# Pain: The Influence of Psychological Factors

Published: 24-04-2019
Last updated: 12-04-2024

The primary objective is to investigate the differences in mentalizing abilities between outpatients with chronic pain and a control group, consisting of outpatients with painful acute injuries or painful somatically explained conditions. The...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Bone and joint injuries |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON49660

**Source**
ToetsingOnline

**Brief title**
Chronic Pain: Better understood

### Condition

- Bone and joint injuries
- Muscle disorders
- Somatic symptom and related disorders

**Synonym**
chronic pain, chronic pain syndrome

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Meander Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** mentalization, mentalizing ability, pain

## Outcome measures

### Primary outcome

The main study parameter is the mentalizing ability of the participants. Mentalizing is the ability to understand the self and others in terms of intentional mental states (e.g. feelings, wishes, desires, and values; Luyten & Fonagy, 2014). Mentalization includes both emotional self-awareness as the awareness for emotional signals in others. It has a cognitive component, the Theory of Mind (ToM); being able to process, reflect on and express one's own and others' intentions and emotional signals. Next, mentalization consists of an emotional component; e.g. being able to experience empathy. The mentalizing ability will be measured using the FHAT, the LEAS-SF and the RFQ.

The Frith-Happe-Animations task (FHAT; Abell, Happe, & Frith, 2000)
The FHAT is a performance-based task measuring theory of mind (ToM). It comprises animated video-clips of 34 to 45 seconds. In these clips two triangles exhibit movement patterns of living beings. Individuals with well-functioning ToM will identify these objects as intentional. Therefore, the FHAT shows a person's ability to recognize ToM in interpersonal situations, while excluding most of the potentially confounding factors present in social settings (Abell et al., 2000; Zunhammer et al., 2015). The FHAT has a ToM-condition and a Goal-Directed(GD)-condition. The ToM-condition comprises of four video-clips, in which two triangles display interaction suggesting

behavior described as ''Surprising'', ''Coaxing'', ''Mocking'', and ''Seducing''. These clips require ToM for correct interpretation. As a control, the GD-condition is included, in which the triangles display behaviors which do not require higher order mentalizing abilities to interpret correctly. These behaviors are ''Fighting'', ''Following'', ''Chasing'', and ''Dancing''. Participants are asked to describe what they have seen after each video-clip. The responses will be scored on an Intentionality and an Appropriateness scale. The 5-point Intentionality scale shows to what extent deliberate actions and intentions are ascribed to the triangles. The 3-point Appropriateness scale reflects how close the given response matches the content of the video, as intended by the designers. A score of 3 is given for the correct interpretation and a score of 0 is given for no answer or ''I don't know'' (Castelli, Happe, Frith, & Frith, 2000).

The Levels of Emotional Awareness Scale - Short Form (LEAS-SF; Lane, Quinlan, Schwartz, Walker, & Zeitlin, 1990)

The LEAS-SF is a performance-based task, proposed to measure the ability to identify and describe emotions. It uses ten vignettes, each describing an imaginary situation in which the participant interacts with a second person. Participants are asked to give a verbal description of the emotions that the situation may invoke in them and in the second person involved (Lane et al., 1990; Zunhammer et al., 2015). The construct of emotional awareness is defined as a type of cognitive processing which undergoes five levels of structural transformation along a cognitive-developmental sequence of levels. These levels

are derived from an integration of developmental theories of Piaget and Werner. The five levels of structural transformation are awareness of (1) bodily sensations, (2) the body in action, (3) individual feelings, (4) blends of feelings and (5) blends of blends of feelings. Answers of participants are scored following these levels of emotional awareness (Lane, & Schwartz, 1987; Subic-Wrana, Beutel, Garfield, & Lane, 2011; Zunhammer et al., 2015).

Reflective Functioning Questionnaire (RFQ; Fonagy et al., 2016)
The RFQ is a brief eight item questionnaire to assess mentalizing abilities. Items are answered on a six-point Likert scale (1 = I do not agree at all to 6 = I very much agree). The RFQ has two subscales, Certainty (RFQ-C) and Uncertainty (RFQ-U), each containing six items. Four items are used to calculate scores on both subscales, while the other four items are unique to each subscale. For a detailed description of scoring procedures see De Meulemeester, Vansteelandt, Luyten, Lowyck, 2018 and Fonagy et al. 2016. Research in French and Italian populations showed satisfactory reliability and construct validity of the two subscales (Badoud et al., 2015; Morandotti et al., 2018).

