University of Adelaide

The HATCh Trial

Hypnosis Antenatal Training for Childbirth

1116160 Allan Michael Cyna PhD Revised Thesis
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Abstract

The evidence appeared to suggest that the use of hypnosis in childbirth: decreases analgesia requirements during labour; decreases oxytocin requirements during labour and, increases the incidence of spontaneous vaginal birth. A research gap was identified that the Hypnosis Antenatal Training for Childbirth (HATCh) Trial was designed to fill. The HATCh Trial was a comprehensive, high-quality, randomised trial that included 448 pregnant women in late pregnancy. It was designed to assess the efficacy of a short, three-session, standardised hypnosis intervention in late pregnancy. The HATCh study findings show that, unlike in all but one previous study, this hypnosis intervention in the third trimester was ineffective in reducing analgesia requirements during childbirth. The increased incidence of induction required in hypnosis groups when compared with controls was unexpected and suggests that hypnosis may have an effect in the non-pharmacological inhibition of spontaneous labour. Subgroup analysis suggested that hypnosis may reduce analgesia requirements when supplemented by yoga. The addition of the HATCh Trial results has substantially increased the heterogeneity of the systematic review. Systematic review sub-group analyses, according to the timing of the hypnosis training during pregnancy, suggest that training in the third trimester is ineffective in reducing analgesia requirements during labour and childbirth. However hypnosis training commencing early in pregnancy, either in the first or second trimester, may decrease pharmacological analgesia use during childbirth.

Further research is required to investigate why hypnosis might inhibit the spontaneous onset of labour and how this effect might be negated, minimised or utilised. Further research is also required to investigate the optimal timing to commence antenatal hypnosis training, the number of sessions and the types of suggestions that might be most effective. Yoga may be a useful adjunct to the hypnosis intervention and should be researched further as a sole technique and together with antenatal hypnosis training during pregnancy. There is a clear need for high quality trials where hypnosis training occurs before the 3rd trimester. Ideally, training after the 3rd trimester should be compared with antenatal hypnosis training before the 3rd trimester.

Declaration

This work contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution to Allan M Cyna and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to this copy of my thesis, when deposited in the University Library, being made available for loan and photocopying, subject to the provisions of the Copyright Act 1968. I also give permission for the digital version of my thesis to be made available on the web, via the University's digital research repository, the Library catalogue, the Australasian Digital Theses Program (ADTP) and also through web search engines, unless permission has been granted by the University to restrict access for a period of time.

Signed:

Allan M Cyna

Date: 28th June 2011

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Chapter 1 – Background: Hypnosis for Pain Relief in Childbirth

Definition

Hypnosis appears to be a state of narrowly focused attention, reduced awareness of external stimuli, and an increased response to suggestions (Greenleaf 1974, Gamsa 2003). Suggestions are fundamental to the therapeutic or adverse effects of hypnosis. They are verbal or non-verbal communications that result in apparent spontaneous changes in perception or behaviour (Woody 2005). These therapeutic communications are directed to the patient's subconscious, and the responses are independent of any conscious effort or reasoning (Yapko 1990). Clinical hypnosis is the skill of using words and gestures (suggestions) during a focused mental state in order to achieve specific therapeutic clinical outcomes. Suggestions may originate from a hypnotherapist communicating with patients in a hypnotic state or from the patients themselves (self-hypnosis). During hypnosis, patients experience an increased receptivity and response to suggestion (Greenleaf 1974). Hypnotic experiences reflect alterations in consciousness that take place in the context of a social interaction (Kihlstrom 2008). Such experiences include the perception of involuntariness, hallucination, compulsion to complete a behavioural sequence, anaesthesia, and amnesia.

The Mythology of Hypnosis

Common myths include the following misperceptions: the hypnotized person is like a robot; hypnosis is a form of sleep; hypnotizable people are weak minded or gullible; hypnosis makes the subject do things that they normally wouldn't do; or the subject is faking it. Although these beliefs are misguided, they raise interesting and important questions about the nature and impact of hypnosis on the individual (Nash 2008).

Attitudes and Beliefs of Professional Groups

General practitioners

The attitudes of health professionals regarding the use of hypnotherapy as a therapeutic modality have been studied previously. Surveys of general practitioners (GPs) in Australia and overseas have shown that hypnosis is generally perceived as an effective form of therapy (Pirotta et al 2000; Hall & Giles-Corti 2000; Reilly 1983). A proportion of the GPs studied have received some training in the use of hypnotherapy, but it is unclear what influence prior training has on their attitudes towards hypnosis. Younger practitioners have been found to be more receptive to hypnotherapy as a treatment modality than their older colleagues (Reilly 1983).

Anaesthetists

Hypnosis has a long history of association with anaesthesia and its practice (Fuge 1986; Baier-Rogowski 1988). Only two reports assessed anaesthetists' attitudes towards hypnotherapy (Scott 1983; Coldrey & Cyna 2004). Both surveys found that many anaesthetists supported the use of hypnotherapy and positive suggestions within clinical anaesthesia. This suggests that

further education, training regarding hypnosis and the use of positive suggestion as an adjunct to routine communication with patients would be well received by the majority of anaesthetists.

Obstetricians

Obstetricians have been surveyed in South Australia regarding their knowledge, attitudes and beliefs towards complementary therapies and alternative medicines (CAM). Hypnosis was considered as one of these therapies (Smith et al 2006). A minority of obstetricians (14%) considered CAM to be a threat to public health. The majority of obstetricians thought they should have some knowledge about CAM and believed that more of an evidence base was required for CAM. The majority of obstetricians (68%) had formally referred a patient for one of the complementary therapies. When questioned specifically on hypnosis, this intervention was considered to be useful and safe to use during pregnancy. The majority of clinicians held positive views toward CAM despite the belief that only limited evidence existed on the safety and efficacy of these therapies (Gaffney 2004).

Midwives

A recent cross-sectional survey was conducted among midwives regarding their knowledge of, and attitudes toward, hypnosis. The midwives were based at two different tertiary referral centres for maternity care; only one of these centres has its own clinical hypnotherapy service. The survey showed that midwives exposed to hypnosis were more likely to support its use and express an interest in hypnotic techniques being taught during midwifery training. The vast majority of midwives agreed that positive suggestion techniques should be taught during midwifery training (Eng & Cyna 2005).

