

Ghent attention and self- regulation in fibromyalgia-I- study (ASEF-I): Protocol

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1. Goals

1.1. Bottom-up and top-down modulation of attention

- To investigate distraction effectiveness (as an index of top down modulation) in fibromyalgia patients (FM) and a matched comparison group (CG)
- To investigate to what extent pain interferes with task performance in FM and a matched CG
- To investigate whether task interference by pain and top-down modulation of attention are related using a within-subject design.
- To investigate whether inhibitory control differs between FM and a matched CG.
- To investigate the predictive value of task interference and top-down modulation of attention for pain for daily pain outcomes in FM patients.

1.2. Self-regulation/ emotion-regulation

- To investigate the relationship between heart rate variability (HRV; an index of self-regulatory capacity), emotion-regulation and daily pain outcomes in FM and a matched CG.
- To compare the level of interoceptive awareness between FM and a matched CG
- To investigate the predictive value of emotion regulation (measured via a variety of methods) for daily well-being patterns in FM and a matched CG

1.3. Habituation to pain

- To investigate pain habituation/sensitization patterns in FM and a matched CG

1.4. Dimensionality of emotions

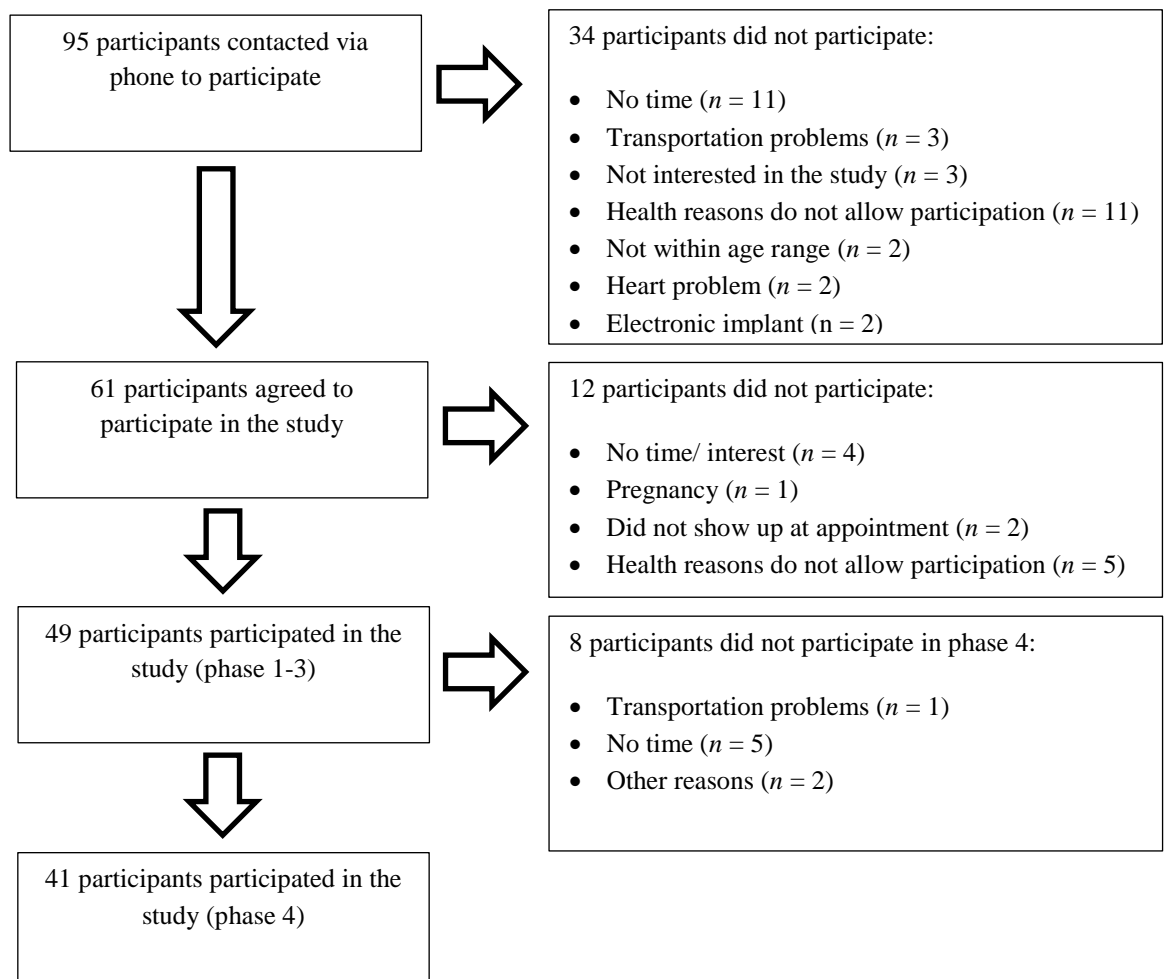
- To compare the emotion dimensions, present in in fibromyalgia patients and a matched comparison group

