Pain Induction: safety guidelines and Procedures

Faculty of Psychology and Neuroscience Maastricht University

The following document describes:

- Aim
- General FPN Safety guidelines and procedures
  - Electrical Safety
  - Reducing Risk for Disease Transmission
  - Additional safety information
- Adverse effects: procedure
- Description of pain induction techniques frequently used at FPN
- Availability and reservation of pain induction equipment
- Checklist for description pain induction procedures in ERCPN proposals

---

Aim of this document

This document describes procedural and safety guidelines for pain induction procedures at the Faculty of Psychology and Neuroscience (FPN). Researchers who incorporate pain induction procedures in their research can turn to this document for helpful information concerning ethical and safety issues.
Ethical procedures and guidelines as described in this document apply to **all** pain induction procedures conducted at FPN. Note that **each** pain induction procedure that is part of study protocols of research conducted at FPN needs approval by ERCPN (see checklist in this document). When the study is part of an approved research line, the **single study form** should be used to provide full description of new or deviating pain induction procedures to the original research line application.

This document has been approved by the Ethics Review Committee of Psychology and Neuroscience (ERCPN).

General FPN Safety guidelines and procedures

Before initiating work with pain induction procedures, researchers are expected to familiarize themselves with safety and technical aspects of this equipment. The principal investigator (i.e., supervisor) is ultimately responsible for proper guidance, training, and supervision of junior researchers and students who conduct experiments that incorporate pain induction procedures.

Electrical safety

In order to maintain electrical safety and avoid exposure of participants and researchers to current the following rules need to be taken into account:

- Always use the pain induction setup in accordance with the legal standards and internal procedures of FPN / UM as also stated in this document.

- Before (first) use of equipment always read the manual of the equipment and make sure to follow the instructions given by the manufacturer and/or Instrumentation Engineering (IE).
- Always connect equipment following the enclosed drawings and /or instructions.
- All equipment used for pain induction procedures is CE certified and checked periodically for safety by FPN Instrumentation Engineering (IE). Be aware that any modification to equipment or addition of new equipment can cause (serious) safety issues and/or noise issues and is not allowed without proper clearance from IE and ERCPN.
- Do not connect new or modify existing equipment without consulting IE first.

Reducing risk for disease transmission

- Wash hands before and after working with a participant.
- Use disposable gloves during skin scrubbing and cleaning (do not re-use gloves).
- Only use new and clean items to clean skin and equipment (do not re-use items).
- Dispose (or disinfect) items that have been in contact with skin immediately after use.

Chemical safety

In order to maintain chemical safety and avoid exposure of participants and researchers to hazardous materials only use chemicals following the legal standards and internal procedures of UM / FPN.

Additional Safety Information

- Please keep the equipment, electrodes, probes, labs, as well as the general lab area and closets, neat and clean
- Note that according to UM Health and Safety policy it is not allowed to bring food or beverages into the lab areas.

Participant screening and information

1) General exclusion criteria for use of pain induction techniques are:
   i. cardiovascular disorders
   ii. pregnancy

   Furthermore, specific exclusion criteria can apply for specific equipment or specific target groups.

2) Participant information: participants should be informed that participation in the study includes exposure to stimuli that can be experienced as uncomfortable in case of sensoric sensation or as painful in case of testing to pain tolerance levels

3) In accordance with guidelines for Pain Research in Humans as put forward by the International association for study of pain (IASP: https://www.iasp-pain.org/resources/guidelines/ethical-guidelines-for-pain-research-in-humans/)
   i. In any pain research, stimuli should never exceed a participant's tolerance limit
   ii. Participants should be able to escape or terminate a painful stimulus at will.
   iii. The minimal intensity of noxious stimulus necessary to achieve goals of the study should be established and not exceeded.

Checking for adverse effects and rest symptoms due to the pain induction

At the end of the experimental session, check for rest symptoms that might originate from exposure to the pain induction. Next to the debriefing on paper, ask the participant whether they feel ok before they leave the test appointment. Inspect the skin area where pain induction was administered for abnormalities and ask the participant about the experience of any after-effects. In case of reported and/or visible rest symptoms, organize a follow-up contact moment with the participant (e.g. by telephone, message), preferably later the same day, to evaluate the status of these adverse symptoms. If symptoms remain: follow "adverse effect procedure" as explained below. All participants in pain induction procedures should be informed that they are expected to contact the researcher when adverse symptoms, considered attributable to the pain induction procedure, occur at a later stage in time (e.g. via debriefing form).

Adverse effects: Procedure
In case of adverse effects, immediately inform ERCPN through ercpn-fpn@maastrichtuniversity.nl and document the adverse event as detailed as possible, include a photo of the damage where possible.

Checklist for describing pain induction procedures in ERCPN proposals

The Project Proposal Meeting – pain (PPM-pain) will evaluate each study including pain induction procedures by means of evaluating criteria mentioned below.

- Specify details of pain induction device used (device model, manufacturer, …)
- Refer to prior approved procedures using similar pain induction techniques where applicable; provide rationale for deviations from previous approved stimulus parameters
- Specify stimulus characteristics: intensity, duration, method and location of stimulus administration, amount of stimuli, …
- Specify exclusion criteria, adapted to the equipment and target group
- Specify how exclusion criteria will be checked
- Indicate how stimulus characteristic are in accordance with safety regulations (e.g. maximal intensity boundaries of equipment, preset boundaries by researcher, tissue damage, …)
- Specify how risk of side effects and or tissue damage is prevented (e.g., chosen intensity level; breaks in between successive administrations of painful stimuli to prevent burn wounds; relocate electrodes/stimulation probe in between trials; …)
- Specify how the pain tolerance limit of participants is respected. It is recommended to determine tolerance in a pre-experimental phase using a calibration procedure (e.g., stepwise procedure with gradually increasing stimulus intensity level).
- Specify how the study set-up allows termination of the stimulus by the participant.
- Specify if and how participants are informed ***beforehand*** about exposure to potential painful stimuli (note. By default, ERCPN requires that participants are fully informed about exposure to aversive, potentially painful stimuli prior to signing up for the study; if researchers consider it necessary to deviate from this, argumentation to ERCPN explaining why this is necessary should be included)

Practical information

Pain induction equipment FPN

- Cold pressor task (for pain and stress procedures : SECPT and MAST)
- Electrocutaneous stimulation

A brief description on safety procedures and regulations concerning these devices is provided in the appendix of this document

In addition to this equipment, other devices are used by individual researchers/ research groups and incorporate: thermal heat pain, ischemic pain, pressure pain, finger weight, cold-hot plate, …

Booking labs and Pain induction equipment

Pain induction devices are available at both locations of FPN (Oxford building and UNS40). Some devices are mobile, meaning that it is possible to implement them in labs in UM buildings at Randwijck. However, for practical reasons, most devices have been assigned to a specific lab. Both labs and equipment can be found in resource booker (https://resourcebooker.maastrichtuniversity.nl).

Devices and labs can be booked by contacting their lab coordinator (see resource booker). Note that use of mobile devices in your study requires a separate reservation for lab and equipment. The possibility to move and install equipment should **always be discussed in advance** with Instrumentation Engineering (IE) and the device coordinator.

Instrumentation

- Head: Huub Hamers (3881919), h.hamers@maastrichtuniversity.nl , UNS40-3.777a
- Johan Gielissen (3884007), j.gielissen@maastrichtuniversity.nl , UNS40- 3.756k
- Luc Offermans (381552), l.offermans@maastrichtuniversity.nl, UNS40- 3756k
- Erik Bongaerts (3882175), erik.bongaerts@maastrichtuniversity.nl , UNS40- 3.756k

Ethical approval

- Ethical approval is required for all studies conducted under the responsibility of FPN staff: click here for a link to the website of ercpn.
- Contact: ercpn-fpn@maastrichtuniversity.nl

Appendix: Cold Pain and Electrocutaneous stimulation

Cold pressor task (Julabo®, Seelbach, Germany)

Brief description: The cold pressor task consists of a Plexiglas box containing an electric immersion cooler (type FT200) and a bath circulator (type ED-19A).
In a CP procedure, the hand is immersed in the water up until the wrist. It is common to standardize skin temperature prior to immersion in the cold water by placing the hand in a bath with water at room temperature. In a pain tolerance procedure, participants are instructed to immerse the hand for as long as they can, thereby respecting a maximal immersion time of 5 minutes. For sensory and affective pain ratings, a fixed immersion time of 60 seconds is recommended.