Evidence of Benefits of Hypnosis

For many years, hypnosis has suffered greatly from misunderstanding and prejudice (Mushin 1973). Hypnosis had its first reported use in the context of surgical anaesthesia through John Elliotson (1791-1868) who had some success in eliminating pain during surgery. He subsequently published his work, *The Zoist* (Elliotson 1849), but failed to receive recognition during his lifetime (Elias 2006). James Braid, a Scottish surgeon working for the Indian Medical Service in the 1840s, performed surgery on several hundred patients in Bengal using hypnosis (Robertson 2009). His success was acclaimed all over the world. After a committee investigation presided over by the Inspector-General of Civil Hospitals, Bengal, a Mesmer hospital was started in Calcutta (McRobert 1972). Large tumours were removed without pain using 'mesmerism', now known as 'hypnosis' in a high proportion of cases. The advent of chloroform anaesthesia with 100% success put an end to the application of hypnosis as an anaesthetic technique during surgery – pioneered by James Esdaile. The details of Esdaile's work can be found in Crawford's *History of the Indian Medical Service* (Crawford 1914). A few years after Morton's demonstration of ether anaesthesia, mesmerism' was all but abandoned and almost forgotten as the increased reliability and effectiveness of ether and chloroform anaesthesia became evident (Snow 2008). The practice of hypnosis languished for decades, becoming little more than a parlour trick in much the same way that 'ether frolics' did before its recognition as an anaesthetic. More recently, the use of clinical hypnosis has become an area of increasing clinical interest and research (Goldmann et al 1988; Lucas-Polomeni 2004; Faymonville et al 2003; Lang et al 2000). Over half a century ago, the British Medical Association (BMA)

reported that hypnosis was a useful therapeutic tool and recommended that obstetricians and anaesthetists should be trained in its use (BMA Working Party 1955). This was followed in 1958 by the American Medical Association advocating the use of hypnosis in medicine and dentistry. Since then increasing reports have been published about the benefits of hypnosis in such widely differing fields as dermatology and the managements of warts (Clawson 1975), migraines (Anderson et al 1975), depression (Deltito & Baer 1986), anxiety (Saadat et al 2006), surgical pain (Montgomery et al 2002), cancer pain and associated nausea (Vickers & Cassileth 2001). Indeed, hypnosis is becoming more widely recognized as a valid form of clinical intervention, particularly for the management of pain or anxiety associated with operative and interventional procedures (Lang et al 2000; Montgomery et al 2002; Nash 2001). There is now clear, convincing evidence for the mechanism of action (Faymonville et al 2006) and the use of hypnosis in anxiety disorders or pain management, particularly in the context of perioperative anxiety (Saadat et al 2006; Lang et al 2006), pain relief (Richardson et al 2006; Jensen & Patterson 2006), irritable bowel syndrome (Gonsalkorale 2005) and obstetric care (Irving 2002).

Functional Neuro-Anatomy of Hypnotic Modulation of Perceptions and Pain

Positron emission tomography (PET) studies on volunteers have shown that changes in brain perception during hypnosis can be imaged. Subjects who were shown colour images but were told they were black and white perceived them as such but also had diminished activity in the colour-discriminating areas of the brain when imaged by PET scan (Kosslyn 2000). The

mechanism of hypnotic analgesia may reduce anxiety and modulate the suffering component of the brain with little effect on the experience of the primary sensation itself (Holroyd 1996). Training in hypnotic analgesia may usefully enhance inhibitory processes of the nervous system that attenuate pain. Advances in neuro-imaging have led to an understanding of the neuro-physiological changes occurring during hypnosis induced analgesia (Maquet et al 1999). PET scan studies have repeatedly shown that the anterior cingulate gyrus is one of the sites in the brain affected by hypnotic modulation of pain (Maquet et al 1999; Faymonville et al 2000; Koyama et al 2005). The suppression of neural activity, between the sensory cortex and the amygdala-limbic system, appears to inhibit the emotional interpretation of sensations that are experienced as pain. The ability to predict the likelihood of an aversive event is an important adaptive capacity. Certainty and uncertainty regarding pain cause different adaptive behaviours, emotional states, foci of attention, and perceptual changes (Benedetti et al 2007). Functional neuro-imaging studies indicate that certain and uncertain expectations are mediated by different neural pathways – the former being associated with activity in the rostral anterior cingulate cortex and posterior cerebellum, the latter with activation changes in the ventro-medial prefrontal cortex, mid-cingulate cortex and hippocampus. Expectation plays an important role (Benedetti 2007), not only in the modulation of acute and chronic pain, but also in other disorders. These disorders are characterized by specific phobias that entail a certain expectation of a negative experience or may take the form of a generalized anxiety disorder, where the expectation of aversive events is uncertain (Ploghaus et al 2003).

The data linking hypnosis to modern genetic and neuro-imaging methods make it clear that hypnosis is not some arcane, idiosyncratic phenomenon, but rather a window into aspects of

brain function that have important implications for learning, development, stress response and neuro-control over somatic processes (Spiegel 2008).

The Effects of Hypnosis on Pain

Since the early 1990s, thousands of patients have opted for hypnosis, either as a substitute for, or more typically as a complement to, anaesthesia in a wide variety of surgical procedures. Belgian anaesthetists (Faymonville et al 1995) have reported how hypnosis can be used as an adjunct sedation procedure and has shown that it provides better pain and anxiety relief than conventional intravenous sedation. The renewed interest in hypnosis as an anaesthetic adjunct administered perioperatively stems in part from the growing number of studies, both randomized (Lang et al 2000; Faymonville et al 1997; Lang et al 1996) and non-randomized (Enqvist & Fisher 1997), showing that patients given preoperative preparation with hypnosis have fewer side effects than controls (Montgomery et al 2002). Researchers (Faymonville et al 1998) report that hypnotised patients can manage on less than 1% of the standard medications required for general anaesthesia, avoiding such effects such as nausea, fatigue, lack of coordination and cognitive impairment. In a 1999 study of thyroid patients, (Faymonville et al 1999) typical hypno-sedated patient returned to work 15 days after surgery, compared with 28 days for those patients receiving general anaesthesia.

A range of psychological factors determine whether pain is experienced or not; these include the degree of pain, the meaning of the sensation, the patient's past experience and their anxiety (DeSousa & Wallace 1977; Rainville et al 2005). Numerous reports have been made on the use of hypnotically-induced anaesthesia as the sole technique (Kroger 1957; Faymonville et al

1998; Fredericks 2000) and as an anaesthetic adjunct to major surgery (Hammond 2008; Faymonville et al 1998; Schulz-Stubner 2000). However, until recently, empirical data was lacking (Barnier & McConkey 2003). A recent meta-analysis of 13 randomised and nine non-randomised studies revealed a significant benefit of hypnosis with surgical patients (Montgomery et al 2002). Mean effect sizes averaged for treatments within studies, type of surgery, type of control condition, type of design, modality of intervention, and sample size for each study found a medium to large average effect size due to hypnosis. These results indicated that surgical patients in hypnosis treatment groups had improved outcomes – such as reduced nausea and vomiting, analgesia use – in more than 89% of patients when compared with control groups (Montgomery et al 2002). These benefits included improved physiological indicators, a reduction in pain scores, decreased use of analgesic medication and shorter treatment and recovery times (Montgomery et al 2000). Similar benefits from the use of hypnosis were demonstrated in a well-designed, randomized, controlled study of 241 patients undergoing painful interventional radiology procedures (Lang et al 2000). This high-quality study showed that pain increased linearly with procedure time in the standard care and structured attention groups but did not increase in those patients using hypnosis.

