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The use of hypnosis to improve pain management during voluntary interruption of pregnancy

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26/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/01/2008	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MCT-68538

Study information

Scientific Title

Acronym
Hyp_IVG

Study objectives
The growing interest of women for complementary and alternative medicines underlines the need to explore new approaches. By the hypnosis technique, it is possible to modify the subjective experiment of pain by suitable suggestions of analgesia. The interruption of pregnancy is a painful intervention with high prevalence. Following a pilot study carried out at the planning Department of Saint-François dAssise Hospital, the main objective is to evaluate by a randomized clinical trial if a short intervention of hypnosis before and during the intervention has a direct impact on the anxiety and the pain perceived by the women at the time of the abortion. The patients who wish to take part in the study will benefit, according to the randomization, of usual care or an intervention of hypnosis. All women, independently of the group, will have access, at their request, to the analgesics usually proposed to the women at the time of abortion. Hypnosis could be a clinical alternative for the relief of pain at the time of the abortion. Its use in acute pain, if it is effective, could constitute an example of integration of a more individualized care among standardized care of high quality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Comité d'éthique de la recherche clinique de l'Hopital St-François d'Assise, Quebec (Canada) on the 11th November 2004.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Voluntary interruption of pregnancy

Interventions
Hypnosis versus standard care.

Standard care group:
After randomization, patients in the standard care group will wait in a comfortable chair for 20 minutes before the procedure, usually in the company of a relative or a friend. The family planning nurse will be available to provide attention to the patient during those 20 minutes. Then the patient will enter the operating room with the nurse and lie supine on a gynecological table. As the abortion will be performed by the physician, the family planning nurse will provide attention and support to the patient, talking and listening to her, giving positive encouragement, reassurance, instructions for relaxation (abdominal and pelvic area) and deep breathing. There will be no instructions for imagery and no suggestions directed at decreasing pain or anxiety.

Hypnosis group:
A medical doctor will complete 30 hours of training in hypnosis prior to conducting the study (Introductory Sessions, Société Québécoise dHypnose). This training will focus on the basic skills of induction, hypnosis theory, and the integration of hypnosis into clinical practice. Demonstrations and opportunities for practice will be provided to enable participants to begin utilizing hypnosis in their clinical practice. The specific script used in this study will be developed with the collaboration of the co-investigators and psychologists in charge of the training. Practice will then be centered on the needs of the current project and the written script will be tested on five female volunteers for acceptability.

Pre-surgical hypnotic intervention:
After randomization, and for the 20 minutes leading up to the procedure, patients in the hypnosis group will sit in a comfortable chair in a different room from the waiting area, where they will meet with the hypnosis provider. First, misconceptions about hypnosis will be cleared up to facilitate a positive attitude. The practitioner will then induce hypnosis by reading from a script prepared for this purpose. Physical and mental relaxation will be initiated by a suggestion of deep breathing, fixation on a part of the hand, and a sensation of floating or heaviness. Several analgesic strategies will then be tried with suggestions generally phrased to facilitate dissociation (e.g. 'the hand' instead of 'your hand'). Focal anesthesia suggestions inducing numbness of the hand (glove anesthesia) will be given to the patient with additional suggestions to transfer the numbness to the abdominal area by placing the hand on the abdomen. Suggestions for imagery will be introduced, including feelings of a warm or a cold wave of light spreading in the body, and relaxation in a safe and pleasant place that they particularly like. Direct suggestions to decrease pain intensity (like a rheostat) and unpleasantness (feeling more comfortable) during the surgical procedure will also be introduced. The patient will also be told that she is able to ask for anything that would increase her comfort during the surgical procedure. The total duration of the pre-surgical hypnotic induction was 20 minutes.

Surgical hypnotic intervention:
The patient will then be asked to walk to the surgery room with the hypnotist. The patient will be told that if she 'comes out' of hypnosis, she will be able to get back into this state once in the surgery room. Once she will be positioned supine on the surgical table, the hypnotist practitioner will suggest that she goes back deeper into hypnosis. Hypnosis will continue throughout the procedure to buffer response to painful stimuli using the same suggestions of

well-being and imagery, and emphasizing decreased intensity and unpleasantness of pain using the preferred analgesic strategies that were introduced during the pre-surgical induction. The patient will be told again that she can ask for anything that would increase her comfort at any time during the procedure. At the end of the surgical procedure (removal of the speculum), the patient will receive suggestions to end hypnosis and become alert.

