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Self-management migraine Headache Education (SHE)

Submission date
07/11/2012

Recruitment status
No longer recruiting

Registration date
08/11/2012

Overall study status
Completed

Last Edited
06/05/2016

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
Migraine is a common health condition, affecting around 18% of women and 8% of men in the UK. It is usually in the form of a severe headache at the front or side of the head, but can also cause symptoms in the rest of the body such as nausea, dizziness and even paralysis (inability to move). Migraines can be severely disabling, affecting personal, social and wok life. The current standard treatment for migraine is medication, however due to a strong link with mental health, it is thought to also be influenced by emotional factors. Previously, cognitive behavioural therapy (a type of talking therapy aiming to change the pay a person thinks and behaves) and relaxation techniques (such as deep breathing and muscle relaxation) have been found separately to be effective at treating headaches. Self-management headache education (SHE) is a therapy programme which combines these two techniques and has been developed for people suffering from migraines. The aim of this study is to investigate the effectiveness of SHE in the treatment of migraines compared to standard medical care alone.

Who can participate?
Adults who have been suffering from migraines at least three days a month for the last six months.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive standard medical care alone. Those in the second group receive standard medical care and self-management headache education (SHE). This involves three face-to-face one-to-one sessions every two weeks with two telephone calls between sessions. The sessions themselves involve teaching participants about identifying and managing triggers of migraines, including stress, as well as learning relaxation techniques. Participants in both groups complete a number of questionnaires after 4 and 8 weeks. They are also interviewed in order to describe their view of their migraine headache and their experience of its management, and suggest any changes to the SHE intervention, as well as provide feedback on how they value the questionnaires used.

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

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
March 2012 to March 2013

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Profgessor Leone Ridsdale
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11265

Study information

Scientific Title
Self-management migraine Headache Education (SHE)

Acronym
SHE

Study objectives

The aim of this study is to evaluate the efficacy of Self-management Headache Education (SHE) in the treatment of migraines.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East London regional ethics committee, 17/12/2010, ref: 10/H0805/79

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Migraine headache

Interventions
Participants are randomly allocated to receive SHE plus standard medical care or standard medical care alone.

SHE comprises of three face-to-face sessions on a one-to-one basis with the nurse, at approximately two-week intervals, with 2 telephone calls in-between. Each session lasts for approximately 50 minutes. Each phone call takes 10-20 minutes. The nurse reviews homework, and discusses individual triggers, worrying thoughts and the impact of migraine on work and social life. New homework with relaxation and headache diary-keeping is assigned, and subsequently reviewed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Headache frequency (days per month) at 8 weeks and 4 months

Secondary outcome measures

1. Headache impact (HIT-6) at 8 weeks and 4 months
2. Health costs (Client Services Receipt Inventory) at 4 months
3. Migraine disability (MIDAS) at 8 weeks and 4 months
4. Patients' headache related beliefs (Illness Perception Questionnaire-Revised) at 8 weeks and 4 months
5. Psychological morbidity (Hospital Anxiety and Depression Scale) at 8 weeks and 4 months

Overall study start date
01/03/2012

Completion date
31/03/2013

Eligibility

Key inclusion criteria
1. Adults (men and women), aged 18 -75
2. Years with migraine which started at least 6 months previously, and occurred on 4 or more days in the previous month.
3. A reasonable level of the English language is expected

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Key exclusion criteria
1. A physical condition likely to cause headache, with symptoms and signs like subacute progressive focal neurological deficit, newonset seizures, headaches accompanied by vomiting plus papilloedema and the presence of cranial nerve palsy.
2. Pregnancy
3. An organic brain syndrome
4. Current psychotic illness or substance dependency
5. Currently undergoing psychological therapy
6. Being unable to complete a self report questionnaire for whatever reason including inability to speak and read English

Date of first enrolment
01/03/2012

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
National Institute for Health Research

Sponsor details
30-32 Hyde Terrace
Leeds
United Kingdom
LS2 9LN

Sponsor type
Government

ROR
https://ror.org/0187kwz08

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
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2015		Yes	No