The Use of Hypnosis in Pregnancy and Childbirth

Nearly half a century ago, the extant literature was reviewed (Robin 1962). It was concluded that, during parturition, women in childbirth are subject to amnesia, distorted perception, and increased suggestibility. Isolated enthusiastic reports of labours conducted under hypnosis have appeared over the years in the medical press. However, with the exception of two

reports (Kroger & De Lee 1943; Abramson & Heron 1950), no large series of cases have been reported in the English language. The physiological as well as the psychological consequences of anxiety may be reduced by the anaesthetist using intuitive skills, including suggestion, without fully appreciating how they elicit therapeutic patient responses. Sometimes anaesthetists trained in the use of hypnosis purposefully use suggestive or hypnotic induction techniques (Baier-Rogowski 1988). In a study of patients having vaginal termination of pregnancy pre-operative, hypnosis was found to provide a quick and effective way to reduce pre-operative patient anxiety and anaesthetic requirements for gynaecological day-case surgery (Goldmann et al 1988). This anxiolytic effect associated with preoperative hypnosis has been confirmed recently in both preoperative hypnosis administered to adults (Saadat et al 2006) and in the context of cancer pain in children (Zeltzer & LeBaron1982).

Numerous cases and case series have been documented in the obstetric population where hypnosis has been claimed to be of advantage (Kroger & DeLee 1943; Irving & Pope 2002). The well-recognised problems associated with current analgesia techniques, together with the increasing medicalisation of childbirth (Johanson et al 2002) have led many women to look for alternative means of relieving labour pain (Smith et al 2006). It has been estimated that up to 25% of women obtain complete analgesia when using hypnosis for pain relief in labour (Bonica 1984).

Childbirth and Pain

Pain during labour and childbirth represents a complex interaction of multiple physiological and psychological factors (ANZCA working party 2005). As labour becomes more

imminent, this can be a time of conflicting emotions such as, fear, apprehension, excitement, and joy together with a sense of potential fulfilment. Tension, anxiety and fear are factors contributing towards a woman's perception of pain and may also affect her labour and birth experience. Sensations associated with labour have been described as among the most intense forms of pain that can be experienced (Melzack 1984). A labour contraction or crowning during labour and childbirth can cause an emotional experience and suffering that is frequently described as pain. However, for some women the exact same intensity of sensations can be interpreted as a powerful experience leading to an overwhelming sense of joy and achievement. The meaning and interpretation of labour has its origin in the brain – without interpretation of sensations as suffering in the brain, pain does not exist!

Labour pain is traditionally thought to be caused by uterine contractions, the dilatation of the cervix and, in the late first stage and second stage, by the stretching of the vagina and pelvic floor to accommodate the baby. However, the complete removal of pain does not necessarily mean a more satisfying birth experience for some women (Morgan et al 1982). Hypnosis is not infrequently considered by women interested in minimising their chances of requiring a medical intervention during childbirth. Mind-body interventions such as relaxation, meditation, visualisation and focusing techniques, for example, on breathing, are commonly used for labour (Vickers 1999). Several Cochrane systematic reviews provide further background information on the following topics: 'Continuous support for women during childbirth' (Hodnett et al 2007), pharmaceutical methods of pain relief, 'Epidural versus non epidural analgesia or no analgesia in labour' (Anim-Somuah et al 2005), and 'Types of intra-muscular opioids for maternal pain relief in labour' (Elbourne & Wiseman 2004). Systematic review evidence of the effects of hypnosis

for pain relief in childbirth suggests that hypnosis can decrease analgesia requirements during labour, decrease the use of oxytocic labour augmentation and increase the incidence of vaginal birth (see a detailed discussion of this evidence in Chapter 2).

Potential adverse effects of analgesia techniques on pain in labour and childbirth

Techniques such as epidural analgesia can deprive the mother of an optimal birth experience (Morgan et al 1982). Invasive medical procedures such as epidural analgesia are also associated with adverse effects such as post-dural puncture headache and neurological injury (Bromage 1999; Weeks 1999). Although long-term sequelae are rare, such complications can be debilitating and extremely distressing (Weir 2000). In addition, all pharmacological interventions cross the placenta to some degree and may have other physiologically adverse effects on the mother, which leads to concerns about adverse effects on the foetus (Decca et al 2004).

The recent ANZCA working party report emphasises that non-pharmacological treatment options should be considered before analgesic medications are used, particularly just before delivery (ANZCA working party 2005). However, medical interventions involving the use of anaesthetic and analgesic drugs have become increasingly common, even when labour and childbirth are proceeding uneventfully (Johanson et al 2002). Women's desires for and expectations of pain relief during labour and delivery vary widely (ANZCA working party 2005), and high-quality pain relief does not necessarily equate to a high level of satisfaction (Shapiro et al 1998). In the developed world, in countries such as Australia, women have increasing rates of medical interventions during childbirth (Chan et al 2008) despite reservations regarding their

associated adverse physical and psychological effects for both mother and baby (Bailham & Joseph 2003). Concerns from within the medical community, midwives and mothers have failed to halt this growing trend (De Costa & Robson 2004). Hypnosis appears to be associated with a reduction in the level of medical intervention in childbirth and the associated risks to both mother and baby (Cyna et al 2004). It has been used as an adjunct to the birthing process for more than a century (Mottershead 2006). Interestingly some workers (Goldman 1992; McCarthy 1998) have reported that hypnotically trained pregnant women rarely experience postnatal depression. The introduction of chemical analgesia in the 19th century (Martin et al 2001) and negative myths associated with hypnosis (Barnier & McConkey 2003) have led to a decline in its use. Recently, there has been a resurgence in the use of hypnosis in the obstetric community (Harmon et al 1990; Freeman et al 1986; Martin et al 2001) and terms such as 'Hypnobirthing' (Wainer 2000) are used with increasing frequency within obstetric and midwifery departments. Potentially, medical hypnosis could be used alone for pain relief as part of a woman's care during childbirth (Greer 1956). In practice, however, hypnosis is best seen as an adjunct to facilitate patient care and enhance the effects of other analgesics (Faymonville et al 1998; Faymonville et al 1999; Schulz-Stubner 1996; Schulz-Stubner 2002).

