ISRCTN65803720 https://doi.org/10.1186/ISRCTN65803720

LIVELIFE: effectiveness of two types of support for low mood

Submission date	Recruitment status	[ ] Prospectively registered
13/10/2008	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/11/2008	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/04/2013	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
https://www.onlineassessment.org.uk/lowmoodresearch/index.pl

Contact information

Type(s)
Scientific

Contact name
Dr Paul Farrand

Contact details
School of Psychology
University of Exeter
Room 235
Washington Singer Laboratories
Perry Road
Exeter
United Kingdom
EX4 4QG
+44 (0)1392 262497
P.A.Farrand@exeter.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ASRB4082

Study information

Scientific Title
Effectiveness of two types of support for low mood: a randomised controlled trial and economic analysis

Acronym
LIVELIFE

Study objectives
Compared to the treatment as usual (TAU) by general practitioner (GP) and continued monitoring control group alone, patients receiving NHS Direct telephone support for free to use web-based cognitive behavioural therapy (CBT) self help (Living Life to the Full) will have:
1. Improved mood measured on the Beck Depression Inventory (BDI-II)
2. Improved symptoms and social functioning measured on the 9-item Patient Health Questionnaire (PHQ-9) (depression), 7-item Generalised Anxiety Disorder (GAD-7) (anxiety), and Work And Social Adjustment Scale (WASAS) for social functioning questionnaires
3. Lower health care costs (EQ-5D and Client Services Receipt Interview [CSRI])
4. Improved mental health literacy
5. Improved acceptability

Ethics approval required
Old ethics approval format

Ethics approval(s)
Devon and Torbay Research Ethics Committee gave approval on the 5th March 2008 (ref: 08 /H0202/31)

Study design
Single centre, randomised, phase III, controlled trial with single blinding on the study, research and analysis teams

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Patient information material found at: https://www.onlineassessment.org.uk/lowmoodresearch/index.pl?p=1

Health condition(s) or problem(s) studied
Mild to moderate depression, with or without anxiety

Interventions
Status of trial amended to 'stopped' as of 05/04/2013 due to notification of lack of resources.

Intervention:
Up to 60 minutes of telephone support for a free to use cognitive behavioural self help web site called Living Life to the Full with treatment as usual from General Practitioner.

Control:
Continued monitoring and treatment as usual from General Practioner.

Duration of treatment is up to 60 minutes of telephone support. Duration of follow up for both arms is dictated by time taken to complete the follow up questionnaires which would be about 45 minutes in total over all follow-up sessions.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Beck Depression Inventory II at 4 months follow up.

Secondary outcome measures
1. Beck Depression Inventory II at 8 weeks, 4 months and 1 year
2. PHQ-9 depression measure at 8 weeks, 4 months and 1 year
3. GAD-7 anxiety measure at 8 weeks, 4 months and 1 year
4. Work And Social Adjustment Scale (WASAS) questionnaire at 8 weeks, 4 months and 1 year
5. Modified (shortened) EQ5D at 4 months and 1 year
6. Modified (shortened) version of the Client Service Receipt Inventory (CSRI) at 4 months and 1 year
7. Single item satisfaction scale at 8 weeks, 4 months and 1 year
8. Four items assessing mental health literacy at 8 weeks, 4 months and 1 year

Overall study start date
20/10/2008

Completion date
28/02/2011

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Aged 16 and above, either sex
2. Currently experiencing mild to moderately severe levels of depression - or depression and anxiety as defined by a score of 5 - 19 on the Patient Health Questionnaire 9 (PHQ-9)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
184

Key exclusion criteria
1. Aged under 16 years
2. Do not wish to adopt a self-help format
3. Cannot read/understand the written and audio content
4. Do not have a telephone and computer
5. Do not have access to broadband
6. Have active suicidal intent (defined as a score of 2 or more on the BDI-II suicide item)
7. Have more severe depression (a score greater than 19 on the PHQ)
8. An alcohol intake above 31 and 22 units for men and women respectively
9. People with drug dependency defined as using street drugs every day
10. A history of bipolar disorder
11. Psychosis and depression
12. Currently or have in the last 6 months been referred for supported self-help
13. Those who have started or changed antidepressant type in the last month

Date of first enrolment
20/10/2008

Date of final enrolment
28/02/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

School of Psychology
Exeter
United Kingdom
EX4 4QG

Sponsor information

Organisation
University of Exeter (UK)

Sponsor details
Washington Singer Laboratories
Perry Road
Exeter
England
United Kingdom
EX4 4QG

Sponsor type
University/education

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

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
NHS Direct (UK) - competitive funding (ref: ASRB4082)

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