ISRCTN66142865 https://doi.org/10.1186/ISRCTN66142865

Helping urgent care users cope with distress about physical complaints

Submission date
02/11/2016

Recruitment status
No longer recruiting

Registration date
16/11/2016

Overall study status
Completed

Last Edited
05/10/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 taking 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Secondary outcome measures
.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

Overall study start date
01/01/2014

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. ≥ 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 144; UK Sample Size: 144

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
England

United Kingdom

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
Somecotes
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

Sponsor details
Head of Research Governance
Research and Graduate Services
King’s Meadow Campus
Lenton Lane
Nottingham
England
United Kingdom
NG7 2NR
+44 115 9515679
sponsor@nottingham.ac.uk

Sponsor type
University/education

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

Publication and dissemination plan
A multi-faceted educational approach such as workshops, brief academic papers and electronic and paper disseminated information such as BITEs and video clips will be used appropriately for both internal and external communication. The results will be publicised through the extensive arrangements for dissemination locally within the CLAHRC (through road shows, website and annual conferences) as well as publications in peer reviewed journals, alongside local, national and international scientific conferences.

Intention to publish date
31/12/2018

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?
Basic results		29/01/2019	29/01/2019	No	No
Protocol article		25/02/2016	05/10/2022	Yes	No
HRA research summary			28/06/2023	No	No