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AMP WellBeing Intervention trial

Submission date
05/02/2013

Recruitment status
No longer recruiting

Registration date
25/02/2013

Overall study status
Completed

Last Edited
07/10/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People experiencing low mood or anxiety may benefit from a wellbeing programme designed specifically for older people or people who are members of minority ethnic communities. The primary aim of the study was to explore the potential benefit of trained advisors offering personalised wellbeing plans. We also evaluated whether people find these types of services acceptable. Another aim of the study was to enhance patients' coping skills and self-management strategies by encouraging the development of informal support networks.

Who can participate?
The study was open to people with low mood or anxiety who were registered with one of 16 general practices in four deprived neighbourhoods in Liverpool and Manchester. In two neighbourhoods the study was open to people aged fifty or above. In the third neighbourhood it was open to people of Somali heritage, and in the fourth it was open to people of South Asian heritage.

What does the study involve?
People who agreed to take part were allocated to one of two groups, those receiving personalised well-being care plans and those receiving usual care. The groups were selected by a computer which had no information about the individual. People chosen to be in the usual care group received everything they would have received if they had not taken part in the study. In addition, we monitored the effects of their care. People selected to receive a personalised wellbeing plan were allocated a case manager who offered a range of interventions. They had choice about whether to take part in individual sessions, group sessions or other types of activities. They developed the plan together, setting goals and targets and meeting with the case manager on at least 3 occasions over a 4 month period. While being part of the study, which ever group they were in, people were asked to complete four short questionnaires at the end of the study, and for some information including age, education and personal circumstances. At the end of the study people were also asked to take part in an interview to discuss their experiences of the wellbeing programme.

What are the possible benefits and risks of participating?
We hoped that people's mood and sense of wellbeing would improve whichever group they were allocated to. The information gained from the study will also help us to improve healthcare services in the future for people who need help with regards to their mood and wellbeing.

Regarding risks, people in the wellbeing group may have been asked to take part in activities that they did not usually do. However, the case manager was available for support, and to offer assistance with child care and interpreters. Being part of the usual care group did not have any side effects.

Where is the study run from?
The study was run from two centres, one in the University of Liverpool and the other in the University of Manchester

When is the study starting and how long is it expected to run for?
September 2010 to December 2011

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Prof. Christopher Dowrick
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Study website
http://www.amproject.org.uk

Contact information

Type(s)
Scientific

Contact name
Prof Christopher Dowrick

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8326

Study information

Scientific Title
Exploratory randomised controlled trial of a wellbeing intervention for under-served groups

Acronym
AMP WBI

Study objectives
A wellbeing intervention based on cognitive-behavioural principles, with an emphasis on social participation, would be acceptable and more effective than treatment as usual for under-served patients with symptoms of depression or anxiety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North-West 8 Research Ethics Committee, 29/07/2010, ref: 10/H1003/38

Study design
Exploratory multi-centre single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Anxiety and/or depression

Interventions
One third of participants were randomised to receive treatment as usual, i.e. no clinical intervention from the research team.

Two thirds of participants were randomised to receive the wellbeing intervention. The wellbeing intervention focused on brief cognitive behavioural strategies aimed at decreasing anxiety and depression and social isolation. The title wellbeing was designed to maximise engagement and reduce stigma, and to enhance linkage with our community engagement interventions. We incorporated a patient-centred interview and shared problem statements, goals and wellbeing

plans. The intervention was delivered by wellbeing facilitators. Participants were offered an initial patient-centred assessment session with a wellbeing facilitator, and collaboratively devised a wellbeing plan. The wellbeing plan specified desired health or social care changes based on self-identified goals. Significant emphasis was placed on the patient as the 'agent of change', incorporating patients' prior experience and coping strategies into the intervention and addressing stigma, expectations, and illness trajectory to better engage patients. Once the goals had been identified, the participant chose up to three ways to obtain support to achieve them: individual sessions with their wellbeing facilitator; group sessions with other participants; or direction (signposting) to appropriate public or third sector services in their locality.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
CORE-OM, a 34-item self report scale designed to measure global distress, including subjective well being, life/social functioning and risk measured at baseline and 20 weeks

Secondary outcome measures
1. PHQ-9 for depression
2. GAD-7 for anxiety
3. The Work and Social Adjustment Scale
4. The EQ-5D for quality of life
Measured at baseline and 20 weeks

Overall study start date
20/09/2010

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Male and female aged 50 and over for Croxteth and Wythenshawe participants
2. Aged 18 and over for Picton and Longsight participants
3. Somali heritage in Picton and South Asian (Pakistani or Bangladeshi) in Longsight; registered with one of the 16 primary care practices working with the AMP Development Partnership
4. Scoring 10 or more on the Patient Health Questionnaire 9 (PHQ)-9 and/or the Generalized Anxiety Disorder 7 (GAD-7)

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Currently deemed to be at significant risk to themselves or others
2. Significant learning disabilities and cognitive impairment

Date of first enrolment
20/09/2010

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Liverpool
Liverpool
United Kingdom
L69 3GL

Sponsor information

Organisation
University of Liverpool (UK)

Sponsor details
Faculty Support Office
Faculty of Health and Life Sciences
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Sponsor type
University/education

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

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research - Programme Grant RP-PG-0606-1071

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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?
Results article	results	01/08/2014		Yes	No
Results article	results	17/02/2016		Yes	No