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Cognitive behaviour therapy for excessive worry over health in medical patients

Submission date
17/06/2008

Recruitment status
No longer recruiting

Registration date
20/06/2008

Overall study status
Completed

Last Edited
17/05/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hypochondriasis, or health anxiety, is a significant problem in all parts of clinical practice, but has been largely ignored by services until recently. Our studies, and those of others, suggest that between 1 in 4 and 1 in 10 of all those attending medical clinics have significant health anxiety and this accounts for both considerable suffering and unnecessary use of resources. One of the characteristics of those with severe health anxiety is that it persists and leads to frequent medical consultations in both primary and secondary care. This represents a significant drain on health service resources at a time of considerable cost pressures, and, in addition, the symptoms of health anxiety are highly troubling and disturbing, are associated with much time off work, and adversely affect social functioning. In a study of treatment in a genitourinary medicine clinic, we found that a short course of cognitive behaviour therapy (CBT) was highly effective at reducing health anxiety, and that these benefits are maintained over a period of one year. We also found that the number of consultations in both general practice and the clinics fell in those in the active treatment group over one year but the savings made were small as the costs of investigations are relatively low. We are now planning a larger study of CBT to treat health anxiety in cardiology, respiratory medicine, gastroenterology and endocrinology clinics, where such anxiety is more common than in genuitourinary medicine.

Who can participate?
Patients aged between 16 and 75 attending four medical specialty clinics (in cardiology, respiratory medicine, gastroenterology and endocrinology) who have significant health anxiety

What does the study involve?
Participants are randomly allocated to one of two groups. One group is treated with CBT adapted for health anxiety in the form of between 5 and 10 one-hour sessions, which will address abnormal worries about health and ways of overcoming them. The other group is treated with a single 45-minute explanatory interview describing the nature of health anxiety and how it tends to be perpetuated. We measure patients' functioning, anxiety and quality of life, as well as health service and employment costs, at the start of the study and at 6 monthly intervals for two years, to see whether the costs of treatment are offset by savings on attendance and investigations over 2 years.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
October 2008 to September 2012

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Prof. Peter Tyrer
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 07/01/26

Study information

Scientific Title
Cognitive behaviour therapy for Health Anxiety in Medical Patients

Acronym
CHAMP

Study objectives
Cognitive behaviour therapy adapted for health anxiety is a cost-effective way of treating patients with significant health anxiety in medical clinics.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/070126
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/51731/PRO-07-01-26.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham Research Ethics Committee 1, 13/06/2008, ref: 08/H0403/56

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypochondriasis/mental health

Interventions
Arm 1: Cognitive behaviour therapy adapted for health anxiety (Warwick/Salkovskis model). Treatment will be given for between 5 and 10 one hour sessions for each patient, and will address abnormal worries about health and ways of overcoming them.

Arm 2: Single explanatory interview of the nature of health anxiety. This will be a single interview of 45 minutes describing the nature of health anxiety and how it tends to be perpetuated.

Duration of interventions: up to 6 months
Duration of follow-up: 2 years

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Reduction in health anxiety scores 1 year after randomisation.

Key secondary outcome(s))
1. Reduction in health anxiety scores 2 years after randomisation
2. Presence or absence of diagnosis of hypochondriasis at 1 and 2 years after randomisation
3. Reduction in generalised anxiety and depression, assessed using the Hospital Anxiety and Depression Scale (HADS) at 1 and 2 years after randomisation
4. Improvement in social function and quality of life, assessed using the Social Functioning

Questionnaire (SFQ) and Euroqol EQ-5D at 1 and 2 years after randomisation
5. Total costs of health care (primary and secondary) 1 and 2 years after randomisation
6. Change in presenteeism and absenteeism at work 1 and 2 years after randomisation

Completion date
30/09/2012

Eligibility

Key inclusion criteria
Patients attending four medical specialty clinics (in cardiology, respiratory medicine, gastroenterology and endocrinology) who:
1. Have significant health anxiety (score of 20 or more on the Health Anxiety Inventory)
2. Are aged between 16 and 75 (both males and females)
3. Are living independently
4. Are permanent residents in the area
5. Have sufficient understanding of English to read and complete the questionnaires
6. Give written consent for the interviews, including audiotaping of half the sessions
7. Give written consent for access to their medical records

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients who are:
1. Considered too ill in medical terms by their consultants to be considered for the study
2. In the process of being investigated for significant pathology and for whom cognitive behaviour therapy might confuse or cause distress
3. Those who have significant cognitive impairment

Date of first enrolment
01/10/2008

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College London
London
United Kingdom
W6 8RP

Sponsor information

Organisation
Imperial College London (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/01/2014		Yes	No
Protocol article	protocol	14/06/2011		Yes	No