Surgical procedure:
The surgical procedure will be similar to the ones outlined in the clinical policy guidelines and the paper by Burnhill. In the operating room, the standard procedure will begin by a brief preoperative discussion with the physician performing the abortion. The procedure will be performed by one of four physicians involved in this study. The patient will then lie back on the gynecological table. After a manual pelvic examination, the surgeon will insert a sterile vaginal speculum (Step 1) and will then inject 1 to 2 cc of 0.5% lidocaine at 12 oclock on the cervix and an additional 5 cc each at 4 and 8 oclock at 1 to 2 cm-deep for a total volume of 12 cc of lidocaine. Dilators will be used to dilate the cervix sufficiently (Step 2, maximal dilatation) to admit a rigid vacuum cannula of 8 to 12 mm depending of the gestational age (typically a 9 mm cannula is used for a 9 week gestational age). The uterine contents will be evacuated with suction (Step 3) with a uterine aspirator at maximum vacuum. Suction will follow by a sharp curetage (Step 4) to confirm that the uterus was empty. If necessary, a re-aspiration of the uterine contents will be performed. The patient will recover for a few minutes on the table and will then walk to the recovery room. Most of the patients will be discharged within 1-2 hours after the end of the procedure.

At each step of the procedure, women usually experience pain, the most painful step being the suction of the uterine contents (Step 3). Cervical dilatation is also a painful and difficult part of surgical evacuation, and cervical priming may have a very important effect on the amount of pain that the patient experiences. Furthermore, women often experience pain before the surgical procedure. To help with cervical dilatation, laminaria tents will be used, 4 to 20 hours before the abortion. Indications for the use of laminaria tents will include women whose pregnancies were greater than or equal to 9 weeks, stenosis and surgical history of the cervix, age less than 20, gravida greater than or equal to 5.

During the surgical procedure, patients will be monitored continuously by pulse oxymetry for oxygen desaturation and for changes in blood pressure and heart rate.

Initial assessment on arrival:
Self reported anxiety and pain. Patient self-reported anxiety and pain will be assessed before randomization. In both the hypnosis group and the control group, the practitioner will ask the patient to rate her anxiety and pain on an 11-point verbal numerical scale. Anxiety levels will be assessed on scales from 0 to 10 (0 = not anxious at all; 10 = the most anxious that you can be). Intensity of pain will be rated on separate scale from 0 to 10 (0 = no pain at all; 10 = the most intense pain possible). These verbal scales have been validated for pain and anxiety.

Other measurements: Furthermore, before randomization, expected pain intensity will be assessed. The Pain Catastrophizing Scales (PCS) will be used to assess emotions previously shown to affect pain. A questionnaire assesses the belief in hypnosis in the two groups before randomisation.

During the surgical procedure:
Assessment of medication requirement. Intravenous sedation during abortion will be assessed as a dichotomous variable (requested or not requested by the patient) at any step of the surgical procedure: insertion of speculum, maximum dilation, suction, and end of curettage abortion.

Irrespective of her group, each patient will be allowed to receive sedation as she wants and whenever she wants during the procedure.
Assessment of pain and anxiety. Patient self-reported anxiety and pain (intensity and unpleasantness) will be assessed using the same 11-point verbal scales described above at each of the 3rd step of the procedure (aspiration).

During recovery:
Once again, patient self-reported anxiety and intensity of pain and relief will be assessed using the same scales described above. Additional questionnaires will be administered to obtain demographic information (maternal age, gestational age, parity, previous history of abortion). The physician who will perform the abortion will also complete a questionnaire describing oral medication administered before or after the abortion and the pre-surgical use of a laminaria tent to facilitate cervical dilation. His appreciation of the overall success of the procedure will be assessed with a short series of questions regarding surgical difficulties on a ten-point scales (ranging from the worse to the best). The duration of the procedure will be calculated from the total time spent by the women in the surgical room.

Trial details received: 12 Sept 2005

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Duration of procedure
2. Susceptibility of hypnosis
3. Belief in hypnosis
4. Expected pain and relief

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/12/2004

Completion date
01/09/2005

Eligibility

Key inclusion criteria
1. Women of 18 years old and older
2. Pregnancy term greater than or equal to 6 weeks and less than 14 weeks
3. Signature of consent form for the pregnancy interruption
4. Signature of consent form for the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
350

Key exclusion criteria
1. Incapacity to complete consent form
2. Medical indication of fentanyl premedication
3. Use of antidepressants
4. Consumption of drugs the day of abortion
5. Incapacity to understand the French language

Date of first enrolment
01/12/2004

Date of final enrolment
01/09/2005

Locations

Countries of recruitment
Canada

Study participating centre
Hôpital Saint-François d'Assise-CHUQ
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/04sjchr03

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-68538)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration