EEG as predictor for depressive and pain complaints.

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Primary Objective: 1. An explorative study to investigate whether a change in pain complaints or depressive symptoms can be predicted using baseline EEG/ERP measures derived from vulnerability experiments.Secondary Objective(s):1. To explore changes...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36587

Source
ToetsingOnline

Brief title
EEG, depressive and pain complaints.

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
depresive and paincomplaints

Health condition

pijnklachten

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: depressive complaints, EEG, pain complaints

Outcome measures

Primary outcome

Main endpoints are: change in pain-report and depressive complaints.

Secondary outcome

not applicable.

Study description

Background summary

The basic goal of the present research project is to carry out a prospective study within the general population, focusing on the predictability of two outcome parameters: 1) a change in pain complaints, 2) a change in depressive symptoms. As such, the present study may lead to a better and more fundamental insight into etiology, maintenance and recovery mechanism of these two health-related outcomes.

In this study we are interested in two types of complaints: depressive complaints (like sadness, loss of interest etc.) and pain complaints. The choice of these two problem areas is based on the fact that they are both highly prevalent. In the Netherlands it is estimated that the one-year prevalence of depression within adults (18-65 years) is 5.8 percent . However, sub-threshold depressive symptom are much more common. Similarly, chronic *benign* pain complaints (pain that exists for more than 3 months, which cannot be sufficiently explained from underlying physical pathology) are observed in 18 percent of the general population. This estimate will even be larger in case also acute and subacute pain complaints will be included. Because of the high prevalence of depressive and pain complaints in the general population it is the intention to use a random selection of subjects from the population of Maastricht. We expect that we will observe at both measurement moments:
1. Pain complaints (acute, intermittent, chronic): plm. > 18%.

2. Depressive complaints: plm. 5-10%.
3. All remaining subjects will be classified as *healthy*, i.e. without actual pain and / or depressive complaints.
Finally, we expect that in a number of subjects the health-status will be changed from t=0 to t=6 months (see below).

Both outcome measures, being pain and depressive complaints will be measured with questionnaires (with good psychometric properties). From clinical practice it is known that these two complaints are often associated with each other. One of the interesting secondary research questions is whether these interrelated clinical problems demonstrate different EEG activity.

Finally, note that we do not classify subjects with a DSM-IV-diagnosis such as major depression or with the IASP classification *chronic benign pain*. We are interested in a change of a continuous symptom score, unlike a change in a traditional dichotomy 'ill-healthy'.

The rational of this research project will be illustrated by the following example applied to depressive symptoms. Within a given period of time (in our study 6 months) four possible courses in the level of (sub-threshold) depressive symptoms can be envisaged.
First, as will occur in most cases, there is an unchanged, stable situation of complaints. Second, people can experience a (meaningful) increase in complaints. Third, a decrease of complaints may also be observed. Fourth people without complaints can be remain free of complaints. An increase (as measured, for with the depression score on a questionnaire) may give an indication that an etiological or augmenting mechanism is active. On the other hand, a decreasing score may be indicative of an ongoing recovery. An unchanged score is interesting in two ways. First, starting from a point with already existing complaints, the unchanged score may be indicative of a symptom-maintaining mechanism (e.g. an operant reinforcement mechanism). In the case of a symptom-free start, it may give information that a symptom-free state is being continued (e.g. active resilience mechanisms).

Embedding in current research lines and theoretical background.
There are two reasons why the present study focuses on these two health problems. First, as already mentioned above, the prevalence of these health problems is relatively high. The second argument is based on the fact that the department of Psychiatry and Neuropsychology (MUMC) has experimental as well as clinical experience in these two health problems. With respect to pain, a recent dissertation has been completed by Vossen. The results of this dissertation show the importance of objective EEG / ERP measures in pain assessment. In addition, the hypothesized predictive link between pain measures in a laboratory setting and pain ratings in the home setting could be demonstrated. Furthermore, it was demonstrated that depressive patients with chronic back pain showed less to no habituation to experimental pain stimuli, thus demonstrating the importance of a diminished habituation as a mechanism in

the etiology / maintenance of chronic pain. In addition, a large body of literature exists emphasizing the relationship between complaints (such as pain, depression) and personality factors. The influence of factors such as neuroticism and extraversion /introversion have been demonstrated both experimentally as well as
clinically. Vossen concluded, that longitudinal studies are needed to get more insight in the aetiology and chronification of pain complaints and the influence of personality and psychological problems.