2. Recruitment of chronic pain patients

Recruitment procedure: FM were recruited via the Multidisciplinary Pain Clinic of a University Hospital. FM patients were informed about the opportunity to participate in future studies by means of a poster in the waiting room of the hospital. Participants who were interested in taking part in future research left their contact details after receiving more information from their caregiver, and reading an information letter. In the period January-March 2014, ninety-five patients were contacted to participate in this study. Sixty-one patients who fulfilled the criteria agreed to participate. However, later on, a further 12 patients decided not to participate. The final sample of participants for phase 1-3 (questionnaires, lab session 1 and end-of-day-diary) consisted of 49 individuals with FM. For phase 4 (lab session 2), eight participants decided not to participate for various reasons. As such, the final sample for phase 4 was 41 individuals with FM.

Inclusion and exclusion criteria: (1) aged between 18 and 65 years; (2) sufficient knowledge of the Dutch language; (3) a diagnosis of FM according to the criteria of Wolfe et al. (2010) and (4) the absence of neurological conditions. Individuals were also excluded when they were unable to use their fingers, reported abnormal sensation on the stimulated location, when their eyesight was not normal or corrected-to-normal (e.g., by glasses), when being pregnant or when wearing an electronic implant.

Fig 1. Flow chart of recruitment FM patients



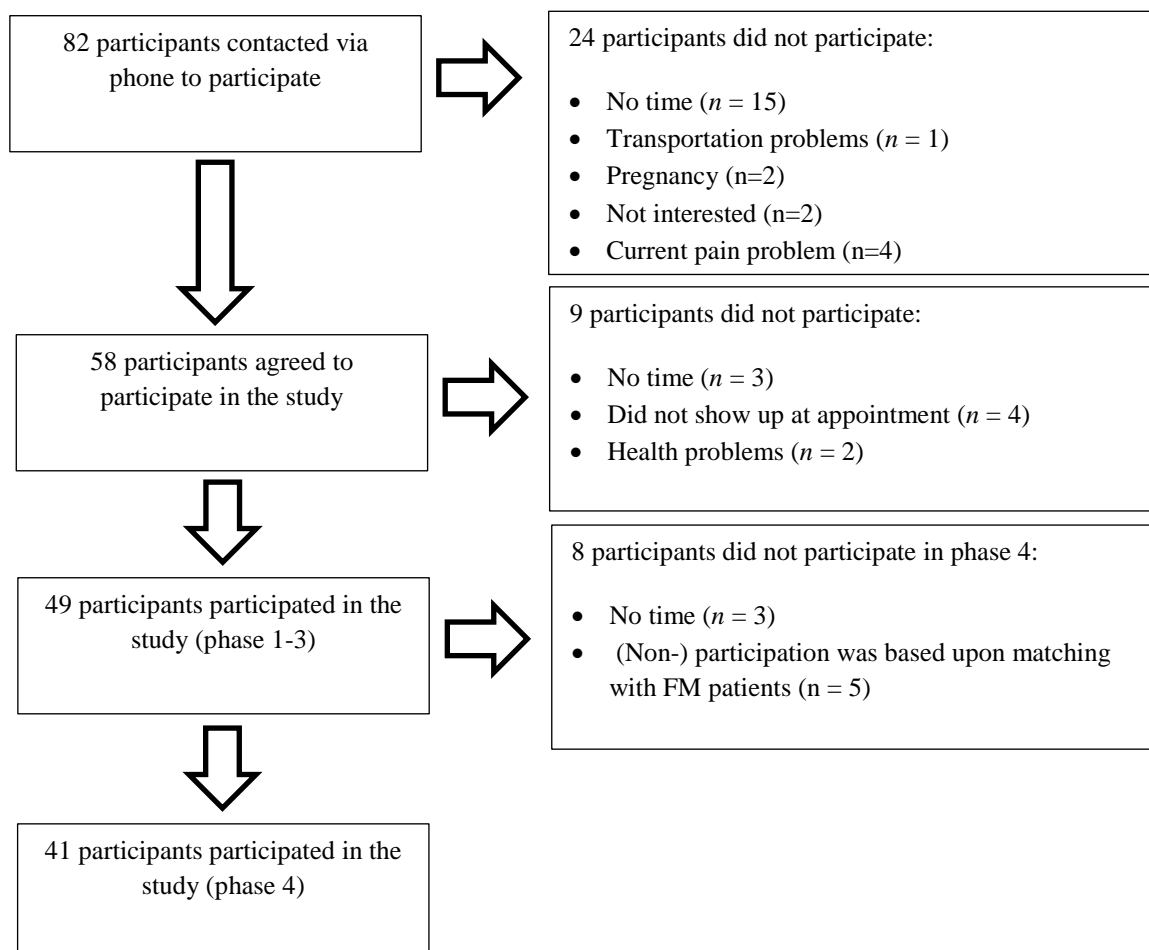
3. Recruitment of the comparison group

Control subjects were matched on group level with chronic pain patients for age, sex and SES.