**Secondary outcome**

The secondary study parameters are childhood adversities, attachment style and the quality of the patient-doctor relationship. Childhood adversities are defined as maltreatment before the age of seventeen. This maltreatment can consist of physical abuse, emotional abuse, sexual abuse, physical neglect, and emotional neglect (Thombs, Bernstein, Lobbestael, & Arntz, 2009). The

occurrence and extent of childhood adversities are measured by the CTQ-SF. Last, the experienced quality of the patient-doctor relationship is assessed by the PDRQ-9 (Van der Feltz-Cornelis, Van Oppen, Van Marwijk, De Beurs, & Van Dyck, 2004).

Childhood trauma questionnaire - Short Form (CTQ-SF; Bernstein et al., 2003)
The Childhood Trauma Questionnaire - Short Form (CTQ-SF) is a 28-item retrospective self-report questionnaire designed to assess five dimensions of childhood maltreatment: (1) Physical Abuse, (2) Emotional Abuse, (3) Sexual Abuse, (4) Physical Neglect, and (5) Emotional Neglect. Items are scored on a 5-point Likert-scale and are structured to reflect the frequency of maltreatment experiences (never true, rarely true, sometimes true, often true, very often true). The psychometric properties of the Dutch CTQ-SF were found to be satisfactory: internal consistencies were Cronbach's alpha .91 for Physical Abuse, .89 for Emotional Abuse, .95 for Sexual Abuse, .63 for Physical Neglect, and .91 for Emotional Neglect. In addition, scores on the five CTQ-SF scales among Dutch respondents showed good convergent validity with responses on a semi-structured interview for childhood trauma (Thombs et al., 2009).

The other secondary parameter is attachment style. Attachment styles can be defined as internal working models with a specific set of mental representations about the self in interaction with others that is developed in the relationship with primary caregivers (Bowlby, 1969). Attachment styles are relatively stable over time. In terms of their affective-motivational

characteristics, these global beliefs are referred to as anxiety about rejection and abandonment and avoidance of intimacy and interdependence (Crowell, Fraley, & Shaver, 1999). These two dimensions can be combined into four attachment styles, one secure and three insecure subtypes: preoccupied, dismissing and fearful (Bartholomew & Horowitz, 1991; Hinnen, Sanderman, & Sprangers, 2009). Attachment style is measured by the ECR-M16.

The Experiences in Close Relationships Scale - Modified Short Form (ECR-M16; (Lo et al., 2009)

The ECR-M16 is a 16-item self-report questionnaire designed to assess attachment patterns in a variety of close relationships. Items are rated on a likert-scale, ranging from 0 (strongly disagree) to 7 (strongly agree). Participants receive the instruction ''The following statements concern how you feel in close relationships with others. In the following statements the term ''other people'' refers to people to whom you feel close. Use the rating scale to indicate how much you agree or disagree with each statement''. The psychometric properties of the ECR-M16 were found to be satisfactory. The internal consistencies of the scales were good, with Cronbach's alpha .83 for attachment-related avoidance and Cronbach's alpha .84 for attachment-related anxiety. The correlation between the two subscales was small, r = .27. Finally, test-retest reliability was satisfactory, with a correlation of .73 for the attachment avoidance subscale and .82 for the attachment anxiety subscale (Lo et al., 2009).

Patient Doctor Relationship Questionnaire-9 (PRDQ-9; Van der Feltz-Cornelis et al., 2004)

The PRDQ-9 is a brief measure of the doctor-patient relationship from the patients perspective. The nine items are answered on a five-point Likert scale (1 = not at all appropriate to 5 = totally appropriate). Two sample items are: *my clinician understands me* and *my clinician and I agree on the nature of my medical symptoms*. A mean score of all nine items is calculated. A higher score means more satisfaction about the relationship. The psychometric quality of the Dutch PDRQ-9 shows good internal consistency, adequate test-retest reliability and the ability to discriminate between patient groups.

