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WELLFOCUS study: to investigate an intervention to improve well-being in people with psychosis

Submission date
12/11/2012

Recruitment status
No longer recruiting

Registration date
14/12/2012

Overall study status
Completed

Last Edited
04/10/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Well-being is important for everyone, including people with severe mental illness. Well-being can help to improve functioning, resilience, and life satisfaction and may protect against mental illness.
Positive Psychotherapy (PPT) was developed in the field of positive psychology. It aims to increase well-being by building positive emotions, character strengths, and meaning. So far, PPT has been shown to decrease symptoms and increase well-being in people with depression and other common mental disorders. There are no established interventions to increase well-being in people with severe mental illness, but PPT is a promising approach. In a previous project we adapted PPT to be suitable as a group therapy for people with psychosis. We have done so with the input of service users, professional carers, and experts in the field. In this study we will show how the adapted intervention can be best delivered to people with psychosis.

Who can participate?
Adults with an experience of psychosis from a London NHS Trust.

What does the study involve?
Participants will receive the WELLFOCUS programme, in group therapy format in addition to their usual care, or continue to receive their usual care as before. Participants will be assessed with a range of questionnaires before and after the study period and they will be asked to participate in personal interviews and focus groups.

What are the possible benefits and risks of participating?
Participants may experience increased personal well-being and there are no known risks for participants.

Where is the study run from?
Institute of Psychiatry at Kings College London, UK

When is study starting and how long is it expected to run for?
Recruitment will start in early 2013 the study is expected to run until 2015.

Who is funding the study?
Guys & St Thomas Charity, UK

Who is the main contact?
Dr Beate Schrank
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Study website
http://www.researchintorecovery.com

Contact information

Type(s)
Scientific

Contact name
Prof Mike Slade

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G101016

Study information

Scientific Title
Pilot randomised controlled trial of a modified intervention to improve well-being in people with psychosis

Acronym

WELLFOCUS

Study objectives
No specific hypothesis is tested as this is a pilot randomised controlled study. This means that it will establish if the intervention works as it is expected to and if it can be delivered as planned in a research setting. The results will help to further adapt the intervention and the research process and help to plan a big study to investigate the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please contact beate.schrank@kcl.ac.uk to request a patient information sheet

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

Interventions
Participants will be randomised into either of the following groups:
1. The WELLFOCUS intervention: adapted PPT for people with psychosis in a group format, once a week over 12 weeks, in addition to treatment as usual.
2. Treatment as usual

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Personal well-being assessed using the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)

Secondary outcome measures
1. Quality of life as assessed by the Manchester Short Assessment of Quality of Life (MANSA)
2. Happiness as assessed by the Short Depression-Happiness Scale (SDHS)
3. Hope as assessed by the Integrative Hope Scale (IHS)
4. Savouring as assessed by the Savouring Beliefs Inventory (SBI)
5. Symptoms and functioning as assessed by Brief Psychiatric Rating Scale (BPRS)
6. The Health of the Nation Outcome Scale (HoNOS)
7. The Global Assessment of Functioning (GAF)

Overall study start date
01/01/2013

Completion date
01/01/2015

Eligibility

Key inclusion criteria
Adults with a primary diagnosis of psychosis who are not currently receiving in-patient care or are in prison, speak and understand English and are sufficiently well to participate

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Serious cognitive impairment
2. Unable to give informed consent

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Kings College London
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
Kings College London (UK)

Sponsor details
Institute of Psychiatry
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Sponsor type
University/education

Website
http://www.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity ref: G101016

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type

Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/06/2014		Yes	No
Results article	results	01/01/2015		Yes	No
Results article	results	01/06/2016		Yes	No