Safety of Hypnosis in Childbirth

Two published reports recount complications of hypnosis associated with an obstetric patient. One involved a parturient prior to labour exhibiting psychotic symptoms believing that she had been assaulted (Werner et al 1982) and the other involved a treatable post-partum anxiety and compulsive behaviour associated with the use of hypnosis during labour (Cyna 2003). Other

problems reported in the literature with the use of (non-obstetric) medical hypnosis have been mainly associated with age regression techniques used by inexperienced practitioners or on patients with psychoses (Werner et al 1982). It has been recommended that hypnosis should be used by practitioners within their field of expertise (Hoffman 1961). This is consistent with the view of a BMA report confirming the relevance and appropriateness of the use of hypnosis by obstetricians and anaesthetists (BMA Working Party 1955). The misconceptions surrounding hypnosis include that it is too time consuming and that it limits free will or induces amnesia of the birth experience. These fallacies have been dispelled both 30 years ago (Werner et al 1982) and, more recently (Nash 2001). The fears surrounding the supposed dangers of hypnosis in obstetrics seem to have little basis in reality, although such opinions may have been a deterrent to its application (Werner et al 1982). Claims that hypnosis is a safe and valuable tool in pregnancy and childbirth (Erickson 1994; McCarthy 2001) are supported by numerous reports in the literature describing the successful use of hypnosis as an analgesia adjunct during childbirth (Cyna et al 2004; August 1960; Bejenke 1996). Hypnosis appears to offer substantial benefits for both mother and baby. However, very few cases of side effects related to the use of hypnosis during pregnancy and childbirth have been documented (Cyna 2003).

Evidence of the Effectiveness of Hypnosis in the Management and Prevention of Anxiety and Postnatal Depression

Hypnosis has recently been advocated as a useful non-pharmacological intervention in the treatment of depression (Yapko 1992; Yapko 2001). It appears to be helpful in reducing common symptoms of major depression such as agitation and rumination and thereby may decrease a

sense of helplessness and hopelessness. Hypnosis may also be effective in facilitating the learning of new skills and reduce the likelihood of relapses, thus simultaneously addressing issues of risk factors and prevention (Yapko 2001).

Several reports indicate a low incidence of postnatal depression associated with women preparing for childbirth using hypnosis techniques, although comparative data is lacking (August 1960; McCarthy 1998). In addition, convincing evidence in the perioperative setting suggests that the use of hypnosis decreases patient anxiety and reduces overall costs (Lang & Rosen 2002; Lang et al 2000; Faymonville et al 1997).

Validated Outcome Measures of Relevance in Pregnancy

Several outcomes have been measured previously in relation to pregnancy and childbirth, including measures of pain, anxiety and depression. In addition, because of the unique nature of the hypnosis intervention in this research study, a measure of hypnotisability would be of value.

The Spielberger State Anxiety Measure

The 'State' component of the Spielberger State/Trait Anxiety Measure is considered to be a useful validated measure of patient anxiety (Spielberger et al 1983). The state anxiety inventory involves asking 20 statements to evaluate how an individual has felt over the previous seven days. Individuals respond to each item on a four-point Likert Scale indicating the frequency with which they feel a certain emotion. The scores for this item range from 20–80 (Spielberger 2004).

A cut-off score for high anxiety has been derived previously from Spielberger and colleagues, which provides normative data for females. The mean anxiety score for this normative group was 34.2 (SD 9.87). The cut-off between high and low anxiety states was set 1 SD above the mean, that is scores greater than 44 were classed as high anxiety (Spielberger et al 1983; Millar et al 1995).

Measuring the Effects of Hypnosis on Depression

Postnatal depression affects 12% to 15% of childbearing women, with prevalence varying from 3% to 30% depending on the method and time of assessment (Pope et al 2000). The Edinburgh Postnatal Depression Scale (EPDS) was developed in 1987 to act as a specific measurement tool to identify depression in new mothers. The scale has since been validated, and evidence from a number of research studies has confirmed the tool to be both reliable and sensitive in screening for depression. It is now one of the most common methods of assessing depression in pregnancy; it consists of ten statements that evaluate how an individual has felt over the previous seven days (Cox 1987). For each statement, individuals underline the one of four possible responses that comes closest to how they have been feeling. Response categories are scored as 0, 1, 2 and 3 according to increased severity of the symptom. Scores range from 0–30. Questions 3, 5, 6, 7, 8, 9 and 10 are reverse scored (i.e., 3, 2, 1, 0). Individual items are totalled to give an overall score. The EPDS has been recommended for routine use to identify women at risk for postnatal depression (Teissèdre & Chabrol 2004). A score above 12 is widely used to indicate probable depressive disorder. Validation of the scale showed that all those found to have definite major depression when interviewed had scored above 12 on the scale. Use of

this threshold gave an overall sensitivity of 86% and specificity of 78% for all forms of depression (Cox 1987). Although a score of less than 12 is frequently considered to indicate an increased risk of having depression, such a score indicates the likelihood of depression but not its severity. The EPDS is designed to assist rather than replace clinical judgement (Warner et al 1996).

Measuring hypnotisability and the effects of pregnancy on hypnotisability

Hypnotisability is generally thought to be a trait that remains stable over time. High levels of test-retest reliability have been observed over periods of 10 (Hilgard 1965) and 25 years (Piccione et al 1989). Numerous attempts have been made to assess the responsiveness to hypnosis in a systematic and scientific fashion. The 'gold standard' of hypnosis scales is currently considered to be the Stanford Hypnotic Susceptibility Scale. This scale is administered individually and consists of a hypnotic induction followed by twelve test suggestions. In research situations, a group scale such as the Harvard Group Scale of Hypnotic Susceptibility (Shor & Orne 1962) is often used to test large numbers of people. All the currently used scales involve a hypnosis induction procedure, except for the Creative Imagination Scale (CIS).

Anecdotally, hypnotherapists have found pregnant women as a group to be easily hypnotizable (August 1960). However, only one previous comparative study compares hypnotisability in pregnant and non-pregnant women. Researchers studying a group of Hungarian women found that pregnant women in the second and third trimester had a significantly higher ‘susceptibility’ to hypnosis than non-pregnant women (Tiba 1990). Using the 12-point Harvard Hypnotisability Scale, where a score of 12 indicates a highly hypnotizable subject, the study

found that 180 pregnant women scored an average of 8.12, compared with the Hungarian average of 5.15. Primigravidas were particularly hypnotizable, reaching an average of 9.0. The Hungarian study also used the CIS (Barber 1978) to assess the imaginative capacity of pregnant women (Tiba 1990). This scale is self-appraising, and the maximum score is 40. Pregnant women had a significantly higher score of 25.0, compared with 20.7 for non-pregnant women. The average score also increased from 23 in the second trimester to 27 in the third trimester. No study to date has measured the same participants at two time points, thus allowing participants to act as their own controls. If women who were pregnant were shown to be more responsive to hypnosis than non-pregnant women, this would provide additional support for the rational use of hypnosis during childbirth.

