Hypnosis Antenatal Training for Childbirth (HATCh): a randomised controlled trial [NCT00282204]

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Received January 15, 2006; Accepted March 5, 2006.

Abstract

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 and < 39 weeks gestation, planning a vaginal birth, not in active labour, with a singleton, viable fetus of vertex presentation, are eligible to participate. Allocation concealment is achieved using telephone randomisation. Participants assigned to hypnosis groups commence hypnosis training as near as possible to 37 weeks gestation. Treatment 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 sequential interim analyses when 150 and 300 participants have been recruited. All participant data will be analysed, by a researcher blinded to treatment allocation, 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 this trial will provide evidence to guide clinical practice.

Go to:

Background
Pain during labour and childbirth represents a complex interaction of multiple physiological and psychological factors [1]. Techniques such as epidural analgesia, have been shown to be the most effective form of pain relief in labour[2] but, can deprive the mother of an optimal birth experience[3] and are associated with adverse effects such as post-dural puncture headache and neurological injury [4,5]. Although, long term sequelae are rare, such complications can be debilitating and extremely distressing when they occur [6]. All pharmacological interventions cross the placenta to some degree which leads to concerns of adverse effects on the fetus. The recent Australia and New Zealand College of Anaesthetists (ANZCA) working party report emphasises that non-pharmacological treatment options should be considered before analgesic medications are used particularly just before delivery [1]. Women's desires for and expectations of pain relief during labour and delivery vary widely [7] and high quality pain relief does not necessarily equate with a high level of satisfaction [8]. The increasing medicalisation of childbirth [9] has led many women to look for alternative means of relieving labour pain [10].

Fear, anxiety and maternal feelings of a loss of control frequently play a role in the incidence and intensity of pain during childbirth and are associated with an increased risk of post-traumatic stress disorder[11] and postnatal depression [12,13]. Hypnosis is a psychological intervention that has been shown to provide analgesia and reduce anxiety and in the peri-operative setting [14-16] and since the mid 1980s has been advocated as a useful tool in the management of depression [17,18]. Claims that
hypnosis is a safe and valuable tool in pregnancy and childbirth [19-21] is supported by numerous reports in the literature describing the successful use of hypnosis as an analgesia adjunct during childbirth. [22-24] For many years hypnosis has suffered greatly from misunderstanding and prejudice [25]. However, more recently the use of clinical hypnosis has become an area of increasing clinical interest and research [26-28]. Advances in neuro-imaging have led to an understanding of the neuro-physiological changes occurring during hypnosis induced analgesia [29]. The anterior cingulate gyrus has been repeatedly demonstrated, by positron emission tomography, to be one of the sites in the brain affected by hypnotic modulation of pain. [29-31] The suppression of neural activity, between the sensory cortex and the amygdala – limbic system, appears to inhibit the emotional interpretation of sensations being experienced as pain. Hypnosis appears to be a state of narrow focused attention, reduced awareness of external stimuli, and an increased response to suggestions [32,33]. Suggestions are verbal or non-verbal communications that result in apparent spontaneous changes in perception or behaviour. These therapeutic communications are directed to the patient's subconscious and the responses are independent of any conscious effort or reasoning [34]. Potentially, medical hypnosis could be used alone for pain relief as part of a woman's care during childbirth. In practice however, hypnosis is best seen as an adjunct to facilitate and enhance other analgesics. The well recognised problems associated with current analgesia techniques and the increasing medicalisation of childbirth has led many women to look for an alternative means of relieving pain in labour [10]. Bonica estimates that up to 25% of women obtain complete analgesia when using hypnosis for pain relief in labour [35]. The responsiveness of women to hypnosis appears to be increased in pregnancy and in primiparous when compared with multiparous women [36,37]. A wide variety of personnel have used hypnosis effectively including medical students, [38] psychologists, [39,40] hypnotherapists [37] and obstetricians [41,42]. Systematic review evidence suggests that learning hypnosis techniques for use in childbirth would allow mothers to reduce their need for pharmacological analgesia, and other interventions such as intravenous oxytocics, and increase their chance of having a spontaneous vaginal birth [10,22,43]. Until recently, evidence of the effectiveness of hypnosis as an analgesia adjunct during childbirth was limited to three small trials being of adequate quality for meta-analysis. In addition the maternal populations under investigation did not have access to an "on demand" epidural service for labour analgesia which is widely available in many developed countries. A recent large study from the USA investigating the preparation of women for childbirth using hypnosis in the 1st trimester [44] will soon be available for inclusion in an updated meta-analysis. Neither the intervention nor the number of sessions were standardised in this study which was performed over a ten year period in the USA. Such features of previous studies limit the reproducibility of the intervention and decrease external validity.

Since April 2002, we have been developing an antenatal hypnosis training program for women in late pregnancy (after 35 weeks gestation) to be utilised for anxiolysis and as an analgesia adjunct during childbirth. Initially, we were seeing women on an individual basis. However increasing demand for hypnosis preparation for childbirth from mothers, midwives and obstetricians at our institution has led us to our current practice of training groups of 5–10 women/week in self hypnosis techniques developed along the lines described by Waxman, [45]. McCarthy [21,46] and Bjenke
The hypnosis training program has continued to develop over the last three years utilising advice from senior clinical hypnotherapists in Australia and New Zealand with expertise and substantial experience of preparing over 1000 women in hypnosis preparation for childbirth. The intervention lasts approximately one hour and the hypnosis sessions are held for three consecutive weeks. Birth outcomes of 77 antenatal women taught hypnosis in preparation for childbirth between January 2003 and August 2004 were compared with parity matched controls delivering after 37 weeks gestation during 2003 at our institution. Primiparous women, receiving hypnosis preparation, used fewer epidurals than controls 18/50 (36%) vs 765/1436 (53%) (RR 0.68, 95%CI 0.47,0.98) and less augmentation 9/50 (18%) vs 523/1436 (36%) (RR 0.48, 95%CI 0.27,0.90) [47]. These findings are consistent with those of our systematic review [22].

Number of hypnosis sessions
Although most clinical hypnotherapists use three or more sessions antenatally when training women with hypnosis preparation for childbirth, Rock et al found hypnosis effective in untrained mothers during their labour [38]. Our clinical experience at our own institution suggests that the intervention is optimally delivered when three sessions are scheduled in late pregnancy. Interestingly, despite differences between trials in the timing and number of hypnosis interventions reported, outcomes are consistently in favour of hypnosis [22]. However, this could simply reflect possible publication bias.

Timing of the intervention
Tiba suggests that as pregnancy progresses responsiveness to hypnosis and suggestion increases [36]. Our experience over the last three years has found that the vast majority of women have little difficulty learning this technique in the last four weeks of pregnancy.

Groups vs individual administration of hypnosis
Leeb successfully used hypnosis in groups of up to 20 women in preparation for childbirth[48] while Harmon demonstrated a range of beneficial outcomes following antenatal hypnosis training in groups of 15 women [39]. Our own experience suggests that group hypnosis is effective and allows far more women to receive the intervention than would be the case with individual administrations. Some practitioners claim that an individualised approach is more effective but this has not been shown in a study of the effectiveness of hypnosis in treating hyperemesis [49].

Multiparous vs nulliparous
Previous randomised comparisons of hypnosis in this setting have investigated nulliparous women only. Two hypnosis studies investigating multiparous women used parity matched controls. These reports show similar (but reduced) treatment effects in favour of hypnosis [37,47].

Evidence of the effectiveness of hypnosis in the management and prevention of anxiety and postnatal depression
Hypnosis has recently becoming advocated as a useful non-pharmacological intervention in the treatment of depression [17,50]. There are several reports of a low incidence of postnatal depression associated with women preparing for childbirth using hypnosis techniques although comparative data is lacking [23,46] In addition,
there is convincing evidence in the peri-operative setting that the use of hypnosis decreases patient anxiety and reduces overall costs [28,51,52].

