

Hypnosis can reduce pain in hospitalized older patients

Submission date 16/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/08/2016	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Chronic pain is a common and serious health problem in the elderly. Various epidemiological studies estimate that between 25% and 65% of elderly people who live in the community and up to 80% in institutionalized elderly people. The most common chronic, non-malignant pain conditions in the elderly are musculoskeletal pain located in the joints and back due to osteoarthritis or osteoporosis fractures in addition to neuropathic pain such as post-herpetic neuralgia and peripheral neuropathy. Living with pain has an impact on elderly people's overall functioning and quality of life. Patients suffering from chronic pain often have depression, sleep disturbances and impaired functionality with an impact on their quality of life. The management of an elderly patient with chronic pain includes both pharmacological and non-pharmacological treatment.. The increased risk of polypharmacy, adverse side-effects and intoxication in elderly adults, compared to younger adults, is well recognized, leading to an increased interest in non-pharmacological approaches. These include psychological support, physiotherapy, massage or hypnosis for example. Hypnosis is an altered state of consciousness or state of focused attention to verbal stimuli induced by the therapist (hetero-hypnosis) or the subject himself (self-hypnosis). To enter 'hypnosis' means "to enter" in "another" state, a transition from a normal ordinary state of consciousness. The patient is always in control and can stop the process whenever he desires to do so. The practice of self-hypnosis has been shown in studies to be an important element in the long term control of chronic pain. Self-hypnosis can be taught to the patient as a tool to modify behavior regarding nociceptive perception. It allows him to take an active part in his own pain management using personal resources and experiences. The aim of this study is to test whether hypnosis is a feasible and effective treatment for pain in older patients currently in hospital.

Who can participate?

Adults aged 60 who have experienced chronic pain for at least 3 months

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 are allocated to the intervention (hypnosis) group. Those in group 2 were allocated to the control (massage) group. Participants in the intervention group receive a brief hypnosis treatment. This involves three hypnosis sessions, each lasting 30 minutes , one day a week. Participants in the control

group receive three massage sessions, each lasting 30 minutes, one day a week. All participants are asked to report on the pain they experience and how it is affecting their daily lives at the start of the study and then after one week, two weeks, when they are discharged from hospital and then, finally, at 12 weeks later.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital Geneva (Switzerland)

When is the study starting and how long is it expected to run for?
January 2010 to December 2010

Who is funding the study?
University Hospital Geneva (Switzerland)

Who is the main contact?
Dr Sophie Pautex
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocole 10-232/Psy 10-029

Study information

Scientific Title

Hypnosis can reduce pain in hospitalized older patients: a randomized controlled study

Study objectives

Our hypothesis was that hypnosis would be feasible and effective in decreasing pain intensity in hospitalized older patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethic committee University Hospital Geneva, 20/12/2010, ref: Protocol 10-232/Psy 10-029.20.12.2010

Study design

Randomized controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Potentially eligible patients were identified by the team in charge of the patient or by the pain and palliative care consultation team.

Interventions

A single center randomized controlled trial using a two arm design (hypnosis versus massage) to assess the immediate and prolonged effect of hypnosis on the management of chronic pain in elderly patients.

Hypnosis:

The session was designed as suggested by Jensen and Petterson as a "brief hypnosis treatment". Three sessions of 30 minutes (once a week according to the general condition of the patient) were conducted by a physician trained in medical hypnosis. We opted for a short number of sessions, because of the patients' length of hospitalization. Before the session it was explained to the patients that the intervention consists in teaching them specific skills to help provide pain relief. The session was divided in the classical phases of hypnosis including induction, deepening and post hypnotic suggestions. During induction, patients were asked to imagine themselves in a nice place and to make some suggestions (selected according to their personal history) for analgesia and comfort. We practiced deepening and post hypnotic suggestions to obtain an effect of the treatment on the long run and to encourage the practice of self-hypnosis. Post-

hypnotic suggestions were given by the therapist during the session that allow anchor and influence in the therapeutic goal established with the patient's perception of pain, time, memory, anxiety. Self-hypnosis was taught to the patient, with the aim to give them some form of control over pain.

Massage:

Massage is a technique that provides relaxation and improves well-being which helps reduce the feeling of pain. Three sessions of 30 minutes (once a week according to the general condition of the patient) were conducted by a nurse with a certification in massage. Patient was comfortably installed in a quiet room. At each session the patient could choose the area of massage: back massage or hands and arms or legs and feet (possibly abdomen or face).

Intervention Type

Behavioural

Primary outcome measure

The third question of the Brief Pain Inventory (BPI) (average pain) measured at inclusion (T0), week one (T1) and two (T2), at discharge (T3) and 12 weeks (T12) later

Secondary outcome measures

The second part (pain interference with daily activities; 7 items) of the BPI measured at inclusion, at T0, T1, T2 and T3[20]. The BPI measures interference of pain with daily activities over the last 24 hours (mood, walking ability, normal work [including household], relationships, sleep, and enjoyment of life).The items are rated on a 0 to 10 scale, where 0 = no interference and 10 = interference as bad you can imagine. Mean interference score was calculated

Overall study start date

01/01/2010

Completion date

31/12/2010

Eligibility

Key inclusion criteria

Potentially eligible patients were identified by the team in charge of the patient or by the pain and palliative care consultation team. Patients were included starting from the fifth day of hospitalization, after stabilization of their acute illnesses.

Inclusion criteria were:

1. Chronic pain for more than 3 months with impact on daily living activities.
2. Intensity of pain higher than 4 on a numerical pain rating scale (0-10) at inclusion despite adequate analgesia.
3. EStatus examination >25
4. Post-traumatic stress disease
5. Active skin disease with a contraindication for massage

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

50

Key exclusion criteria

1. Deafness
2. Patient in his last days of life
3. Psychosis
4. Delirium (according to DSM-IV)
5. Cognitive impairment

Date of first enrolment

01/01/2010

Date of final enrolment

01/12/2010

Locations

Countries of recruitment

Switzerland

Study participating centre

University Hospital Geneva
Rue Gabrielle-Perret-Gentil 4
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Sponsor information

Organisation

University Hospital Geneva

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Sponsor type

Hospital/treatment centre

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ROR

<https://ror.org/01m1pv723>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Geneva (Switzerland)

Results and Publications

Publication and dissemination plan**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/01/2016		Yes	No