Rationale for a Systematic Review

Hypnosis has been recognised by the BMA as an effective clinical tool (BMA Working Party 1955). Its utilisation is biologically plausible as brain-imaging studies using PET scan (Faymonville et al 2003; Faymonville et al 2000; Maquet et al 1999) are clarifying the sites of action of hypnotic analgesia. The use of hypnosis enhances patient autonomy by teaching skills to women. The available evidence suggests that hypnosis preparation for childbirth is very likely to be of benefit and without significant harmful effects. A systematic review was indicated to establish the state of evidence regarding the effects of hypnosis in childbirth in order to identify research gaps in this setting.

Chapter 2 – Systematic Review: Hypnosis Preparation for Labour and childbirth

Introduction

Three systematic reviews have been published prior to the HATCh trial investigating the evidence from comparative trials reporting the affects of hypnosis on the pain of labour and childbirth (Smith et al 2006; Cyna et al 2004; Huntley et al 2004). This chapter presents data from the Cochrane systematic review conducted in 2004 and later published in 2006 (Smith et al 2006) prior to the commencement of the HATCh trial.

Hypnosis for Childbirth Pain

Objectives of a preliminary systematic review

A systematic review was undertaken, examining the effects of hypnosis for pain management in labour and on maternal and peri-natal morbidity.

Primary objective

This review primarily examined the effects of hypnosis on pain and its management in labour as measured by the following factors:

- The women's rating of labour pain
- The need for pharmacological intervention

Secondary objective

Secondary aims included the effects of hypnosis on the following:

- Maternal satisfaction or maternal emotional experience
- Labour and childbirth such as duration of labour and mode of delivery
- The baby's condition, such as admission to the special care baby unit (SCBU), Apgar score < 7 at 5 minutes

Criteria for considering studies

Types of studies

All published and unpublished randomised and quasi-randomised controlled trials published up to the end of 2005 were included in the systematic review.

Types of participants

All primiparous or multiparous women who were not in labour or who were in spontaneous or induced labour were considered for inclusion.

Types of intervention

Hypnosis used in the antenatal period at any time including during labour was considered. The Hypnosis intervention could be implemented with or without concurrent use of other pharmacological or non-pharmacological interventions and compared with placebo, no treatment or pharmacological forms of pain management.

Types of outcome measures

Primary

(5) Use of pharmacological pain relief in labour

(6) Maternal satisfaction or maternal emotional experience with pain management in labour

Secondary

Maternal outcomes

These were length of labour, mode of delivery, instrumental vaginal delivery, need for augmentation with oxytocin, perineal trauma (defined as episiotomy and incidence of second-, third- or fourth-degree tears), maternal blood loss (postpartum haemorrhage defined as greater than 600 ml), perception of pain experienced, satisfaction with general birth experience, assessment of mother-baby interaction and breastfeeding at hospital discharge. The presence of postnatal depression was considered for reporting as a dichotomous outcome, or as a score (Cox 1987).

Neonatal outcomes

These included an Apgar score of less than seven at five minutes, admission to neonatal intensive care unit, need for mechanical ventilation and neonatal encephalopathy.

Search methods for identification of studies

We used the Cochrane Pregnancy and Childbirth Group methods used in reviews, and the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the trials search co-ordinator

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from the following:

(1) Quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL)

(2) Monthly searches of MEDLINE

(3) Hand searches of 30 journals and the proceedings of major conferences

(4) Weekly current awareness search of a further 37 journals

Details of the search strategies for CENTRAL and MEDLINE, the list of hand-searched journals and conference proceedings and the list of journals reviewed via the current awareness service can be found in the section titled 'Search strategies for identification of studies', within the editorial information about the Cochrane Pregnancy and Childbirth Group. Trials identified through the search activities described above are given a code (or codes) depending on the topic. The codes are linked to review topics. The Trials Search Co-ordinator searches the register for each review using these codes rather than keywords. In addition, the CENTRAL (*The Cochrane Library* 2006, Issue 1), MEDLINE (1966 to February 2006), CINAHL (1980 to February 2006)

and EMBASE (1980 to February 2006) were searched using a combination of subject headings and text words. The subject headings included 'obstetrics', 'labour', 'birth', and 'pain'. Text words included 'meditation', 'imagery' or 'visualisation', 'relaxation', 'hypnosis', and 'breathing exercises'. No language restrictions were applied.

Methods of review

Trials investigating the use of hypnosis were evaluated by the author as part of a Cochrane review on complementary and alternative therapies for pain relief in labour (Smith et al 2006) for their appropriateness for inclusion. In case of uncertainty about inclusion of the study, the full text was retrieved. The original author was contacted for further information where possible. If disagreement arose between review authors about the studies to be included that could not be resolved by discussion, assistance from the third review author was sought. Following an assessment for inclusion, we assessed the methodology of the trial. The data were extracted onto hard copy data sheets. Three authors extracted the data and assessed the quality.

Two review authors assessed and extracted data for each trial. Included trials were assessed according to the following four main criteria:

(1) Adequate concealment of treatment allocation (e.g., opaque, sealed, numbered envelopes)

(2) Method of treatment allocation (e.g., computer randomisation, random-number tables)

(3) Adequate documentation of how exclusions were handled after treatment allocation - to facilitate intention-to-treat analysis

(4) Adequate blinding of outcome assessment

Letters were used to indicate the quality of the included trials (Higgins & Green 2005), such as in the following examples:

(1) A was used to indicate a trial at a high level of quality in which all the criteria were met;

(2) B was used to indicate that one or more criteria were partially met or it was unclear if all the criteria were met;

(3) C was used if one or more criteria were not met;

Data was directly entered from the published reports into the Review Manager software [RevMan 4.2 for Windows 2003] with double data entry performed by a co-investigator. Where data were not presented in a suitable format for data entry, or if data were missing, we sought additional information from the trial investigators by personal communication in the form of a letter or e-mail. Due to the nature of the interventions, double blinding of assessments was sometimes not possible. Therefore, studies without double blinding of assessments were considered for inclusion. Data extracted from the trials were analysed on an intention-to-treat basis (when this was not done in the original report, re-analysis was performed if possible). Where data were missing, we sought clarification from the original authors. Statistical analysis was performed using specific software designed for this purpose (Review Manager software 2003). For dichotomous data, the researchers calculated relative risks and 95% confidence intervals (CIs). Weighted mean difference and 95% CIs were calculated for continuous data. Trials with losses to follow up greater than 25% were subject to a sensitivity analysis. We tested for heterogeneity between trials using the I^2 statistic. Where significant heterogeneity was

present (> 40%), we used a random-effects model. No trials reported outcomes by parity and therefore no sub-group analyses by parity were undertaken.

