ISRCTN74390532 https://doi.org/10.1186/ISRCTN74390532

Integrating Behavioural Activation and Physical Activity promotion (BAcPAc)

Submission date
26/03/2013

Recruitment status
No longer recruiting

Registration date
26/03/2013

Overall study status
Completed

Last Edited
21/08/2015

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
By 2020 depression is expected to represent the second highest burden of disease among all general health problems. Psychological Well-being Practitioners (PWPs) are a new workforce created as part of the IAPT (Improving Access to Psychological Therapies) programme implemented across England. PWPs undertake a range of evidence-based low-intensity psychological interventions including Behavioural Activation (BA), which seeks to reduce depressed mood by increasing daily functioning. BA has been established as an evidence-based treatment for depression. Physical Activity is also recommended by NICE for people with depression. As patients with depression often also have chronic disease and physical health problems, there have already been proposals to extend the role of the PWP beyond the treatment of mental health to include an increased focus upon the promotion of positive health behaviours including physical activity. However, such efforts have thus far been stifled by the lack of appropriate interventions through which to do this, alongside lack of training in the skills to promote Physical Activity. The aim of this study is to design and evaluate an enhanced version of evidence-based behavioural activation (BA) treatment for people with depression by adding a focus on physical activity (PA) in a novel intervention (BAcPAc). The PWPs supporting this arm will receive additional training in supporting the BAcPAc intervention informed by the developmental work already undertaken by members of the research team.

Who can participate?
80 people with depression, aged 18 to 90 years, and referred to one of two IAPT services in South West England, will be recruited into the study.

What does the study involve?
Participants will be randomly allocated to receive either BAcPAc or normal care (for 4 months or 12 weekly sessions) within a written self-help format that represents treatment-as-usual. Measures of PA, depression and wellbeing will be collected at the start of the study and after 4 and 12 months. Participants in this study who are allocated to receive normal care will receive BA through IAPT services as normal.

What are the possible benefits and risks of participating?
BA has been shown to be an effective treatment for depression. Participants receiving the

enhanced version of BA (BAcPAc) may potentially increase their physical activity levels. Regular physical activity is recommended by NICE for people with depression and can produce a rapid sense of wellbeing, and longer-term benefits of reduced depression. Regular physical activity also has numerous physical benefits and is recommended for the general health of the population. Potential risks for participants increasing physical activity are very low as the focus of all recommendations for increasing physical activity will be on moderate intensity activity, and increasing the frequency and duration of activity that the participant is already doing. The PWP will receive training to ensure the activity the participant will be undertaking is within their existing capability.

Where is the study run from?
The research team are based at the University of Exeter, with collaboration from University of Exeter Medical School and Peninsular Clinical Trials Unit.

When is the study starting and how long is it expected to run for?
Recruitment started in April 2013 and is due to end in April 2014.

Who is funding the study?
BAcPAc is funded by the NPRI-4 (Medical Research Council and partners).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13288

Study information

Scientific Title
Integrating Behavioural Activation and Physical Activity promotion (BAcPAc): A pilot randomised controlled trial with depressed patients

Acronym
BAcPAc

Study objectives
Depression is a serious public health issue, and by 2020 depression is expected to represent the second highest burden of disease among all general health problems, and combined with anxiety is estimated to cost the UK economy £17bn in lost output and direct health care costs annually. The potential costs of depression may be far higher with the financial burden associated with sustained inactivity, a key symptom associated with depression, alongside an increased risk of obesity, diabetes, and stroke. Psychological Well-being Practitioners (PWPs) are a new workforce created as part of the IAPT (Improving Access to Psychological Therapies) programme implemented across England. PWPS undertake a range of evidence based psychological interventions including Behavioural Activation (BA), which seeks to reduce depressed mood by increasing daily functioning. Physical Activity is also an evidence based therapy for depression in its own right and is recommended by NICE for people with depression. Given the high rates of comorbidity between patients with depression, chronic disease and physical health decrements there have already been proposals to extend the role of the PWP beyond the treatment of mental health to include an increased focus upon the promotion of positive health behaviours including physical activity. However, such efforts have thus far been stifled by the lack of appropriate interventions through which to do this, alongside lack of training in the skills to promote Physical Activity.

The aim therefore is to enhance a routine, evidence-based behavioural activation (BA) treatment for people with depression by adding a focus on physical activity (PA) in a novel intervention (BAcPAc). The PWPs supporting this arm will receive additional training in supporting the BAcPAc intervention informed by the developmental work already undertaken by members of the research team in phase I.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13288

On 04/03/2014 the overall trial end date was changed from 30/09/2013 to 30/04/2014.

On 03/07/2014 the overall trial end date was changed from 30/04/2014 to 05/07/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Frenchay in Bristol, initially approved 26/11/2012, amendment approved 26/03/2013, ref: 12 /SW/0291

Study design
Pilot randomised controlled trial, Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Depression; Disease: Depression

Interventions
40 patients will be randomly allocated to Behavior Activation (normal care) and 40 will be randomly allocated to Behaviour Activation plus Physical Activity (BAcPAc).

BAcPAc, Adapted Behavioural Activation delivered by Psychological Wellbeing Practitioners with an new emphasis on increasing or adding sustainable physical activity into scheduled routine, necessary or pleasurable activities.

Follow Up Length: 12 month(s)

Intervention Type
Behavioural

Primary outcome measure
Depression PHQ9; Timepoint(s): baseline, 4 months, 9 months, 12 months

Secondary outcome measures
1. Blood pressure; Timepoint(s): baseline, 4 months, 9 months
2. Body mass index (BMI) ; Timepoint(s): baseline, 4 months, 9 months
3. EQ5D; Timepoint(s): baseline, 4 months, 9 months
4. Health and social care service use; Timepoint(s): baseline, 4 months, 9 months
5. ISI; Timepoint(s): baseline, 4 months, 9months
6. SF-36; Timepoint(s): baseline, 4 months, 9 month

Overall study start date
18/02/2013

Completion date
05/07/2014

Eligibility

Key inclusion criteria
1. Male and female, aged 18 and over, upper age limit 90 years
2. Soring between 10-23 on the Participant Health Questionnaire (PHQ-9), (which indicates moderate to moderately severe depression)
3. With an episode of depression confirmed using the structured diagnostic Clinical Interview Schedule (CIS-R)
4. Participants will be asked to confirm if they are able to walk continuously for five minutes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Key exclusion criteria
Current exclusion criteria as of 04/03/2014:
1. Diagnosis of severe and enduring mental health problem,
2. Currently or prior to current episode of depression, doing at least 30 minutes accumulated moderate/vigorous intensity physical activity on 5 or more days of the week,
3. Score of 2/3 on PHQ-9 suicide risk question
4. Alcohol problem
5. Drug addiction
6. Inability to use written self-help materials in English

Previous exclusion criteria:
1. Diagnosis of severe and enduring mental health problem,
2. Currently or prior to current episode of depression, doing at least 30 minutes accumulated moderate/vigorous intensity physical activity on 5 or more days of the week,
3. Score of 2/3 on PHQ-9 suicide risk question
4. Changed or newly prescribed antidepressant in previous month
5. Alcohol problem
6. Drug addiction
7. Inability to use written self-help materials in English

Date of first enrolment
01/04/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Exeter
Exeter
United Kingdom
EX4 4QG

Sponsor information

Organisation
University of Exeter (UK)

Sponsor details
The Queen's Drive
Exeter
England
United Kingdom
EX4 4QJ

Sponsor type
University/education

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

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) Grant Codes: MR/J000337/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	29/05/2014		Yes	No
Results article	results	20/08/2015		Yes	No