

The effect of mindfulness based intervention in cognitive functions and psychological well-being applied as an early intervention in schizophrenia and high risk mental state

Submission date 07/09/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/09/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/05/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

According to projections of the World Health Organization (WHO), 15% of all disabilities will be associated with mental illnesses by 2020. One of the mental disorders with the largest social impacts due to high personal and family costs is psychosis. Psychosis is the name given to a group of mental conditions in which cause people to perceive or interpret things differently from those around them. One of the most common causes of psychosis is schizophrenia, a condition that causes a range of psychological symptoms, including hallucinations (hearing and /or seeing things) and delusions (believing something that is not true). At present, national and international clinical guidelines recommend a treatment approach that aims to minimize the time a patient goes without treatment for and to continue treatment during all the phases of the illness. One of the most effective psychological treatments for treating schizophrenia and other psychotic disorders at the world level is cognitive behavioural therapy (a type of talking therapy which helps patients cope by changing the way they think and behave). Recently, CBT has introduced several tools and strategies that promote psychological processes based on acceptance and mindfulness (a technique involving being more aware of the present moment). A large number of studies support the effectiveness of mindfulness in dealing with various mental health problems, including psychosis. The aim of this study is to determine the efficiency of a mindfulness-based program in increasing mental abilities and emotional well-being of patients with a first episode of schizophrenia and high risk mental state (those at risk of developing an episode of psychosis).

Who can participate?

Patients aged between 15 and 35 who live in Santiago, Chile and have been diagnosed with schizophrenia (first episode) and a high-risk mental state.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive standard treatment, which may involve a combination of medication and therapy. Those in the

second group take part in the mindfulness-based therapy in addition to their usual treatment. This involves taking part in eight mindfulness workshops adapted for people with psychosis, which last for around 1.5 hours, and take place once a week for eight weeks. Before the program begins and then one week and three months after it ends, participants in both groups complete a number of questionnaires to measure their mental abilities and emotional wellbeing. Participants who receive the mindfulness training are also interviewed about their experiences of the program four weeks after the program ends.

What are the possible benefits and risks of participating?

Participants may benefit from gaining skills for coping with distressing experiences and improved emotional wellbeing. There are no notable risks associated with participating in this study.

Where is the study run from?

1. Psychiatric clinic of the University of Chile (Chile)
2. Psychiatry Service of Hospital el Pino, South Metropolitan Health Service (Chile)
3. REDGESAM; Mental Health clinical network (Chile)

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

November 2015 to July 2018

Who is funding the study?

National Fund for Scientific and Technological Development (Chile)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

11150846

Study information

Scientific Title

The effect of mindfulness based intervention in cognitive functions and psychological well-being applied as an early intervention in schizophrenia and high risk mental state: a randomized controlled trial protocol in a Chilean sample

Study objectives

Hypotheses:

1. Mindfulness-based interventions will increase executive function, specifically a statistically significant increase is expected in attention, working memory and social cognition rates compared to the control group
2. Subjective psychological well-being rates will increase significantly in the mindfulness group compared to the control group
3. The outcomes in the areas described will persist three months after; however, impacts will be greater on people who continue practicing mindfulness compared to those who do not continue with the practice

Research questions:

1. What are the benefits and shortcomings found during the workshop?
2. Do patients continue with this practice and mainstream the outcomes into other areas of their lives?
3. What differences and similarities are perceived by patients between mindfulness and traditional psychosocial interventions?

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Ethics Committee scientist social sciences, arts and humanities at the Pontifical Catholic University of Chile, 23/12/2015
2. Ethics Committee research scientist at the Clinical Hospital of the University of Chile, 29/06/2016. ref: 032

Study design

Multi-centre randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Schizophrenia and high risk mental state

Interventions

Participants will be randomly allocated (a simple randomized sampling will be used) to the trial or control group by independent researchers using a stratified block randomization procedure with a computer-generated allocation sequence. Health experts who will implement the MBIs will be blind to this procedure and they will not carry out the assessment.

Control group: Participants will receive standard care for this illness (TAU), in other words, pharmacology and psychosocial intervention under clinical guidelines (e.g. social skills workshop).

Intervention group: Participants will be provided with the mindfulness-based intervention (MBI), plus treatment as usual, divided into 24 patients diagnosed with a first episode of schizophrenia and 24 patients in a high-risk mental state (groups do not include both profiles). This means that both groups will be submitted to 8 sessions of mindfulness workshops adapted for patients with psychosis. The proposed duration for each session is one hour and a half. The frequency is once a week. The intervention will take place at each participating clinical centre and it will be led by a mindfulness instructor specifically trained for this target audience.

Follow up for all participants involves assessment, application of neuropsychological tests and self-reporting questionnaires one week and three months after completing the workshop. Additionally, four weeks after completing the workshop participants will be submitted to semi structured interviews at each participating clinical centre.

Intervention Type

Behavioural

Primary outcome(s)

Cognitive function is assessed using the Measurement and Treatment Research to Improve Cognition in Schizophrenia (MATRICS) at baseline, 1 week and 3 months post-intervention

Key secondary outcome(s)

1. Psychological well-being is measured through the Ryff's Psychological Well-Being Scales (PWB) at baseline, 1 week and 3 months post-intervention
2. Self-esteem is measured through the Rosenberg Self-esteem Scale at baseline, 1 week and 3 months
3. Mindfulness is measured through the Five Facet Mindfulness Questionnaire (FFMQ) at baseline, 1 week and 3 months post-intervention
4. Affect is measured through the Positive and Negative Affect Schedule (PANAS) at baseline, 1 week and 3 months post-intervention
5. Worry is measured through the Penn State Worry Questionnaire (PSWQ-11) at baseline, 1 week and 3 months post-intervention
6. General symptomatology is measured through the Depression, Anxiety and Stress Scale (DASS-21) at baseline, 1 week and 3 months post-intervention
7. Subjective experience is measured through a semi structured interview at four weeks after completing the intervention

Completion date

30/07/2018

Eligibility

Key inclusion criteria

1. Patients diagnosed with a first episode of schizophrenia or in high-risk of psychosis, as applicable
2. Aged between 15 and 35 years
3. Clinical stability defined by medical and psychometric criteria (e.g. PAANS)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

1. Risk of suicide
2. Severe intellectual disability (mental retardation)
3. Medical illness inconsistent with the intervention
4. Substance abuse or dependence in the past six months

Date of first enrolment

01/10/2016

Date of final enrolment

30/12/2017

Locations**Countries of recruitment**

Chile

Study participating centre

Psychiatric clinic, University of Chile (Clínica Psiquiátrica Universidad de Chile)

La Paz 1009

Recoleta

Región Metropolitana

Santiago

Chile

8431617

Study participating centre

Hospital el Pino

Psychiatry Service, South Metropolitan Health Service

Avenida Padre Hurtado 13560
San Bernardo
Metropolitan Region
Santiago
Chile
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Study participating centre

REDGESAM S.A.

Av. Nueva Providencia 2155
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Sponsor information

Organisation

Universidad Austral de Chile

ROR

<https://ror.org/029ycp228>

Funder(s)

Funder type

Government

Funder Name

National Fund for Scientific and Technological Development (Fondo Nacional de Desarrollo Científico y Tecnológico)

Alternative Name(s)

National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Chile

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/05/2017		Yes	No