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

Submission date 12/11/2012	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
		[X] Protocol		
Registration date 14/12/2012	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 04/10/2018	Condition category  Mental and Behavioural Disorders	[] Individual participant data		
04/10//018	Mental and Benavioural Disorders			

# 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 beate.schrank@kcl.ac.uk

#### Study website

http://www.researchintorecovery.com

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Mike Slade

#### Contact details

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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 Denmark Hill London England United Kingdom SE5 8AF

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jennifer.liebscher@kcl.ac.uk

#### 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