Description of studies

Twenty comparative trials were found, studying 8915 women, where the effects of hypnosis in labour and childbirth have been investigated. Only five of these studies were randomised controlled trials meeting criteria for inclusion in this systematic review. These trial reports included data on 749 women using hypnosis for pain management (Freeman et al 1986; Harmon et al 1990; Rock et al 1969; Martin et al 2001; Mehl-Madrona 2004). Details of excluded studies are published elsewhere (Cyna et al 2004).

Allocation concealment

One study was coded C as it used the last digit of the hospital patient identification number, although an attempt to conceal this number was made until the patient had been included (Rock et al 1969). The other four trials were coded B due to unclear concealment.

Method of allocation

Two studies (Freeman et al 1986; Martin et al 2001) stated that allocation was random but failed to report the method used. One study (Harmon et al 1990) used random-number tables while another (Mehl-Madrona 2004) used an unspecified type of random-number generator. The method of alternation reported by one study (Rock et al 1969) was inadequate – the hospital number was used.

Blinding

The nature of the intervention meant that it was impossible for the therapist to be blind. In two studies (Harmon et al 1990; Martin et al 2001), the participant, care providers and outcome assessors were blind to their group allocation; the analyst was not blind to the group allocation. Participants were unblinded in two studies (Mehl-Madrona 2004; Rock et al 1969), but the outcome assessors were blinded. In one study (Freeman et al 1986), it was unclear whether the patient, outcome assessor or personnel performing the data analyses were blinded.

Intention-to-treat analysis

Two trials carried out an intention-to-treat analysis (Mehl-Madrona 2004; Rock et al 1969). It was unclear in one trial whether an intention-to-treat analysis was performed (Martin et al 2001). The remaining trials did not report that an intention-to-treat analysis was performed.

Losses to follow-up

There were no losses to follow up in two studies (Harmon et al 1990; Rock et al 1969) trials. In one study (Freeman et al 1986), 13 women withdrew for medical reasons, and four women did not attend hypnosis (20.7% of the total). In one study (Martin et al 2001) hypnosis trial, five adolescents (11%) were lost to follow up, three moved out of the area and two women, one in each group, did not complete the study protocol. Loss to follow up was not reported in one study (Mehl-Madrona 2004).

Systematic review: Included studies

Rock et al 1969

Study design

Parallel design, single-blind, randomised control trial of hypnosis versus standard care.

Setting

The maternity ward at a University Hospital in the United States

Study participants

Forty women in early spontaneous labour with cervical dilatation no greater than 4 cm were randomised to hypnosis or to standard care following admission to the labour ward. No additional exclusion criteria were stated.

Randomisation

The authors used quasi-randomisation. The allocations were made by using the last digit of the hospital history number: for odd numbers, women were allocated to the experimental group, for even numbers they were allocated to control.

Allocation concealment

Allocation concealment was carried out by only revealing the patient number until criteria for entry had been fulfilled and a decision had been made to admit the patient into the study. The *Allocation concealment* grade was determined as A – Adequate.

Masking

Women were not blind, but the outcome assessor was blinded. No other details were stated on blinding of study personnel.

Interventions

For women receiving hypnosis, a standard script was used during labour on a one-to-one basis. This included relaxation, focused attention, self-hypnosis prompts and suggestions to elicit glove and abdominal anaesthesia. The control group received standard care.

Outcomes

The trial examined the use of pain relief during labour, women's views of their experience, the participant's assessment of the treatment procedures and postnatal depression. *Follow-up* No women withdrew from the study and follow up was complete. No power analysis was reported.

Analysis

An intention-to-treat analysis was performed.

Freeman et al 1986

Study design

Single-blind, randomised controlled trial. Randomised control trial of self-hypnosis versus standard care. The trial examined the effect of hypnosis on the duration of pregnancy and labour, analgesic requirements and mode of birth.

Setting

Women were recruited from an antenatal clinic in England.

Study participants

Eighty-two primiparous women with a normal pregnancy who wished to avoid an epidural. No additional exclusion criteria stated.

Randomisation

The generation of the allocation sequence was not stated.

Allocation concealment

No details were reported on concealment. *Allocation concealment* grade: B – Unclear

Masking

Women were not blind, but the outcome assessor was blinded. No other details were stated on blinding of study personnel.

Interventions

Women were seen individually on a weekly basis from 32 weeks of pregnancy. Women were encouraged to imagine warmth in one hand and shown how to transfer this to the abdomen. The control group received standard antenatal care. The control group received standard care

Outcomes

Duration of pregnancy, duration of labour, analgesic requirements and mode of delivery.

Follow-up

Seventeen women (20.7%) were excluded from subsequent analysis by the authors due to pre-eclampsia (one), breech presentation (three), delivery by caesarean section (nine) and failure to attend hypnosis sessions (four).

Analysis

No power calculation or baseline characteristics have been presented. No intention-to-treat analysis was performed.

Harmon et al 1990

Study design

Single-blind, randomised controlled trial. After determining hypnotic susceptibility, women were randomised to self-hypnosis or a control group.

Setting

An obstetric private practice in the United States

Study participants

Sixty nulliparous women aged 18–35 years at the end of the second trimester of pregnancy were the subjects of this trial. Women with a history of psychiatric hospitalisation, depression during pregnancy, obstetric risk, or with borderline hypertension were excluded. No baseline characteristics were reported.

Randomisation

The allocation sequence used random-number tables.

Allocation concealment

The allocation sequence was not concealed. Allocation concealment was graded as B – Unclear.

Masking

The outcome assessor and analyst were not blind to the woman's group allocation. Women were blinded.

Interventions

Women receiving hypnosis were given an audio recording recording of the hypnotic induction. The control group were given an audio recording of 'Practice for Childbirth'. All

women were told to practice their recordings daily. Hypnotisability was assessed, and the 60 women were divided into 30 women assessed as possessing low hypnotisability and 30 as possessing high hypnotisability. The control group of 15 women with low and 15 women with high hypnotisability listened to their recording at the beginning of each treatment session. These women were asked to concentrate on their breathing exercises, general relaxation, and focal point visualisation. Women in the two hypnosis groups of highs and lows heard the live hypnotic induction during session one and heard the recorded hypnotic induction at the start of sessions two to six. The women in the control group were taught standard relaxation, distraction, and breathing techniques. Treatments were conducted over six one-hour, weekly sessions.

Outcomes

Women rated the type and degree of pain experienced during childbirth, and obstetric outcomes were collected on length of first and second stage of labour, use of medication in labour and mode of delivery, Apgar scores at 1 and 5 minutes. Psychological assessment involved the use of the Minnesota Multiphasic Personality Inventory Form R antenatally and postnatally within 72 hours of delivery.

Follow-up

No losses of data were reported of the stated planned outcomes.

Analysis

There was no power calculation.

Martin et al 2001

Study design

Single-blind, randomised-controlled trial comparing self-hypnosis with a control group involving supportive counselling

Setting

Public health department of a teaching hospital in Florida, United States

Study participants

Forty-seven teenagers, 18 years or younger, with a normal singleton pregnancy before their 24th week of pregnancy.

Randomisation

The allocation sequence was not stated.

Allocation concealment

Unclear - No details were provided on concealment of the allocation sequence, graded B

Masking

Blinding not stated

Interventions

The four-session study intervention took place over the course of eight weeks. The treatment group received childbirth preparation in self-hypnosis that included information on labour and delivery. The control group received supportive counselling. The study intervention began with individual meetings during regular clinic visits between 20–24 weeks. Continuing clinic visits were scheduled on a biweekly basis, with the intervention run over the course of 8 weeks.

Outcomes

Medication use, complications, surgical intervention during delivery, length of hospital stay for mothers and neonatal intensive care, admissions for infants

Follow-up

Five teenagers were lost to follow up (10%).

Analysis

There was no power calculation. No details on the baseline characteristics were provided.

Mehl-Madrona 2004

Study design

Randomised controlled trial of hypnosis compared to supportive psychotherapy

Setting

Women were recruited from three states in the United States via referrals from health professionals.

Study participants

Five hundred and twenty women in the first or second trimester of pregnancy were recruited. Women were excluded if they were in the third trimester of pregnancy, had an anxiety disorder, major depressive disorder or other specified psychiatric disorders.

Randomisation

The allocation sequence was generated by a random-number generator.

Allocation concealment

Inadequate – C

Masking

Participants were not blind, but the outcome assessors were blind.

Interventions

The hypnosis technique involved problem solving and brief psychoanalytical-based psychotherapy. The hypnosis method was that described by David Cheek. Hypnosis training also included antenatal visualisation to guide the woman through an imaginary experience of giving birth. Participants attended an average of five sessions. However, the number of sessions varied widely, with one woman receiving 90 sessions. The control group received one session of supportive psychotherapy.

Outcomes

The emotional state of the woman and birth outcomes including mode of birth, induction and augmentation, neonatal resuscitation, use of pain relief including use of epidural; a measure of depression using the Beck depression Inventory and anxiety using the Taylor Manifest Anxiety Scale

Follow-up

Loss to follow up was not stated.

Analysis

An intention-to-treat analysis was performed.

Systematic Review: Results

Primary outcomes

Need for pain relief

A decreased need for pharmacological pain relief in women allocated to the hypnosis groups was noted when compared to the control groups (RR 0.53, 95% CI 0.36 to 0.79 [727 women]). All five trials reported on the use of pharmacological pain relief in labour. In one trial (Freeman et al 1986), no difference in the use of pain relief was observed between women receiving hypnosis and the control group (RR 1.06, 95% CI 0.40 to 2.82, [65 women]), although women rated to have a good or moderate response to hypnosis had relatively fewer epidurals than those rated to have a poor responsive (4/24 versus 4/5, $P < 0.05$). In one study (Martin et al 2001), women receiving hypnosis used less anaesthesia than women in the control group (RR 0.65, 95% CI 0.38 to 1.11 [42 women]). A third study (Harmon et al 1990) reported on the use of narcotics; fewer women in the hypnosis group used narcotics than in the control group (RR 0.21, 95% CI 0.08 to 0.55, [60 women]). The largest study (Mehl-Madrona 2004) reported that women receiving hypnosis required less pharmacological pain relief (RR 0.42, 95% CI 0.33 to 0.52) and less use of epidural analgesia (RR 0.30, 95% CI 0.22 to 0.40 [520 women]). In the oldest study (Rock et al 1969), a reduced incidence in the use of pain relief in those women allocated to the hypnosis intervention was noted when compared with the control group (RR 0.67, 95% CI 0.48 to 0.94). The I^2 statistic indicated significant heterogeneity; so a random-effects model was used for the meta-analyses of the five trials reporting this outcome (Figure 2.1).

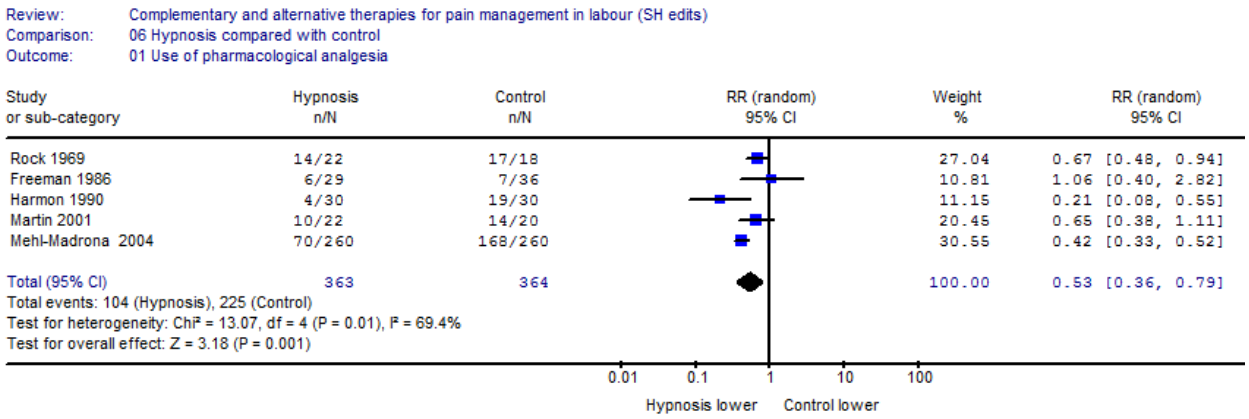


Figure 2.1: Meta-analyses of randomised controlled trials investigating the effects of hypnosis on pain during labour and childbirth

The decrease in analgesia use shown above is reflected also in the one trial where epidural analgesia for labour was named as an outcome. The data reported in one study (Mehl-Madrona 2004) study on epidural use in control and hypnosis groups is depicted in Figure 2.2 below.