Water temperature: Although no exact guidelines have been formulated in the literature, there is consensus that water temperatures between 2 and 6 °C are to be used to examine pain responses in adult populations (Mitchell, McDonald, Brody, 2004). Higher temperatures are often recommended in children populations (5-10 °C) (VonBaeyer; Piira, Chambers et al, 2005; Birnie, Parker & Chambers, 2014).
For SECPT/MAST procedure, a water temperature between 2-4 degrees is recommended.

Known Side effects: There are no known persistent side- or after-effects. Short lived aftereffects include general redness of the immersed limb and tingling sensations immediately after removing hand form the water. These after effects are known to resolve in 5-10 minutes after hand withdrawal.

Duration: maximal immersion time can vary between 5 and 10 minutes. By defaults, our pain lab uses a maximal duration of 5 minutes (pain ratings are known to be maximal at this point, no additive value of longer immersion time).
In case of repetitive immersions (e.g. SEPCT/MAST protocol), total immersion time should not exceed 10 minutes.

Additional procedural **safety guidelines** when working with the CPT
In order to minimalize risks at fainting and consequences thereof please follow these procedural guidelines:

- Additional exclusion criterion: Reynaud's disease
- Participants should be seated while performing the CPT.
- Participants cannot participate when they have not eaten or drunk anything in the 4 hours preceding the study. Instruct participants explicitly to eat something in the 4 hours before the session (i.e., in a reminder email) and check this with an open-ended question at the beginning of the test day. (Note. For SECPT/MAST procedures, a time window between 2.5 and 2 hours preceding the test appointment is recommended).

Electrocutaneuous stimulation: Digitimer DS5 or DS7a: Digitimer, Welwyn Garden City, England; http://digitimer.com/products/research/stimulators

Brief description: Both the DS5 and the DS7a are commercial stimulators that are EC certified and tested for EMC conformity of medical Devices. The stimulators can deliver discrete or tonic unpleasant, painful, and nonpainful electrical stimuli.

DS7A delivers sinuswave pulses (maximal duration = 2 ms), varying in intensity from 1 to maximally 99.99 mA. DS5 can deliver more complex electrical stimulation, making use of different waveforms. It can be used to deliver trains of electrical pulses and tonic electrocutaneous stimulation of intensities between 1 and maximally 10 mA (220V, 50Hz).

Stimulus location: Stimuli are delivered at hand, ankle, lower inner arm (wrist), or upper arm (triceps tendon). Prior to placing electrodes, skin area is prepared by applying a mild, alcoholfree skin wash or by applying a scrub gel.

Electrodes: Stimuli are delivered through 2 re-usable surface Ag/AgCl electrodes (e.g. SensorMedics; 0.8-1.0 cm diameter) or bar stimulation electrodes (0.8 cm; e.g., digitimer) filled with electroconductive gel (e.g., K-Y gel). Electrodes are typically placed at an interelectrode distance of 1cm.
Electrodes should be cleaned after each use using a cotton and a mild, alcohol free disinfection wash.

Known Side effects: Electrocutaneuos stimulation is suitable to use for both discrete and tonic pain stimulation for prolonged periods of time without adverse effects.
There are no known persistent side- or after-effects. The most often reported and generally short-lived effect is a redness of the skin area due to removal of stickers that were placed on skin for holding electrodes, or redness of skin to allergic reaction to skin preparation gel or electroconductive gel.

Additional procedural **safety guidelines** when working with electrocutaneuous stimuli:

- Persons wearing electronic implants (e.g. pacemaker) are not eligible to participate in research with electrocutaneous stimulation. This should be actively checked in each participant.
- Stimulating electrodes should be placed at one limb at one side of the body (not thoracically or trans- thoracically to prevent current from crossing the heart and risk of cardiac fibrillation)
- When single electrodes are used, they should be properly marked to prevent them from being switched with other re-usable single measurement electrodes.
- It is recommended to use an electrode holder that fixes the electrodes at constant interelectrode distance and prevents switching of electrodes (e.g. bar stimulating electrode,0.8mm; Digitimer).
- Electrocutaneous stimulation cannot be used simultaneously with other tasks including immersion in or exposure to fluids, such as the cold pressor task.
- Do not place electrodes on damaged skin (wounds, skin irritation, ...)