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

Submission date
02/08/2016

Recruitment status
No longer recruiting

Registration date
02/08/2016

Overall study status
Completed

Last Edited
18/10/2017

Condition category
Mental and Behavioural Disorders

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

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WC1E 7HB

Additional identifiers

Protocol serial number
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)
Camden and King's Cross NHS Ethics Committee, 14/06/2016, ref: 16/LO/0652

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

Primary study design
Interventional

Study type(s)
Prevention

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(s)
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)

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex

All

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
United Kingdom

England

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)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Other

Funder Name
British Psychological Society

Alternative Name(s)
The British Psychological Society, BPS

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

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