Recruitment procedure: A comparison group was recruited from a participant pool which is recruited via advertisement in a local newspaper, flyers and the university website. Inclusion and exclusion criteria were similar as in the chronic pain group, except for participants should not report any current pain problems. In the period January-March 2014, 82 individuals were contacted by the researcher to participate in the study. Fifty-eight individuals who fulfilled the criteria agreed to participate. However, later on, further nine persons did not participate. The final sample of the comparison group for phase 1-3 (questionnaires, lab session 1 and end-of-day-diary) consisted of 49 individuals not reporting a current pain problem. For phase 4 (lab session 2), eight participants did not participate for various reasons. As such, the final sample for phase 4 was 41 individuals not reporting a current pain problem.

Inclusion and exclusion criteria: (1) aged between 18 and 65 years; (2) sufficient knowledge of the Dutch language; (3) no current pain problem and (4) the absence of neurological conditions. Individuals were also excluded when they were unable to use their fingers, reported abnormal sensation on the stimulated location, when their eyesight was not normal or corrected-to-normal (e.g., by glasses), when being pregnant or when wearing an electronic implant.

Fig 1. Flow chart of recruitment healthy participants



4. Procedure

The procedure for the participants consisted of four phases:

- Online assessment of questionnaires
- Laboratory session 1 (at university lab)
- Diary assessment
- Laboratory session 2 (at university lab)

4.1. Phase 1: Online assessment of questionnaires

In Phase 1, participants filled out several online questionnaires and demographic information. When participants were unable to fill out these questionnaires, they filled them out on a paper version:

