

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/04/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/04/2013	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 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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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

04/03/2013

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

90

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)

Sponsor details

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Sponsor type

University/education

Website

<http://www.nuigalway.ie/psy/>

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**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration