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Mindfulness training for cognitive impairment in people experiencing psychosis

Submission date
10/10/2017

Recruitment status
No longer recruiting

Registration date
16/10/2017

Overall study status
Completed

Last Edited
21/11/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Schizophrenia spectrum disorders are chronic and severe mental disorders that affects how a person thinks, feels, and behaves. Research has shown that cognitive limitations in schizophrenia spectrum disorders limit the effectiveness of the treatments delivered to patients. Therefore several therapies have been developed to deal with cognitive impairment. Recent years have witnessed how mindfulness has been receiving a lot of interest from the scientific community. Mindfulness through meditation helps people to learn to observe sensations, and one's reactions to them, with clear, gentle and non-judgemental awareness, and in so doing to let go of self-defeating habitual reactions to difficult experience. Studies in healthy people have shown that mindfulness increases well-being and quality of life in disorders and medical conditions where symptoms persist in spite of usual treatment. The effects of mindfulness-based interventions over cognitive functions in general population have been examined with broadly positive findings. Studies have shown that mindfulness is safe and beneficial for people with distressing psychosis. The premise behind mindfulness interventions for any disorder is that even when symptoms persist, people can learn to respond to them differently and thus be less distressed and disabled by them. Therefore, when mindfulness is adapted to psychosis the primary outcome is well-being instead symptoms (although it has been reported that mindfulness reduces negative symptoms of schizophrenia). Even though the increasing number of studies reporting mindfulness benefits over quality of life of people diagnosed with schizophrenia, no study has looked at the effect of mindfulness over cognitive impairment. This is an important issue for practitioners due cognitive impairment usually implies a ceiling effect over the outcomes of rehabilitation treatment. The aim of this study is to explore the potential benefits of adding mindfulness to standard rehabilitation treatment delivered in a rehabilitation community centre.

Who can participate?
Adults aged 18 to 65 who are diagnosed with schizophrenia.

What does the study involve?
Participants enrolled in the study received the standard rehabilitation care recommended by clinical guide treatments: drug prescription (controlled by regular psychiatrist from the local hospital service) and rehabilitation treatment (psychological cognitive therapy and strategies for

preventing relapse) delivered by routine clinical staff from the rehabilitation centre. Participants allocated to rehabilitation treatment enhanced with mindfulness received the same treatment than the other group, but they also received a week session of mindfulness. Participants were required to go to a venue lent by the city council each time a week for the 26 week program.

What are the possible benefits and risks of participating?
It is likely that participants allocated to mindfulness could increase their well-being and psychological quality of life. As pointed by recent studies, there is no risk derived from participate of mindfulness training when it is carried over following the recommendations to adapt it to psychotic patients. So we do not expect side effects above the standard rate communicated by clinical guides for both treatment arms.

Where is the study run from?
UCR "Son Serralta" Community Rehabilitation Centre (Spain)

When is the study starting and how long is it expected to run for?
February 2013 to January 2016

Who is funding the study?
1. Board of Innovation, Research and Tourism of the Balearic Islands (UK)
2. Spanish Ministry of Economy and Competitiveness (UK)
3. European Social Fund (UK)

Who is the main contact?
Professor Enric Munar
Mr Emilio Lopz-Navarro

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1806/2015

Study information

Scientific Title
Integrated Rehabilitation Treatment enhanced with mindfulness compared with Integrated Rehabilitation Treatment in people with schizophrenia spectrum disorders: Effects over executive functions and theory of mind skills

Study objectives
Integrated Rehabilitation Treatment (IRT) enhanced with mindfulness is better than IRT alone enhancing executive functions and theory of mind skills.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics Committee of the University of Balearic Islands, 17/07/2013, ref: Registry number: 6163

Study design
Interventional pilot single-centre 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 the contact details below to request a patient information sheet: Dr. Enric Munar enric.munar@uib.cat

Health condition(s) or problem(s) studied
Schizophrenia disorder and schizophrenia-related disorders following DSM-IV criteria

Interventions
Participants contacted by their regular psychiatrist to perform an interview to be informed about mindfulness and what participation in the trial would involve as well to assess eligibility. At the end of the interview each patient, or his legal guardian, are invited to participate and sign informed consent. After sign informed consent, randomisation identification is assigned to each patient and recorded in the clinical record form. Participants are randomly allocated by software to Integrated Rehabilitation Treatment (IRT) or IRT plus mindfulness group, with a group size for mindfulness of 10-12. Cohorts are randomised once numbers are sufficient to begin a mindfulness group.

Participants are randomly allocated to one of two groups:

Active Control: Participants receive Integrated Rehabilitation Treatment (IRT) consisting in pharmacothreapy combined with 26 one hour weekly sessions of cognitive behaviour therapy techniques for symptom management as well strategies for preventing relapse and conflict management. Drug prescription is delivered by local hospital psychiatric service, so research staff was not involved on it. Cognitive behaviour therapy techniques and strategies for preventing rellapse and conflict management were delivered by routine staff members from the community centre where the study took place. IRT contains no mindfulness training.

