

# LIVELIFE: effectiveness of two types of support for low mood

<b>Submission date</b> 13/10/2008	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/11/2008	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/04/2013	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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 Practitioner.

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(s)**

Beck Depression Inventory II at 4 months follow up.

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre****School of Psychology**

Exeter

United Kingdom

EX4 4QG

## Sponsor information

**Organisation**

University of Exeter (UK)

**ROR**

<https://ror.org/03yghzc09>

## Funder(s)

**Funder type**

Government

## Funder Name

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

# Results and Publications

## 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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes