Hypnosis Antenatal Training for Childbirth (HATCh): a Randomised Controlled Trial

This study is currently recruiting patients.

Verified by Women's and Children's Hospital January 2006

Sponsored by: **Women's and Children's Hospital**

Information provided by: Women's and Children's Hospital

ClinicalTrials.gov Identifier: NCT00282204

Purpose

Antenatal hypnosis is associated with a reduced need for pharmacological interventions during childbirth. This trial seeks to determine the efficacy or otherwise of antenatal group hypnosis preparation for childbirth in late pregnancy.

Condition	Intervention	Phase
Pregnancy Analgesia	Behavior: antenatal hypnosis + audio compact disc on hypnosis Behavior: Audio compact disc on hypnosis	Phase II Phase III

MedlinePlus consumer health information

Study Type: Interventional
Study Design: Prevention, Randomized, Single Blind, Active Control, Factorial Assignment, Safety/Efficacy Study

Official Title: Hypnosis Antenatal Training for Childbirth (HATCh): a Randomised Controlled Trial

Further study details as provided by Women's and Children's Hospital:

Primary Outcomes: The use of pharmacological analgesia during labour and childbirth will be collected from the birth register where all analgesia is documented by the attending midwife
Secondary Outcomes: 1. Maternal rating of the overall pain experienced during labour and childbirth; 2. Mode of delivery; 3. Use of oxytocics; 4. Postnatal depression; 5. Maternal anxiety; 6. Neonatal Apgar score at 5 minutes < 7; 7. Maternal admission to the High Dependency Unit (HDU) or the Intensive Care Unit (ICU); 8. Maternal rating whether the birth experience was. Worse / better / same as expected; 9. Maternal rating of control during the

labour during the birth; 10. Maternal rating whether the birth was rated positive or negative experience; 11. Length of neonatal nursery stay; 12. Length of maternal stay in hospital; 13. Number of women breast feeding at discharge from hospital and at 6 weeks and 6 months
Expected Total Enrollment: 450

Study start: December 2005

Background: Although medical interventions play an important role in preserving lives and maternal comfort they have become increasingly routine in normal childbirth. This may increase the risk of associated complications and a less satisfactory birth experience. Antenatal hypnosis is associated with a reduced need for pharmacological interventions during childbirth. This trial seeks to determine the efficacy or otherwise of antenatal group hypnosis preparation for childbirth in late pregnancy.

Methods / Design: A single centre, randomised controlled trial using a 3 arm parallel group design in the largest tertiary maternity unit in South Australia. Group 1 participants receive antenatal hypnosis training in preparation for childbirth administered by a qualified hypnotherapist with the use of an audio compact disc on hypnosis for re-enforcement; Group 2 consists of antenatal hypnosis training in preparation for childbirth using an audio compact disc on hypnosis administered by a nurse with no training in hypnotherapy; Group 3 participants continue with their usual preparation for childbirth with no additional intervention. Women > 34 < 39 weeks gestation, with a singleton, viable fetus, vertex presentation, who are not in active labour or planning a vaginal birth are eligible to participate. Allocation concealment is achieved using telephone randomisation. Participants assigned to hypnosis groups are trained as near as possible to 37 weeks gestation. Group allocations are concealed from treating obstetricians, anaesthetists, midwives and those personnel collecting and analysing data. Our sample size of 135 women / group gives the study 80% power to detect a clinically relevant fall of 20% in the number of women requiring pharmacological analgesia – the primary endpoint. We estimate that approximately 5-10% of women will deliver prior to receiving their allocated intervention. We plan to recruit 150 women / group and perform interim analyses when 150 and 300 participants have been recruited. All participants will be analysed according to the “Intention to treat” principle with comprehensive pre-planned cost- benefit and subgroup analyses.

Discussion: If effective, hypnosis would be a simple, inexpensive way to improve the childbirth experience, reduce complications associated with pharmacological interventions, yield cost savings in maternity care, and provide evidence to guide clinical practice.

Eligibility

Genders Eligible for Study: Female

Criteria

Inclusion Criteria:

- women > 34 < 39 weeks gestation; singleton, viable fetus, vertex presentation, who are not in active labour (active labour is defined as cervical effacement and dilatation associated with regular uterine contractions) and who are planning a vaginal birth.

Exclusion Criteria:

Previous hypnosis preparation for childbirth; poor understanding of English requiring translator; women who are already enrolled in another pregnancy trial where analgesia requirements are an outcome measure; active psychological or psychiatric problems such as: active depression requiring treatment by a psychiatrist; schizophrenia; prior psychosis; severe intellectual disability. Women with pain caused by specific pathological entities such as: congenital neuromuscular disorders; spina bifida; metastatic disease; osteoporosis; rheumatoid arthritis; fractures,are also excluded

Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00282204

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More Information

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