

# Helping urgent care users cope with distress about physical complaints

<b>Submission date</b> 02/11/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/11/2016	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 05/10/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Each year many people make use of Accident & Emergency departments, walk in centres or make an urgent same day appointment with their GP. This is "unscheduled care". Doctors may be unable to tell these patients what exactly is causing their symptoms, which can be painful and cause distress if they are not able to be treated. Six percent of the population have excessive anxiety or worry about their health. Health anxiety costs the NHS in England an estimated £3 billion per year in unnecessary costs. Health anxiety is persistent worry about health and can have a severe detrimental and debilitating impact on overall health. Despite the availability of effective treatment for health anxiety, few people take it up. Psychological therapy delivered remotely (over the telephone or the internet) has been found to help patients where anxiety or stigma may cause reluctance to access mental health services face-to-face. Remotely delivered psychological therapy has equivalent rates of recovery and patient satisfaction to face-to-face delivery. Given the accessibility and cost benefits, remotely delivered therapy may be a suitable delivery option for this patient group. In this study, a remotely delivered cognitive behavioural therapy (a type of talking therapy which aims to change the way a person thinks and behaves) to people with high health anxiety that access unscheduled/urgent care. The aim of this study is to investigate the effectiveness of this program.

### Who can participate?

Adults who have had at least two consultations, referrals or hospital admissions in the last 12 months who experience health anxiety.

### What does the study involve?

A member of staff from the hospital, GP Practice or out of hours service introduces the study to potential participants. If the patient agrees to be contacted by a researcher then they are called to see if the study is suitable for them. If eligible the member of the research team will arrange to meet with them or ask to carry out an interview over the phone, whichever approach is most convenient. The researcher then answers any questions and asks for written consent to take part in the study. The participants are asked some questions about physical and mental health and use of health services. The interview is expected to last around one and a half hours. Participants would only need to meet with once for this. After this, participants are randomly allocated to one of two study groups. Those in the first group continue to receive usual care only

for the duration of the study. Those in the second group are offered the remotely delivered cognitive behavioural therapy (CBT) program. This involves 6-12 sessions of CBT either via video calling (similar to skype) or over the telephone. CBT sessions aim to identify how thoughts, feelings and actions affect the symptoms experienced. All participants are also asked to complete a set of questionnaires three, six, nine and twelve months after they have been interviewed.

What are the possible benefits and risks of participating?

By taking part participants may receive treatment which helps with their symptoms. The questionnaires and interview completed as part of the research enables reflection on symptoms and emotions and how these have changed over the research period. The study may also help patients in the future to get treatment that helps them manage their difficulties, and cope better with their pain or associated symptoms. Some of the questions asked enquires about symptoms including emotions such as feeling anxious or low. Whilst most people do not mind answering these questions, some people may feel upset. It is important that we ask these questions and find out if treatment can improve these symptoms. Many people find talking about or sharing concerns in a safe and confidential way can be helpful.

Where is the study run from?

Radford Medical Practice (lead site) and 52 other medical practices (UK)

When is the study starting and how long is it expected to run for?

January 2014 to December 2017

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Ms Shireen Patel

shireen.patel@nottingham.ac.uk

## Contact information

**Type(s)**

Public

**Contact name**

Ms Shireen Patel

**Contact details**

NIHR Collaboration for Leadership in Applied Health Research and Care  
(CLAHRC) East Midlands

C Floor

Institute of Mental Health Building

University of Nottingham

Innovation Park

Triumph Road

Nottingham

United Kingdom

NG7 2TU  
+44 115 8231434  
shireen.patel@nottingham.ac.uk

## Additional identifiers

### Protocol serial number

17959

## Study information

### Scientific Title

Helping urgent care users cope with distress about physical complaints: A randomised controlled trial

### Study objectives

The aim of this study is to:

1. Determine the clinical and cost effectiveness of remotely delivered cognitive behaviour therapy for health anxiety in repeated users of unscheduled/urgent primary or secondary care for physical symptoms without an underlying physical health cause#
2. Determine what aspects might facilitate and hinder the delivery of remote CBT and how such treatment might fit into a wider care pathway to enhance patient experience of care

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

NRES Committee - London Riverside, 25/07/2014, ref: 14/LO/1102

### Study design

Randomised; Both; Design type: Treatment, Psychological & Behavioural, Qualitative

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Specialty: Mental Health, Primary sub-specialty: Anxiety

### Interventions

Following eligibility screening and baseline assessment the researcher will enter the service user participants details onto a web-based randomisation system (set up by University of Nottingham Clinical trial Unit; CTU). Participants will be allocated with equal probability to each treatment arm with stratification by region.