IRT enhanced with mindfulness-based therapy: Participants run throughout the 26 week rehabilitation treatment program, and in addition one mindfulness session each week. Mindfulness sessions last for 60 minutes and are run in group format.

Participants are followed up during clinical trial was carried by participants' regular psychiatrist from the local hospital service. Regular psychiatrists were informed by a research team member about patient enrolment in the study.

No follow up assessment was planned after end of the trial.

Intervention Type
Behavioural

Primary outcome measure
1. Executive Functions are measured using the Trail Making Test, Stroop Test, Digits from WAIS-III, and the Controlled Oral Word Association Test at baseline and 26 weeks.
2. Theory of Mind is measured using the Hinting Test and the Reading the Mind in the Eyes Test at baseline and 26 weeks
3. General mindfulness awareness in daily life as a consequence of treatment are assessed by Mindfulness Attention Awareness Scale (MAAS) at baseline and 26 weeks

Secondary outcome measures
1. Symptoms are measured using videotapped Positive and Negative Syndrome Scale at baseline and 26 weeks
2. Demographic information is measured using clinical record form at baseline

Overall study start date
01/02/2013

Completion date
31/01/2016

Eligibility

Key inclusion criteria
1. Age between 18-65
2. Diagnosis of schizophrenia or schizoaffective disorder
3. No changes in psychiatric medication or hospitalization in last month
4. Have signed informed consent
5. Be able to understand and read Spanish language
6. Any gender

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Total final enrolment
56

Key exclusion criteria
1. Significant cognitive impairment
2. Inability to attend mindfulness sessions
3. Posed a risk of violence to the researchers
4. Refused to participate or to sign informed consent

Date of first enrolment
01/08/2013

Date of final enrolment
31/01/2015

Locations

Countries of recruitment
Spain

Study participating centre
UCR "Son Serralta" Community Rehabilitation Centre
C/ de Femenies, 33
Palma de Mallorca
Spain
07013

Sponsor information

Organisation
University of Balearic Islands

Sponsor details
Ctra. de Valldemossa, km 7,5.
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Sponsor type
University/education

Website
http://osr.uib.cat/

ROR
https://ror.org/03e10x626

Funder(s)

Funder type
Government

Funder Name

Board of Innovation, Research and Tourism of the Balearic Islands

Funder Name
Spanish Ministry of Economy and Competitiveness

Funder Name
European Social Fund

Alternative Name(s)
Европейският социален фонд, Evropský sociální fond, Den Europæiske Socialfond, Europäischer Sozialfonds, Euroopa Sotsiaalfond, Ευρωπαϊκό Κοινωνικό Ταμείο, Fondo Social Europeo, Fonds social européen, Europski socijalni fond, Fondo sociale europeO, Eiropas Sociālais fonds, Europos socialinis fondas, Európai Szociális Alap, Fond Soċjali Ewropew, Europees Sociaal FondS, Europejski Fundusz Społeczny, Fundo Social Europeu, Fondul Social European, Európsky sociálny fond, Evropski socialni sklad, Euroopan sosiaalirahasto, Europeiska socialfonden, European Social Fund, Fondo Social Europeo Plus, Европейски социален фонд плюс, Evropský sociální fond plus, Europæiske Socialfond Plus, Europäische Sozialfonds+, Euroopa Sotsiaalfond+, Ευρωπαϊκό Κοινωνικό Ταμείο+, Fonds social européen+, Europski socijalni fond plus, Fondo sociale europeo Plus, Eiropas Sociālais fonds Plus, Europos socialinis fondas +, Európai Szociális Alap Plusz, Europees Sociaal Fonds Plus, Europejski Fundusz Społeczny Plus, Fundo Social Europeu Mais, Fondul social european Plus, Európsky sociálny fond +, Evropski socialni sklad +, Euroopan sosiaalirahasto plus, Europeiska socialfonden+, ESF, ЕСФ, EKT, FSE, ESZA, EFS, ESS, ESR, ESF+, ESZA+, EFS+, FSE+, ESS+, ESR+

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Data will be published in a scientific peer-reviewed journal from the category of Clinical Psychology or Psychiatry.

Intention to publish date
01/03/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to Spanish Organic Law 15/1999 on Personal Data Protection (Articles 8 and 11), data about health-related outcomes cannot be distributed to third-parties without specific consent of the participant or court decision. Data will be held in an external encrypted hard disk.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Daily life coping	23/02/2022	21/11/2023	Yes	No
Results article	Inhibitory control	15/09/2020	21/11/2023	Yes	No