

Protect after depression: a randomised pilot trial of a new wellbeing course

Submission date 02/08/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/08/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/10/2017	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

Depression is a state of low mood and aversion to activity that can affect a person's thoughts, behavior, feelings and sense of well-being. The period after recovery from depression is thought to be an important time, as the risk that a person will relapse reduces during this time. The aim of this study is to test a new wellbeing course and see whether it is useful, and whether it should be offered to more people.

Who can participate?

Adults who have received treatment in Improving Access to Psychological Therapies (IAPT) services and have recovered from an episode of depression or low mood.

What does the study involve?

Participants are asked some questions about how they have been feeling in 3 months and again in 6 months from the end of their IAPT treatment. Half of the participants are randomly allocated to be offered a brief wellbeing course consisting of an introduction telephone call, a 2-hour group workshop, and a follow-up phone call. Participants also receive a booklet with tips and there are tasks to think about between sessions. To see whether the course is useful, the experience of the participants who try the course are compared to those who don't.

What are the possible benefits and risks of participating?

Participating will take up time for the follow-up phone calls, and potentially for the wellbeing course. We will do all we can to make sure the follow-ups are at a time convenient to participants. In previous studies we have found that participants often appreciate the opportunity to reflect on how they are doing during follow-up phone calls. Participants will also receive vouchers as a thank you for these calls. The aim of this study is to better understand and better assist people who have recovered from depression. Participants may contribute to helping someone who recovers from depression in the future. We don't think this study will put participants at a significant risk.

Where is the study run from?

University College London (UCL), in partnership with clinicians in Camden and Islington Improving Access to Psychological Therapies (IAPT) services.

When is the study starting and how long is it expected to run for?
February 2015 to June 2017

Who is funding the study?
British Psychological Society (UK)

Who is the main contact?
Katherine Clarke

Contact information

Type(s)
Public

Contact name
Ms Katherine Clarke

Contact details
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WC1E 7HB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15/0804

Study information

Scientific Title
Protect after depression: a randomised pilot trial of a novel low-intensity intervention

Study objectives
1. Could the 'PRotect' intervention help people to remain well after recovery from depression in an IAPT service?
2. How do service users and clinicians experience the 'PRotect' intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)

Study design

Single-centre pilot randomised controlled trial (individually randomised with 1:1 allocation and independent assignment, single-blind)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Wellbeing after recovery from depression

Interventions

A low-intensity (brief guided self-help style) intervention combining several well-being techniques. The wellbeing course consists of an introduction telephone call, a 2-hour group workshop, and a follow-up phone call. Participants will also receive a booklet with tips and there will be tasks to think about between sessions.

The control group will have no intervention.

Intervention Type

Behavioural

Primary outcome measure

The presence or absence of relapses of depression up to 6 months after randomisation as measured using the depression section of the LIFE (Keller et al., 1987)

Secondary outcome measures

1. Scores on IAPT minimum dataset measures 3 and 6 months after randomisation
2. Self-reported use of wellbeing activities in everyday life

Overall study start date

05/02/2015

Completion date

04/06/2017

Eligibility

Key inclusion criteria

1. IAPT service users who have experienced depression
2. Have received treatment and currently score below threshold for depression symptoms (they are well)
3. Are willing and able to provide informed consent
4. Are willing and able to participate in the intervention, including ability to speak English

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

130

Key exclusion criteria

1. Has current suicidal thoughts
2. Is currently taking part in another piece of research within IAPT services

Date of first enrolment

04/08/2016

Date of final enrolment

04/12/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

iCope - Camden and Islington Psychological Therapies Services

Camden and Islington NHS Foundation Trust

211 King's Cross Road

London

United Kingdom

WC1X 9DN

Sponsor information

Organisation

University College London (UK)

Sponsor details

Joint Research Office (part of the Research Support Centre)

Gower Street

London

England

United Kingdom

WC1E 6BT

Sponsor type

University/education

Website

<http://www.ucl.ac.uk/jro/>

ROR

<https://ror.org/02jx3x895>

Funder(s)

Funder type

Other

Funder Name

British Psychological Society

Alternative Name(s)

BPS

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

04/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No