Service user participants will be randomly allocated to one of two treatment arms: remote CBT intervention (in addition to usual treatment) or treatment as usual only.

Remotely delivered CBT intervention: A team of experienced CBT practitioners will deliver CBT for health anxiety remotely using a treatment manual developed from the CHAMP study (Tyrer, 2013). Six to twelve sessions will be offered. The intervention will address the symptoms of health anxiety from a cognitive-behavioural perspective. This will include safety-seeking behaviours (e.g. reassurance seeking or phobic avoidance); cognitive biases (e.g. misinterpretations of physical sensations due to selectively attending to potential threats); physiological sensations (e.g. pain and discomfort from excessive checking), and affective symptoms (e.g. anxiety and depression). The CBT intervention will be delivered remotely via video calling or over the telephone depending on the participant's preference. Upon completion of the remote treatment intervention participants from the remote intervention treatment arm of the study will be continue to access their usual care services. A summary of the finalised treatment action plan will then be distributed to the participant and their GP or other healthcare providers with the participant's consent.

Treatment as usual: Treatment as usual will be that decided by the service user with their general practitioner and other clinicians they consult for unscheduled care. Treatment as usual will be unconstrained other than it will not be provided by the treatment intervention therapists.

Follow up questionnaires will be completed by participants in both arms at 3, 6, 9 and 12 months. All outcome data will be collected single blind at 3, 6, 9 and 12 months from randomisation except for the SF-36 which will be collected at 6 and 12 months only.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Health anxiety is measured using the short form 14 item Health Anxiety Inventory (HAI) at baseline and 6 months.

### **Key secondary outcome(s)**

- .1 Health anxiety is measured using the Short form 14 item Health Anxiety Inventory (HAI) at baseline 3, 6, 9 and 12 months
2. Generalised anxiety is measured using the 7 item Generalised Anxiety Disorder (GAD) at baseline 3, 6, 9 and 12 months
3. Somatic distress is measured using the 15 item Patient Health Questionnaire (PHQ-15) at baseline 3, 6, 9 and 12 months
4. Depression is measured using the 9 item Patient Health Questionnaire for depression (PHQ-9) at baseline 3, 6, 9 and 12 months
5. Social function is measured using the 8 item Work and Social Adjustment Scale (WSAS) at baseline 3, 6, 9 and 12 months
6. v5 item quality of life on the EQ5D-5L (EuroQol) at baseline 3,6,9 and 12 months
7. Physical and Mental health status is measured using the 36 item Short Form Health Survey (SF-36) at baseline, 6 and 12 months
8. Number of contacts with unscheduled or emergency care established through a totally adapted and stylised Client Service Receipt Inventory (CSRI) at baseline, 3, 6, 9 and 12 months

### **Completion date**

31/12/2017

## **Eligibility**

**Key inclusion criteria**

1.  $\geq 2$  consultations, referrals or hospital admissions with any provider of unscheduled or emergency care (including urgent same day appointment at their general practice) in last 12 months for symptoms such as cardiac, respiratory, neurological, gastrointestinal or genitourinary problems not attributed to identified pathology
2. Scores above the threshold for severe health anxiety of 18 or more on the 14 item short form of the Health Anxiety Inventory (HAI)
3. Age 18 years and over
4. Sufficient understanding of English (spoken and written) to enable full engagement in the intervention
5. Able and willing to give oral and written informed consent to participate in the study

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Pathological medical condition requiring further assessment or acute management, or pregnancy
2. Other severe mental illness (schizophrenia, bipolar disorder, severe major depressive episode, eating disorder) ascertained by the Structured Clinical Interview for DSM-IV Disorders (SCID, Spitzer et al., 2002) or anyone at immediate risk of harm to themselves or other people through their mental state
3. Organic mental disorder (dementia, delirium, substance use disorder, organic mood disorder)
4. Those already receiving specialist mental health intervention, including psychological treatment as part of specialist medical care e.g. pain clinic