Over the last decade, several articles and dissertations have been completed at the department of Psychiatry (MUMC) within the related fields of depression and the influence of genetics. These research projects demonstrate the multidimensional (etiological) nature of depression. In many of these studies, questionnaires are used to assess depression. However it is known that this (questionnaire) data is prone to several forms of bias. The conclusions of these research projects are that future studies should incorporate more objective measures, such as EEG / ERP, EMG and ECG, in addition to questionnaires. Objective measures improve the quality of clinical (diagnostic and effect) assessment.

As stated above, at t = 0 and at t = 6 months four so-called *vulnerability experiments* are carried out. Based on findings in literature four mini-experiments are carried out to get specific insight into crucial factors in the etiological / maintaining mechanisms of both pain and depressive complaints.
1. EEG-experiments investigating attentional bias towards pain and emotional queued words. In a recent review, the significance of attentional bias towards pain as a risk factor in the process of chronification was demonstrated. It is therefore proposed to demonstrate how in a general population sample, attentional bias towards pain and depression related words is associated with cortical activity, as measured with EEG / ERP.
2. A large body of literature exists, showing the relationship between abnormal stress reactivity (measured as muscle-reactivity and heart rate) and the development of chronic pain. Rehabilitation centre *t Roessingh in Enschede in the Netherlands has extensive experience in performing such experiments.
3. As already mentioned above, a dissertation project carried out at Maastricht University demonstrated the importance of abnormal habituation as a possible mechanism in the chronification process of pain.
4. Mood reactivity can be experimentally manipulated by so called *mood inductions*. An example would be looking at pictures or movies with different emotional content. Especially in research concerning depression, the degree of reactivity seems to be a significant *vulnerability* parameter. Because of the strong relationship between pain and depression, abnormal mood reactivity may be an important shared factor in the development of pain and depression.

In sum, this study focuses on predicting changes in two psychopathological

measures (the dependent variables) with changes in cortical reactivity associated with experimental induction of these same psychopathological measures (being the independent / predictor variables). The results of the 4 experimental inductions may provide much better causal evidence linking specific cortical reactivity to specific symptoms and changes within these.
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Study objective

Primary Objective:
1. An explorative study to investigate whether a change in pain complaints or depressive symptoms can be predicted using baseline EEG/ERP measures derived from vulnerability experiments.

Secondary Objective(s):
1. To explore changes in cortical processing (in response to the four vulnerability experiments) in relation to the etiological, maintaining and recovery mechanisms of pain and depressive complaints.
2. To compare the EEG/ERP t0 and t6 months results with those from a breast cancer surgery population (nl34275.068.11) with respect to the development of pain and depressive complaints.
3. Since only siblings will be included, analyses concerning the (possible) influence of a familial component in the EEG responses will be carried out.

Study design

A prospective cohort study with two moments of assessments:
1. baseline t=0
2. follow-up 1 at 6 months

Assessments 1 and 2 consist of an psychophysiological (EEG, ECG, EMG) registration while performing the four vulnerability tasks, as well as the administration of several health-related and personality questionnaires.

Study burden and risks

There is no benefit for subjects participating in the study. A financial (50¤) reward will be given. There are no risks involved. We estimate the burden for the patient as light to moderate because of the following two factors:
1. Two EEG measurements (of 3,5 hours each), take place at the university.
2. The completion of several pain- and health related questionnaires, including a personality questionnaire (NEO).

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

* Age between 18 and 65 years
* Sufficient comprehension of the Dutch spoken and written language
* Written informed consent is obtained

Exclusion criteria

* Regular use of psychopharmaca such as antipsychotics, anxiolytics, etc.
* Consumption of alcohol (> 4units) and / or drugs the evening before
* Regular (excessive) consumption of alcohol (>= 7 units/day) and / or use of drugs (more than once a week).
* Illiteracy or other severe problems with the understanding of spoken and /or written

language).
* Visual and hearing problems

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Not approved

Date:	18-01-2012
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	NL34460.068.11