- Demographic questions (Age, gender, SES, pain duration, medication use,...)
- Multidimensional Pain Inventory - Part 1 (MPI-DV Part 1; Lousberg et al., 1999)
- Pain Disability Index (PDI; Pollard, 1984)
- Pain Catastrophizing Scale (PCS; Sullivan, 1995)
- Spielberger State and Trait Anxiety Inventory - Trait scale (STAI; Van der Ploeg et al., 1980)
- Body Vigilance Scale (BVS; Schmidt et al., 1997)
- Depression Anxiety and Stress Scales (DASS-42; Beurs, 2001)
- Ten-Item Personality Inventory (TIPI; Gosling et al., 2003)
- Satisfaction with Life Scale (SWLS; Diener et al., 1985)
- Emotion Regulation Questionnaire (ERQ; Gross. & John, 2003)
- Perseverative Thinking Questionnaire (PTQ; Ehring, 2007)
- Worry Domains Questionnaire Extended (WDQ+; Rijsoort et al., 1997)
- Cognitive Intrusion and Pain Questionnaire (CPIQ; Attridge et al., 2015)
- Committed Action Questionnaire (CAQ; McCracken, 2013)

4.2. Phase 2: Laboratory session 1 (at university lab)

The laboratory session consisted out of two blocks (of about one hour). Between each block, participants had a break of at least 15 minutes.

4.2.1. Block 1

- Questionnaires (before experimental tasks):
 - American College of Rheumatology criteria of FM according to the paper of Wolfe et al. (2010)
 - Questions concerning pain and fatigue at the moment, smoking and coffee consumption within the last 2 hours
- Measurement HRV (10 min)
- Experimental interference-/top-down modulation paradigm (45 min):
Participants performed 2 types of trials intermixed (depending on the presented cue)
 - Somatosensory localization trials
 - Visual localization trials

⇒ Indices: top-down modulation index; task interference index
- Questionnaires (after experimental tasks):
 - Questions concerning Medication use.
 - Task difficulty, task commitment (e.g., “How much pain do you have at this moment?”, “How difficult did you think the task was?”)

4.2.2. Block 2

- Heartbeat tracking task according to Schandry (1981)
Participants were seated in a chair and needed to count their heartbeats for 4 randomly presented time intervals (25s, 35s, 45s, 55s)
- Habituation paradigm:

Participants perceived 15 similar heat pulses (Medoc) of moderate intensity (individually determined per person) with an inter-trial-interval of 30 seconds. After each pain trial participants rated the stimulus on a pain VAS scale (0= not painful – 10= worst imaginable pain”)

- Explanation of the diary items and diary assessment: each of the items was carefully explained to the participants to make sure participants understood the items correctly.
- Scheduling appointment lab session 2

4.3. Phase 3: Diary

Participants were asked to fill out an online diary at the end of each day for 14 days. Participants were reminded to fill out the diary each day in the evening by means of a text message. The diary took approximately five minutes to complete. Following outcomes were assessed:

- Pain intensity (3 items)
 - Pain intensity in the morning (1 item)
 - Pain intensity over the past day (2 items)
- Fatigue (2 items)
 - Fatigue level in the morning (1 item)
 - Fatigue level over the past day (1 item)
- Disability/interference during the past day (2 items)
- Persistence behavior during the past day (1 item)
- Distractibility during the past day (1 item)
- Pain-related worries during the past day (1 item)
- Non-pain-related worries during the past day (1 item)
- Attention for pain during the past day (1 item)
- Feelings of social understanding (1 item)
- Experienced emotions during the past day (16 items)

4.4. Phase 4: Laboratory session 2 (at university lab)

4.4.1. Block 1

- STOP-IT (Stop-signal task; Verbruggen et al., 2008)
- Diary reconstruction method (DRM; Kahneman et al., 2004)
During this diary assessment people reflected upon yesterday, partitioned yesterday in episodes and answered following questions per episode:
 - Activity during the episode
 - Contact with other people during the episode
 - Pain-related concern during the episode (1 item)
 - Non-pain-related worries during the episode (2 items)
 - Degree of non-pain-related worries (1 item)
 - Domain of non-pain-related worries (1 item)
 - Fatigue during episode (1 item)
 - Pain during episode (1 item)
 - Disability during episode (1 item)
 - Experienced emotions during episode (16 items)

5. References

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