ISRCTN69863201 https://doi.org/10.1186/ISRCTN69863201

A study comparing the effectiveness of an on-line mindfulness and muscle relaxation treatment for chronic headache, compared to mindfulness or muscle relaxation alone, among people from a Russian ethnic background.

Submission date
25/02/2013

Recruitment status
No longer recruiting

Registration date
29/04/2013

Overall study status
Completed

Last Edited
29/04/2013

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
The aim of the study is to investigate whether a six week online mindfulness treatment programme is more successful in the treatment of chronic headache/migraines, than progressive muscle relaxation alone. We are interested in whether mindfulness training may lead to changes in levels of pain, pain acceptance, levels of catastrophising, medication use and illness beliefs. We are also looking at whether social support, locus of control, anxiety and depression play a mediating role in this process.

Who can participate?
The present study aims to recruit at least 90 participants (male and female), who report having a headache present on at least 15 days a month for 3 months. They must be over the age of 18, fluent in Russian and identify their cultural background as Russian.

What does the study involve?
This is an online study. Participants will be invited to take part in the study through links posted on several Russian websites for headache management. Consenting participants will be randomly allocated to one of three groups: mindfulness group, progressive muscle relaxation group, or combined mindfulness and progressive muscle relaxation group. Participants will then be invited to complete nine brief questionnaires which will ask them about their pain, medication use, their thoughts and feelings in relation to their pain, and the support they get from others. Participants will then gain access to six weeks of training in their respective groups. After the training is completed, participants will be asked to fill out the same questionnaires again.

What are the possible benefits and risks of participating?
The effectiveness of mindfulness-based treatments has already been demonstrated with a wide

range of chronic pain conditions among English-speaking participants. Those participants who will receive a mindfulness based treatment are expected to experience reduced levels of pain, become less prone to catastrophising, more accepting of their pain, their medication dependence may be reduced and maladaptive illness beliefs may be transformed into more adaptive ones. Participants in the muscle relaxation group are expected to learn to recognise physical symptoms of stress, and techniques which may be used to alleviate muscle tension arising from stress. Mindfulness based treatments may occasionally have mild effects of depersonalisation, anxiety and faintness. All participants will therefore be provided with contact information for counselling services and helplines.

Where is the study run from?
The present study has been set up in the National University of Ireland, Galway. It will be conducted online.

When is this study starting and how long is it expected to run for?
It is anticipated that website will be launched by mid-March 2013. Data will be collected 12 weeks from this date. There will be a A 4-week and a 3-month follow up.

Who is funding the study?
The National University of Ireland, Galway.

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised controlled trial comparing the differential effectiveness of an on-line mindfulness and progressive muscle relaxation treatment for chronic headache versus mindfulness or progressive muscle relaxation alone, in a Russian ethnic background sample

Study objectives
It is hypothesised that mindfulness training among individuals with chronic headache will lead to changes in the amount of pain interference.

Ethics approval required
Old ethics approval format

Ethics approval(s)
SREC National University of Ireland, Galway, 24th January 2013

Study design
12 week on-line randomised controlled trial with a built-in 4-week and 3-month follow up.

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Chronic headache and migraine

Interventions
Upon completion of baseline measures, participants will be randomised to one of three conditions:
1. Mindfulness based treatment
2. Mindfulness and progressive muscle relaxation treatment combined
3. Progressive muscle relaxation treatment (active control)

Participants will receive on-line audio training in their respective groups for 6 weeks. An audio file will be embedded in the website, and participants will be instructed to log on at least 5 times a week and carry out the exercises. After the 6 weeks they will be invited to re-take the battery of questionnaires. Follow up assessments will be conducted 4-weeks and 3-months after the participant completes the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Brief Pain Inventory Short Form (SF)
2. Chronic Pain Acceptance Questionnaire SF-8

Baseline timepoint is prior to participation in the intervention. The intervention will be conducted for the duration of 6 weeks. 4 weeks follow up will be conducted at 4 weeks after the participant has completed the programme. 3 months follow up will be conducted at 3 months after the participant has completed the programme.

Key secondary outcome(s))
1. Brief Illness Belief Questionnaire
2. Leeds Dependence Questionnaire (adapted for medication dependence)
3. Kentucky Inventory of Mindfulness Skills (attention subscale)
4. Pain Catastrophising Scale
5. Social Support Questionnaire SF-12
6. Hospital Anxiety and Depression Scale
7. Headache Specific Locus of Control Scale SF-9

Baseline timepoint is prior to participation in the intervention. The intervention will be conducted for the duration of 6 weeks. 4 weeks follow up will be conducted at 4 weeks after the participant has completed the programme. 3 months follow up will be conducted at 3 months after the participant has completed the programme.

Completion date
03/06/2013

Eligibility

Key inclusion criteria
1. Male and female, over 18 years of age
2. Ethnic background - Russian
3. Knowledge of the Russian language - fluent
4. A headache is present on at least 15 days a month for 3 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Under 18 years of age
2. Ethnic background: other than Russian

3. Knowledge of the Russian language: less than fluent
4. Psychological disorder diagnosis
5. Uncontrolled blood pressure

Date of first enrolment
04/03/2013

Date of final enrolment
03/06/2013

Locations

Countries of recruitment
Ireland

Russian Federation

Study participating centre
28 Mill House
Ennis
Ireland
N/A

Sponsor information

Organisation
National University of Ireland, Galway (NUIG) (Ireland)

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
University/education

Funder Name
School of Psychology, National University of Ireland, Galway (Ireland)

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes