

Predictors of mood fluctuations in patients with chronic migraine

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON40634

Source

ToetsingOnline

Brief title

Mood in chronic migraine

Condition

- Neurological disorders NEC

Synonym

Cephalalgia, headache

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Provincie Friesland;zorggroep Pasana Friesland

Intervention

Keyword: Chronic migraine, Diary method, Mood, Predictors

Outcome measures

Primary outcome

Our outcome parameter is negative mood.

Secondary outcome

Our secondary outcome parameter is positive mood.

Study description

Background summary

Many patients with chronic migraine (CM) experience co-morbid mood problems (e.g. anxiety, depression, anger). The presence of negative mood can worsen migraine symptoms, impair quality of life and complicate treatment. Therefore, negative mood is a potential modifiable risk factor that should be addressed in the treatment of CM. However, insight into the psychological mechanisms that are responsible for the maintenance and exacerbation of negative mood in patients with CM is currently lacking.

Study objective

The current study will examine psychological predictors of fluctuations in mood in the daily life of patients with CM. First, we will examine the role of within-subjects factors (headache, goal disturbance, rumination) in explaining daily variability in mood within individuals. Second, we will examine the role of more stable factors (history of depression, acceptance, mindfulness, goal adjustment tendency) in explaining differences between individuals in negative mood.

Study design

This study employs a longitudinal observational design. The study includes a baseline assessment using self-report questionnaires. Furthermore, we will use the Experience Sampling Method to sample mood as well as several contextual and cognitive factors at 10 semi-random moments of the day for a period of 7

consecutive days.

Study burden and risks

There are no risks associated with participation in this study. The burden for participants consists of: 1) filling out a baseline questionnaire (30 minutes), 2) attending a briefing interview (60 minutes), 3) completing diaries for 7 consecutive days (beep diary: 10-15 min./day, evening diary: max. 1 min./day), 4) a telephonic debriefing interview (30 minutes).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Aged 18 years or older
- Diagnosis of chronic migraine (according to ICHD-III diagnostic criteria). Onderdeel van deze diagnose is dat hoofdpijn tenminste aanwezig is geweest op minimaal 15 dagen per maand in de voorafgaande 3 maanden.

Exclusion criteria

- Inability to complete questionnaires and diaries in Dutch
- Planned detoxification for medication-overuse headache during or in the 3 months prior to the study period
- Other headache diagnoses than chronic migraine (with exception of medication overuse headache)
- Current pregnancy or less than 1 year after pregnancy
- Currently receiving treatment for major depressive disorder.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-09-2015

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 09-12-2014

Application type: First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	06-03-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL49506.042.14