotic disorder related to a general medical condition or substance-induced psychotic disorder
2. Severe schizophrenia
3. History of any diagnosis of a serious developmental disorder
4. Significant ongoing neurological disorders including epilepsy
5. History of severe head injury
6. Concurrently undergoing other types of cognitive remediation therapy

Date of first enrolment
01/08/2016

Date of final enrolment
01/06/2018

Locations

Countries of recruitment
Malaysia

Study participating centre
Hospital Putrajaya, Hospital Kajang, Hospital Kuala Lumpur and UKM Medical Centre
Department of Psychiatric and Mental Health
Kuala Lumpur and Selangor
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50300

Sponsor information

Organisation

Public Service Department of Malaysia

Sponsor details
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Sponsor type
Government

Website
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ROR
https://ror.org/04kpqhb39

Funder(s)

Funder type
Government

Funder Name
Jabatan Perkhidmatan Awam Malaysia

Alternative Name(s)
Public Service Department of Malaysia, JPA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Malaysia

Funder Name
Universiti Kebangsaan Malaysia

Results and Publications

Publication and dissemination plan
The data from this study will be made into a report which may be published.

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Naniyati Shuib (nani.shuib@gmail.com). The data will be reported in a collective manner with no reference to an individual. Hence the identity of participants will be kept confidential. Data from the study will be archived and may be transmitted outside the country for the purpose of analysis, publishing or presenting the study results without revealing the identity of participants at any time.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2019	09/12/2020	Yes	No
Results article	results	28/12/2019	09/12/2020	Yes	No
Protocol file	version 1.0	18/04/2016	23/09/2022	No	No