# Study description

**Background summary**

Chronic pain is a widespread and an increasingly frequent occurring problem (Breivik, Collett, Ventafridda, Cohen, & Gallacher, 2006; Hoy et al., 2012). Patients with chronic pain report a reduced quality of life, as they often experience great physical discomfort, emotional distress and severe limitations in daily activities. Also, due to high healthcare utilization, it is a financial burden on society (Collins et al., 2005; Dagenais, Caro, & Haldeman, 2008; Juniper, Le, & Mladsi, 2009). The International Association for the Study of Pain (IASP) defines chronic pain as persisting beyond the normal tissue healing time, usually longer than three months, in the absence of an obvious underlying biological cause (Merskey & Bogduk, 1994). It is widely agreed upon that this population is difficult to treat (Allen, Woolfolk, Escobar, Gara, & Hamer, 2006) and that the patient-doctor relationship is an important factor in treatment adherence and success (Ciechanowski, Walker, Katon, Russo, 2001) and in promoting patients resilience (Náfrádi, Kostova, Nakamoto & Schulz, 2018). Clarification on the underlying mechanisms contributing to the condition is necessary to define the appropriate aim of treatment, resulting in a more effective approach.

In the last decades several psychological factors have been found to be associated with the presence of chronic pain. First, there is increasing

evidence that early-life adversities increase the risk of developing chronic pain in later life (Burke, Finn, McGuire, & Roche, 2017). Furthermore, it has been repeatedly demonstrated that attachment insecurity, particularly fearful and dismissing attachment, is overrepresented in chronic pain populations (Davies, Macfarlane, McBeth, Morriss, & Dickens, 2009; Hunter & Maunder, 2015; Kowal et al., 2015; Meredith, Strong, & Feeney, 2005; Meredith, Strong, & Feeney, 2006; Schmidt, Nachtigall, Wuethrich-Martone, & Strauss, 2002). Moreover, empirical evidence suggests that mentalization partly explains the relationship between on the one hand early life adversities and insecure attachment and on the other hand somatoform symptoms, including chronic pain (Hunter & Maunder, 2015).

Mentalizing is the ability to understand behavior in terms of internal mental states such as thoughts, feelings, needs and desires (Luyten & Fonagy, 2014). Previous research suggests that early life adversities and insecure attachment are associated with difficulties in mentalization (Hunter & Maunder, 2015). Moreover, earlier studies suggest that mentalization is associated with experiencing more physical complaints, such as chronic pain (De Gucht & Heiser, 2003). Furthermore, mentalization has a fundamental impact on interpersonal functioning (Hayden et al., 2018). Since patients with chronic pain often have difficulties in mentalizing (Spaans, Veselka, Luyten & Buhring, 2009), forming an effective and satisfactory relationship with their doctor may be complicated (Matthias & Bair, 2010).

Previous studies on mentalization and chronic pain are limited due to methodological problems, such as inappropriate self-report questionnaires and small sample sizes. Self-report questionnaires are suboptimal as they measure how a person perceives him or herself, with somatoform patients often having poor introspective capacities and showing favorable self-presentations (Wineke, Eurelings-Bontekoe, Van Dijke, Van Gool, & Moene, 2015). Few studies have used more appropriate performance-based measures in which results are obtained by observing a person complete an activity. Till date only two studies have used performance-based measures to assess mentalization in chronic pain patients (Schönenberg et al., 2014; Zunhammer, Halski, Eichhammer, & Busch, 2015). These studies suggest that inpatients with chronic pain are impaired in mentalizing. However, this is not generalizable to the much larger group of patients who are treated in an outpatient clinic, since these patients are often less affected by the condition than inpatients. Moreover, these studies did not include other psychological factors (e.g. early life adversities and attachment) that may help to identify who is at risk of experiencing chronic pain and which may be a focus of attention in treatment. Furthermore, none of the earlier studies included a control group consisting of patients with somatically explained pain symptoms. Consequently, it has been difficult to conclude whether the deficits in mentalizing abilities contribute to the development of chronic pain complaints or conversely, that suffering from painful physical conditions may lead to difficulties in mentalizing.