**Date of first enrolment**

24/09/2014

**Date of final enrolment**

31/12/2016

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Radford Medical Practice**

Radford Health Centre  
Ilkeston Road  
Nottingham  
United Kingdom  
NG7 3GW

**Study participating centre**

**The Valley Surgery**

81 Bramcote Lane  
Chilwell  
Nottingham  
United Kingdom  
NG9 4ET

**Study participating centre**

**Queens Medical Centre**

DREEAM  
Emergency Department  
Nottingham University Hospitals NHS Trust  
Queens Medical Centre Campus  
Derby Road  
Nottingham  
United Kingdom  
NG7 2UH

**Study participating centre**

**The Windmill Practice**

Beaumont Street  
Sneinton  
Nottingham  
United Kingdom  
NG2 4PJ

**Study participating centre**

**Sunrise Medical Practice**

Clifton Campus  
Nottingham Trent University  
Clifton Lane  
Nottingham

United Kingdom  
NG11 8NS

**Study participating centre**

**Cripps Health Centre**

The University of Nottingham  
University Park  
Nottingham  
United Kingdom  
NG7 2QW

**Study participating centre**

**Hucknall Road Medical Centre**

Kibworth Close  
Nottingham  
United Kingdom  
NG5 1NA

**Study participating centre**

**Crown Medical Centre**

21 First Ave  
Mansfield  
United Kingdom  
NG21 9DA

**Study participating centre**

**The Family Medical Centre**

171 Carlton Road  
Nottingham  
United Kingdom  
NG3 2FW

**Study participating centre**

**Leen View Surgery**

Bulwell Riverside  
Main Street  
Bulwell  
United Kingdom  
NG6 8QJ

**Study participating centre**  
**King's Mill Hospital**  
Endocrinology and Diabetes  
Sherwood Forest Hospitals NHS Foundation Trust  
Mansfield Road  
Sutton in Ashfield  
United Kingdom  
NG17 4JL

**Study participating centre**  
**Leicester Terrace Healthcare Centre**  
7-8 Leicester Terrace  
Northampton  
United Kingdom  
NN2 6AL

**Study participating centre**  
**Lakeside Surgery**  
Cottingham Road  
Corby  
United Kingdom  
NN17 2UR

**Study participating centre**  
**Nettleham Medical Practice**  
14 Lodge Lane  
Nettleham  
Lincoln  
United Kingdom  
LN2 2RS

**Study participating centre**  
**The Wolds Practice**  
West Road  
Tetford  
United Kingdom  
LN9 6QP

**Study participating centre**

**St Mary's Medical Practice**  
Wharf Road  
Stamford  
United Kingdom  
PE9 2DH

**Study participating centre**  
**Welton Family Health Centre**  
4 Cliff Road  
Welton  
Lincoln  
United Kingdom  
LN2 3JH

**Study participating centre**  
**Birchwood Medical Practice**  
Jasmin Road  
Birchwood  
Lincoln  
United Kingdom  
LN6 0QQ

**Study participating centre**  
**Cliff House Medical Practice**  
82 Burton Road  
Lincoln  
United Kingdom  
LN1 3LJ

**Study participating centre**  
**Old Leake Medical Centre**  
The Medical Centre  
Old Leake  
Boston  
United Kingdom  
PE22 9LE

**Study participating centre**  
**Lindum Medical Practice**  
1 Cabourne Ct  
Lincoln

United Kingdom  
LN2 2JP

**Study participating centre**  
**University Health Centre**  
Marina Building  
Brayford Pool  
Lincoln  
United Kingdom  
LN6 7GA

**Study participating centre**  
**The Sheepmarket Surgery**  
Ryhall Road  
Stamford  
United Kingdom  
PE9 1YA

**Study participating centre**  
**Derby Family Medical Centre**  
1 Hastings Street  
Derby  
United Kingdom  
DE23 6QQ

**Study participating centre**  
**Hockley Farm Medical Centre**  
Braunstone Health & Social Care Centre  
39 Hockley Farm Road  
Leicester  
United Kingdom  
LE3 1HN

**Study participating centre**  
**The Forest Practice**  
Mary Potter Centre  
Gregory Boulevard  
Nottingham  
United Kingdom  
NG7 5HY

**Study participating centre**  
**Churchfields Medical Practice**  
Old Basford Health Centre  
1 Bailey Street  
Old Basford  
Nottingham  
United Kingdom  
NG6 0HD

