ISRCTN24327446 https://doi.org/10.1186/ISRCTN24327446

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

Registration date
12/09/2016

Overall study status
Completed

Last Edited
30/05/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Dr Álvaro I. Langer
alvaro.langer@uach.cl

Contact information

Type(s)
Scientific

Contact name
Dr Alvaro Langer

ORCID ID
http://orcid.org/0000-0003-2983-5274

Contact details
Escuela de Psicología
Campus Isla Teja s/n
Valdivia
Chile
5090000
+569 632276800
alvaro.langer@uach.cl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 similiarities 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

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
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 measure
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

Secondary outcome measures
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

Overall study start date
30/11/2015

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

Age group
Mixed

Sex
Both

Target number of participants
The sample consists of 96 participants, 48 correspond to diagnosed patients with a first episode of schizophrenia (24 in experimental group and 24 in a control group) and 48 patients vulnerable to psychosis that meet the criteria for a high risk mental state specified as Syndrome Symptoms Psychotic attenuated (24 experimental and 24 control).

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
-

Study participating centre
REDGESAM S.A.
Av. Nueva Providencia 2155
Torre A
Office 1003 and 1403
Providencia
Santiago
Chile
7510161

Sponsor information

Organisation
Universidad Austral de Chile

Sponsor details
Independencia 631
Valdivia
Chile

5110566
+56 63 2221500
psicologia@uach.cl

Sponsor type
University/education

Website
https://www.uach.cl/

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

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