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Using talking therapies in general practice to treat pain-related insomnia

Submission date
03/09/2018

Recruitment status
No longer recruiting

Registration date
08/01/2019

Overall study status
Completed

Last Edited
26/10/2020

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic pain patients often also have severe problems sleeping, which can amplify their pain and increase their distress and disability. These patients do request treatment for their insomnia, but such treatment is currently not a main focus in pain management programmes. In primary care drugs remain first-line treatments for pain-related insomnia despite limited evidence of their long-term effectiveness and safety.

Hybrid cognitive-behavioural therapy (Hybrid CBT) is a new approach to tackling pain-related insomnia. It addresses pain and sleep simultaneously, exploiting factors underpinning the persistence of both problems. Delivered as a brief but intensive treatment in secondary care, Hybrid CBT was effective in not only improving sleep and reducing pain interference, but also counteracting fatigue and depression. The improvements were also clinically meaningful, however, it is not yet known if the patient benefits could be translated to primary care.

This study therefore aims to test the feasibility of delivering this promising intervention in a primary-care setting.
Who can participate?
Adults with chronic pain of moderate severity for 6 months or longer, with concomitant insomnia of clinical severity are eligible to take part in this study.

Individuals who have known/suspected medical, psychiatric, or sleep disorders for which CBT for insomnia disorder is contraindicated as first-line treatment will be excluded. Individuals who are not enrolled in another drug or psychological treatment trial, completing a pain management programme or other psychological treatments for pain or sleep will also be excluded.

What does the study involve?
The study involves testing the practicalities of delivering the Hybrid CBT versus a self-help treatment for pain-related insomnia.

Participants will be randomly allocated to one of the two groups, following a 2-week sleep and pain monitoring procedure. Those allocated to the Hybrid CBT group will be offered 4 weekly, face-to-face sessions with a Health Psychologist to work on their sleep and pain issues. Each

session will be 2 hours long and will take place at the participant's local GP surgery. The general approach of this treatment is collaborative; participants will work with their therapist to try out different coping strategies. Those allocated to the Self-help treatment group will be mailed 4 reading booklets (1 each week for 4 weeks) containing information about chronic pain and insomnia. Participants in this group will have the flexibility to decide how much and at what pace they wish to try out the coping strategies introduced in the booklets. At the end of the treatment period, all participants will be asked to repeat the sleep and pain monitoring procedure for 2 further weeks.

What are the possible benefits and risks of participating?
Participants of the study will have access to treatments that are often not available for chronic pain patients because of a shortage of skilled therapists and an absence of infrastructure to deliver CBT for insomnia / pain in medical primary care settings.

Participants in the Hybrid CBT will have to visit their GP surgery to attend the assessment and treatment sessions. As they work with the therapists altering their sleep/wake schedule, it is expected that they will have to go through a temporary phase of mild sleep loss before they experience any improvement in their sleep quality and quantity. There is a chance that they may experience daytime sleepiness during the initial phase of the treatment.

Where is the study run from?
The study is led by the Warwick Pain and Insomnia Study team at the University of Warwick and supported by the Clinical Trials Unit of Warwick Medical School.

When is the study starting and how long is it expected to run for?
April 2016 to March 2017

Who is funding the study?
The study is funded by the National Institute for Health Research. under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PB-PG-0213-30121)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20694

Study information

Scientific Title
Primary care treatment of pain-related insomnia: A feasibility study of a hybrid cognitive-behavioural approach

Acronym
N/A

Study objectives
Hybrid cognitive-behavioural therapy (Hybrid CBT) delivered as a brief but intensive treatment in secondary care has been previously found to improve sleep, reducing pain interference and counteract fatigue and depression in chronic pain patients. It is not yet known if the patient benefits could be translated to primary care. The study will ascertain whether it is feasible to recruit, randomise and retain sufficient patients to receive the Hybrid CBT offered or an alternative self-help intervention, and whether the assessment methods are robust enough for statistical and health economic evaluations in the full trial. The study's findings and additional independent assessments will be used to evaluate the treatment process according to the stakeholders' experience.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands - Solihull, 09/09/2014, ref. 14/WM/1053.

Study design
Qualitative interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Primary Care; Health Category: Neurological; Disease/Condition: Episodic and paroxysmal disorders

Interventions
Hybrid CBT comprised select components of CBT-I and interventions designed to target cognitive-behavioural processes maintaining chronic pain, based on Tang et al. (2014). Each patient was offered a total of 4 individual treatment sessions at weekly intervals. Each session was approximately 2 hours long and took place in a clinic room of a local GP practice.

Self-help control
Existing reading materials was amalgamated (with minimal modification) into 4 booklets to provide a self-help treatment on managing chronic pain and insomnia. The self-help booklets were posted to the patients' home one at a time on a weekly basis. The content of the self-help will give equal coverage on chronic pain and insomnia management.

Intervention Type
Other

Primary outcome measure
1. Insomnia Severity will be using the Insomnia Severity Index (ISI) - total score at 12-weeks and 24-weeks post-randomisation.
2. Pain Interference will be measured using the Brief Pain Inventory (BPI) - Interference Score minus the sleep item at 12-weeks and 24-weeks post-randomisation.

Secondary outcome measures
1. Pain intensity will be measured using the BPI - pain intensity scores at 12-weeks and 24-weeks post-randomisation.
2. Fatigue will be measured using the Multidimensional Fatigue Inventory at 12-weeks and 24-weeks post-randomisation.
3. Anxiety and depression will be measured using the Hospital Anxiety and Depression Scale at 12-weeks and 24-weeks post-randomisation.
4. Quality of life will be measured using EuroQol - EQ- 5D at 12-weeks and 24-weeks post-randomisation.

Overall study start date
29/11/2013

Completion date

31/10/2018

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. A history of chronic pain and insomnia (as indicated by medical records)
3. Pain of at least moderate severity (>4/10 on the present pain intensity numerical rating scale of the BPI) for at least 6 months
4. Clinical insomnia (>15 on the ISI, >3 nights a week, >1 moth in duration)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 48; UK Sample Size: 48

Total final enrolment
25

Key exclusion criteria
1. Diagnosed/suspected medical/psychiatric/sleep disorders (e.g. narcolepsy) for which CBT-I is contraindicated as firstline treatment
2. Recently enrolled in or are completing a pain management programme or other psychological treatments for pain or sleep

Date of first enrolment
26/04/2016

Date of final enrolment
26/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Alcester Health Centre
Fields Park Drive
Alcester
United Kingdom
B49 6QR

Study participating centre
Henley Green Medical Centre
Henley Road,
Henley Green
Coventry
United Kingdom
CV2 1AB

Study participating centre
Chancery Lane Surgery
Chancery Lane,
Chapel End
Nuneaton
United Kingdom
CV10 0PB

Sponsor information

Organisation
University of Warwick

Sponsor details
Research Governance Team
Research & Impact Services
University House
University of Warwick
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England
United Kingdom
CV4 8UW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0213-30121

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/10/2019

Individual participant data (IPD) sharing plan
The 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?
Results article	results	18/03/2020	26/10/2020	Yes	No
HRA research summary			28/06/2023	No	No