The aim of the present study is to examine the differences in mentalizing abilities between an outpatient group with chronic pain and a control group, consisting of patients with painful acute injuries or painful somatically explained conditions. The use of a control group with overall more somatically explained pain symptoms, is necessary to control for the experiencing of pain, this possible effecting mentalizing ability. We will use several performance-based tasks to assess mentalization. Our first hypothesis is that outpatients with chronic pain will manifest poorer mentalizing abilities than the control group. Furthermore, we hypothesize that mentalization mediates the association between childhood adversities and attachment style on the one hand and patient group on the other hand. The third hypothesis is that mentalization mediates the association between attachment style and the quality of the patient-doctor relationship. Our findings could raise the possibility that persons with chronic pain are more often burdened with a fundamental mental deficit in the ability of mentally representing one*s own and others* emotional states. This would require interventions aimed at this fundamental problem, with a variety of treatments suitable for this purpose, such as Mentalization Based Treatment, Focusing, Emotion-Focused Psychotherapy and Dialectical Behavior Therapy. To date, these techniques have not been recognized as treatments for chronic pain, because the latter has not been previously thought to be due to a deficit in mental representation of emotions (Subic-Wrana et al., 2010).

## Study objective

The primary objective is to investigate the differences in mentalizing abilities between outpatients with chronic pain and a control group, consisting of outpatients with painful acute injuries or painful somatically explained conditions. The secondary objective is to examine whether mentalization mediates the association between childhood adversities and attachment style on the one hand and the presence of chronic pain on the other hand. The third objective is to examine whether mentalization mediates the association between attachment style and how patients experience the relationship with their doctor.

## Study design

The design of the study is a case-control design. Mentalizing ability will be measured once, before participants start their treatment program. The mentalizing ability of two groups will be compared: the case groups, consisting of patients with chronic pain and the control group, consisting of patients with painful acute injuries or painful somatically explained conditions. This specific control group is necessary, since none of the earlier studies included a control group consisting of patients with painful somatically explained pain symptoms. Consequently, it has been difficult to conclude whether the deficits in mentalizing abilities contribute to the development of chronic pain

complaints or conversely, that suffering from painful physical conditions may lead to difficulties in mentalizing.

### Study burden and risks

There are no risks associated with participation. The burden for participants will be kept minimal; at one moment in time, at the beginning of the treatment programs, the care as usual will be supplemented with five short questionnaires and two tasks, for the duration of approximately one hour. No incentives will be distributed, since all participants will volunteer without compensation. No extra travel expenses will be made, because the appointment for the study will be matched to existing appointments in the hospital that are part of the care as usual. Participants do receive compensation for extra parking costs, since they are one hour longer in the hospital for the purpose of the current study.

## Contacts

**Public**
Meander Medisch Centrum

Maatweg 3
Amersfoort 3813TZ
NL
**Scientific**
Meander Medisch Centrum

Maatweg 3
Amersfoort 3813TZ
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Inclusion criteria per group:, Case group: referred for treatment and diagnosed with chronic pain by a rehabilitation/pain specialist. Chronic pain is diagnosed when complaints are lasting for at least three months, persisting beyond the normal tissue healing time and in the absence of an obvious underlying biological cause. Control group: referred for treatment and diagnosed by the rehabilitation/pain specialist with a painful acute injury or a painful condition that can be somatically explained. Inclusion criteria for both groups: age between 18 and 65 years and ability to speak Dutch.

### Exclusion criteria

The exclusion criteria for both groups are: younger than 18 years or older than 65 years, inability to speak Dutch, diagnosed mental retardation, substantial cognitive impairments, current major psychiatric disorders and substance abuse (other than pain medication). It is important to note that mild and moderate anxiety and/or depressive symptoms do not result in exclusion.

## Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 15-08-2019 |
| Enrollment: | 174 |
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 24-04-2019 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 22-08-2019 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 11-06-2020 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |
| Approved WMO Date: | 13-10-2020 |
| Application type: | Amendment |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

## 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 | NL68149.100.18 |