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Reducing distress from somatic symptoms

Submission date
24/02/2015

Recruitment status
No longer recruiting

Registration date
13/05/2015

Overall study status
Completed

Last Edited
12/08/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Somatic symptom disorders are mental disorders characterized by physical symptoms that suggest physical illness but which cannot be explained fully by a general medical condition. A new brief psychological therapy may help people worry less. The aim of this study is to test how people find this therapy and whether it works. The researchers want to see whether it reduces worry, especially worries about health and illness. If it is shown to work then it will be possible to use the therapy in NHS services.

Who can participate?
Adults meeting criteria for somatic symptom disorders

What does the study involve?
Participants receive a 'worry intervention' in 6 sessions over 8 weeks, either at home or at the GP surgery. The worry reduction strategies include psycho-education about worry, reviewing of beliefs about worry, increasing awareness of the initiation of worry and identification of individual triggers, use of worry periods, substituting problem-solving in place of worry and relaxation exercises. There are homework exercises between sessions. At the end of the study, participants are invited to take part in another interview to talk about their experience of the therapy sessions and suggest improvements. Participants are paid £15 for each assessment session, and travel expenses are paid.

What are the possible benefits and risks of participating?
It is hoped that participants benefit from the opportunity to engage in the worry intervention. The main possible burden is time taken to complete the questions.

Where is the study run from?
South East England (UK)

When is the study starting and how long is it expected to run for?
June 2014 to August 2015

Who is funding the study?
University of Southampton (UK)

Who is the main contact?
Prof. David Kingdon
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Contact information

Type(s)
Scientific

Contact name
Prof David Kingdon

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12798

Study information

Scientific Title
Reducing worry in patients with somatic symptom disorder using brief cognitive behavioural therapy

Acronym
REDRESS

Study objectives
To determine the acceptability and explore the clinical effectiveness of a worry-based intervention for severe and distressing health concerns.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. University of Southampton Ethics and Research Governance Committee (ERGO12798) National Research Ethics Service, 17/02/2014, ref: 14/SC/0040
2. Southern Health NHS Foundation Trust, 27/05/2014, ref: SHT120
3. Sussex Partnership NHS Foundation Trust, 01/05/2014, ref: 5038-2014

Study design
Observational case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
GP practice

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Somatic symptom disorder

Interventions
Patients with Somatic Symptom Disorder will be offered 6 sessions of individual manualised psychological intervention focussed on worry. A control group is not included in this design.

The worry intervention will be provided in 6 sessions over 8 weeks. Intervention sessions will take place at home or at the participant's GP surgery, to minimise travel and burden for the participant. The worry reduction strategies included are indicated in the anxiety literature to be effective at reducing worry and do not challenge the illness interpretation. The main techniques are psycho-education about worry, reviewing of beliefs about worry, increasing awareness of the initiation of worry and identification of individual triggers, use of worry periods, substituting problem-solving in place of worry and relaxation exercises. Homework exercises are set between sessions. Written information is provided for patients (see appendix B). With patients' consent, sessions will be taped for assessment of adherence and for competence.

At the end of sessions, a consultation letter will be developed with the patient and shared with the patients' referring clinician and their general practitioner.

Intervention Type
Other

Primary outcome measure
Health Anxiety Inventory (Salkovskis, Rimes, Warwick & Clark, 2002). Assessments will take place at baseline and 8 weeks.

Secondary outcome measures
1. Intolerance of Uncertainty Questionnaire (Freeston, Rheaume, Letarte, Dugas & Ladouceur (1994)
2. Penn State Worry Questionnaire (Meyer, Miller, Metzger & Borkovec, 1990)
Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983)
3. EQ-5D (Rabin & de Charro, 2001)
4. Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS, Tennant, Hiller, Fishwick, Platt, Weich, Parkinson et al, 2007)
5. A question around the acceptability of a referral for psychological therapy, developed for this study
6. Number of attendences at A&E,
7. Outpatients and General Practice will also be recorded
8. New physical diagnoses will also be noted.

The scales will provide comparative measures of symptoms, functioning and well being with some estimate of resource utilisation.

Assessments will take place at baseline and 8 weeks.

Overall study start date
01/01/2014

Completion date
31/08/2015

Eligibility

Key inclusion criteria
1. Over 18 years old
2. Meet criteria for Somatic Symptom Disorder

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
1. Under 18 years old
2. Not meeting criteria for Somatic Symptom Disorder
3. Having an insufficient understanding of English to read and complete the study questionnaires

4. Having a primary diagnosis of drug or alcohol misuse
5. Taking part in current Cognitive Behavourial Therapy

Date of first enrolment
17/06/2014

Date of final enrolment
07/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southern Health NHS Foundation Trust
United Kingdom
SO40 2RZ

Study participating centre
Sussex Partnership NHS Foundation Trust
United Kingdom
BN13 3EP

Sponsor information

Organisation
University of Southampton

Sponsor details
Research Governance Office
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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
University/education

Funder Name
University of Southampton

Alternative Name(s)
University of Southampton UK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
It is hoped to present results at the Annual BABCP conference 2015. Results will be also be submitted to a peer-review journal. In addition, results of this pilot study will be included in a grant application for a larger-scale study

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No