**Study participating centre**  
**Ashbourne Medical Practice**  
Clifton Road  
Ashbourne  
United Kingdom  
DE6 1DR

**Study participating centre**  
**Thurmaston Health Centre**  
573a Melton Road  
Thurmaston  
Leicester  
United Kingdom  
LE4 8EA

**Study participating centre**  
**Haywood Hospital Walk In Centre**  
High Lane  
Burslem  
United Kingdom  
ST6 7AG

**Study participating centre**  
**Somercotes Medical Centre**  
22 Nottingham Road  
Somercotes  
Alfreton  
United Kingdom  
DE55 4JJ

**Study participating centre**  
**Whitemoor Medical Centre**  
Whitemoor Lane  
Belper  
United Kingdom  
DE56 0JB

**Study participating centre**  
**Dronfield Medical Practice**  
High Street  
Dronfield  
United Kingdom  
S18 1PY

**Study participating centre**  
**The Deepings Health Centre**  
Godsey Lane  
Market Deeping  
Peterborough  
United Kingdom  
PE6 8DD

**Study participating centre**  
**Church Street Medical Practice**  
11b Church Street  
Eastwood  
Nottingham  
United Kingdom  
NG16 3BS

**Study participating centre**  
**Castle Healthcare Practice**  
Embankment Primary Care Centre  
50-60 Wilford Lane  
West Bridgford  
Nottingham  
United Kingdom  
NG2 7SD

**Study participating centre**

**East Bridgford Medical Centre**

2 Butt Lane  
East Bridgford  
Nottingham  
United Kingdom  
NG13 8NY

**Study participating centre**

**Bushloe Surgery**

Two Steeples Medical Centre  
Abington Close  
Wigston  
United Kingdom  
LE18 2EW

**Study participating centre**

**Castle Street Medical Centre**

Castle Street  
Bolsover  
Chesterfield,  
United Kingdom  
S44 6PP

**Study participating centre**

**Saffron Health**

509 Saffron Lane  
Leicester  
United Kingdom  
LE2 6UL

**Study participating centre**

**Dishley Grange Medical Practice**

32 Maxwell Drive  
Loughborough  
United Kingdom  
LE11 4RZ

**Study participating centre**

**Gosforth Medical Centre**

Gorsey Brigg  
Dronfield

United Kingdom  
S18 8UE

**Study participating centre**  
**Hollybrook Medical Centre**  
Hollybrrrok Way  
Heatherton  
Derby  
United Kingdom  
DE23 3TX

**Study participating centre**  
**Portland Medical Practice**  
60 Portland Street  
Lincoln  
United Kingdom  
LN5 7LB

**Study participating centre**  
**Castle Mead Medical Centre**  
Hill Street  
Hinckley  
Leicester  
United Kingdom  
LE10 1DS

**Study participating centre**  
**Charnwood Surgery**  
Mountsorrel Surgery  
39 Linkfield Road  
Mountsorrel  
United Kingdom  
LE12 7DJ

**Study participating centre**  
**Limes Medical Centre**  
Limes Avenue  
Alfreton  
United Kingdom  
DE55 7DW

**Study participating centre**  
**Hannage Brook Medical Centre**  
Hannage Way  
Wirksworth  
Matlock  
United Kingdom  
DE4 4JG

**Study participating centre**  
**Heartwood Medical Practice**  
Civic Way  
Swadlincote  
United Kingdom  
DE11 0AE

**Study participating centre**  
**St Lawrence Road Surgery**  
19 St Lawrence Road  
North Wingfield  
United Kingdom  
S42 5LH

**Study participating centre**  
**Keyworth Medical Practice**  
Bunny Lane  
Keyworth  
Nottingham  
United Kingdom  
NG12 5JU

**Study participating centre**  
**Torkard Hill Medical Centre**  
Farleys Lane  
Hucknall  
Nottingham  
United Kingdom  
NG15 6DY

**Study participating centre**

**Tong Medical Practice**  
Highfield Health Centre  
2 Proctor Street  
Bradford  
United Kingdom  
BD4 9QA

## Sponsor information

**Organisation**  
University of Nottingham

**ROR**  
<https://ror.org/01ee9ar58>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
National Institute for Health Research

**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

### Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		25/02/2016	05/10/2022	Yes	No
<a href="#">Basic results</a>		29/01/2019	29/01/2019	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No