Safety of hypnosis in childbirth

There are two published reports of a complication of hypnosis associated with an obstetric patient. One involved a parturient prior to labour exhibiting psychotic symptoms believing that she had been assaulted, [53] and the other involved a treatable post partum anxiety and compulsive behaviour associated with the use of hypnosis during labour [54]. Other reported problems with the use of (non obstetric) medical hypnosis in the literature have been mainly associated with the use of age regression techniques, by inexperienced practitioners, or in patients with psychoses [53]. It has been recommended that hypnosis should be used by practitioners within their field of expertise [55]. This is consistent with the view of a British Medical Association report confirming the relevance and appropriateness of the use of hypnosis by obstetricians and anaesthetists [56]. The mythology surrounding hypnosis that it is too time consuming, limits free will or induces amnesia of the birth experience are dispelled both by Werner[53] and more recently Nash [57]. There appears to be little basis for the fears surrounding these supposed dangers of hypnosis in obstetrics, although such opinions may have been a deterrent to its application [53].

Supplementing hypnosis using an audio compact disc (cd) at home and in labour

Several workers ask patients to listen to an audio tape of hypnosis suggestions at home as practice in their preparation for childbirth re-enforcing the techniques learned in the classroom [39,46]. The heterogeneity seen in our systematic review[22] can be explained by the use of supplemental tapes of suggestions, in one of the studies, in addition to live preparation [39] This appears to support the view that it is beneficial for subjects to practice the intervention using taped suggestions at home [21]. There are however no randomised studies to confirm whether listening to hypnotic suggestions, on an audio tape or audio compact disc (cd), is of additional value. However the use of a tape or audio cd for re-enforcing the suggestions is a simple, cheap supplement to our hypnosis sessions that allows the intervention to be standardised and maximises external validity. The effectiveness of standardised over individualised suggestions during hypnosis has been studied previously [58]. If the audio cd is shown to be an effective intervention it could be easily implemented in other hospitals with no experience of hypnosis preparation for childbirth.

Development of the structured intervention delivered by audio cd on hypnosis

Audio cds on hypnosis were developed in our institution following increasing requests from patients for a supplement to what was learned in the live hypnosis sessions. An experienced physician who has practiced full time hypnotherapy for over 10 years and whose practice involves regular hypnotherapy preparation for childbirth observed our hypnosis group sessions for several weeks and took notes of the types of suggestions utilised during each session. Our antenatal hypnosis training sessions are based on published scripts of suggestions, by experts in the administration of hypnosis in childbirth, combined with our own clinical experience. A final written script for each session based on our current clinical practice in training women using hypnosis in preparation for childbirth was agreed by the hypnotherapist members of our research team. These scripts were used to produce three audio cds that mirrored
our current hypnosis preparation for childbirth training program. The audio cds were produced at a local recording studio and each lasted between 21 and 32 minutes. A 4th audio cd lasting 18 minutes has also been developed for use during labour and childbirth. Multiple copies were made through our institution’s digital media department. The cds are labelled with a caution that they should not be used while operating machinery or driving. Two lead investigators’ names (AMC and MIA) and contact phone numbers of our institution are shown on each cd label. Participants were advised that the cds are for their use alone as part of the HATCH trial. Although there is evidence of the effectiveness of hypnosis for labour analgesia, too few women have been rigorously investigated in late pregnancy and trial heterogeneity prevents clear recommendations of what constitutes an effective intervention. Further adequately powered well-designed trials are required.

This trial seeks to determine the efficacy or otherwise of antenatal group hypnosis preparation for childbirth in late pregnancy.
The specific aims of this study are to assess whether antenatal hypnosis preparation for childbirth:
1. is an effective way of reducing maternal use of pharmacological analgesia
2. reduces the incidence of adverse effects on the mother
3. reduces the incidence of adverse affects on the baby
4. impacts on the mother’s emotional well being
5. is cost effective
Additional specific aims
6. To compare two methods of delivering antenatal group hypnosis in a double blind fashion, one method using a hypnotherapist to deliver the intervention followed by an audio cd on hypnosis for re-enforcement of the techniques learned. The other method is to use the an audio cd on hypnosis alone administered by a nurse with no hypnotherapy training.