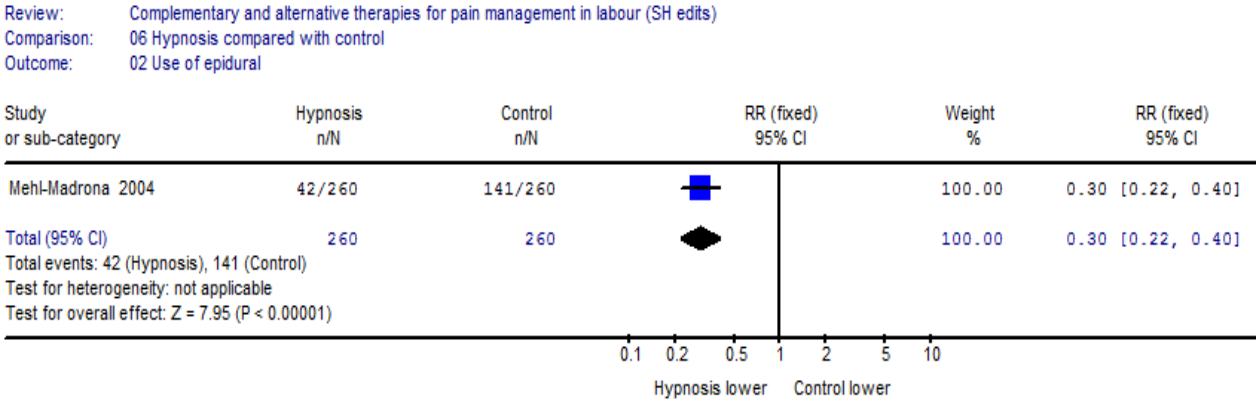


Figure 2.2: The effects of hypnosis on epidural use

Secondary outcomes

Maternal satisfaction and maternal experience of labour

One trial reported on maternal satisfaction with pain relief (65 women) (Freeman et al 1986). Women in the hypnosis group reported greater satisfaction than those in the control group (RR 2.33, 95% CI 1.15 to 4.71 [65 women]). According to another study (Rock et al 1969), women reported their experience as less painful ($P < 0.01$), although no data were presented. In addition, no women reported postnatal depression during their follow-up visit. In one study, anxiety and depression scale data were presented according to whether the birth was complicated or uncomplicated as defined by the author (Mehl-Madrona 2004). Another study (Harmon et al 1990) found no overall difference in measures of depression using the Minnesota Multiphasic Personality Inventory between women in the hypnosis and control groups (WMD-2.7, 95% CI -7.82 to 2.42).

Mode of delivery

The three trials reporting on mode of delivery (Freeman et al 1986; Harmon et al 1990; Mehl-Madrona 2004) found more women had a spontaneous vaginal birth in the hypnosis group than in the control group (RR 1.32, 95% CI 1.19 to 1.46 [645 women]). One study (Mehl-Madrona 2004) reported that women required caesarean sections at a significantly lower rate in the hypnosis group (RR 0.46, 95% CI 0.30 to 0.72 [520 women]).

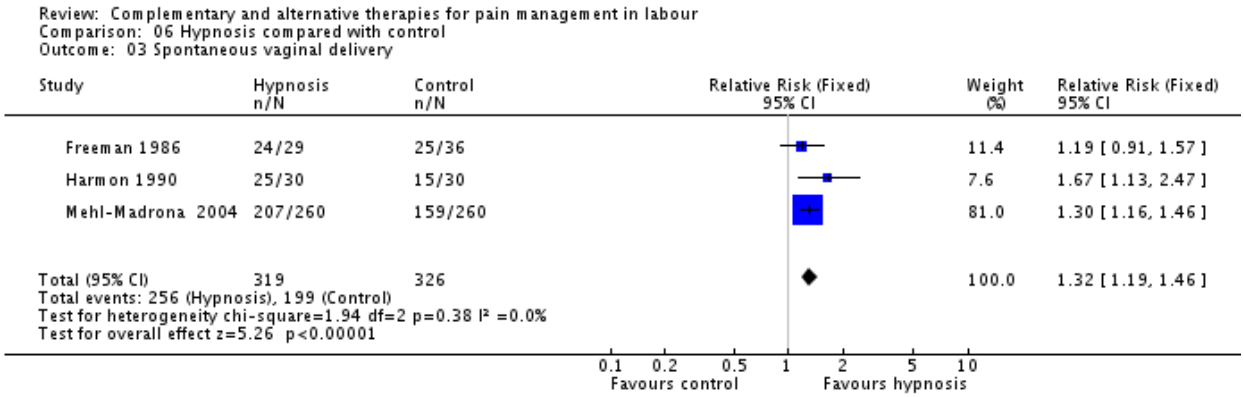


Figure 2.3: The effects of hypnosis on spontaneous vaginal birth

Use of augmentation

Three trials reported on the use of augmentation with oxytocins (Harmon et al 1990; Martin et al. 2001; Mehl-Medrona 2004). One trial combined augmentation with induction in the trial report. On contacting the author, additional information was requested to separate these outcomes, and this has now been provided (Mehl-Madrona 2004).

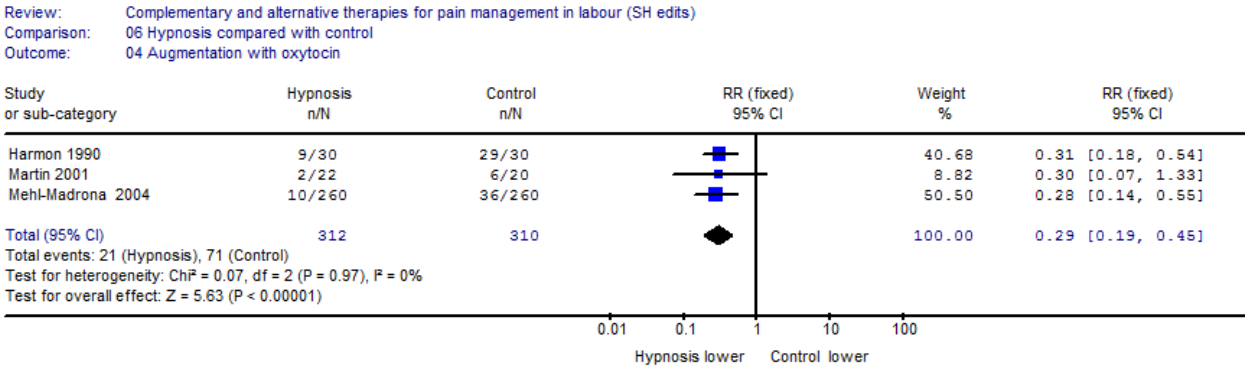


Figure 2.4: The effects of hypnosis on the use of oxytocics

Women in the hypnosis groups used less oxytocin than women in the control groups (RR 0.29, 95% CI 0.19 to 0.45 [622 women]), and women were reported by one study (Mehl-Madrona 2004) as less likely to require an induction of labour with hypnosis preparation for childbirth as compared to the control group (RR 0.34, 95% CI 0.18 to 0.65 [520 women]).

Length of labour

Only one study defined length of labour (as time from 5 cm to full dilatation), and found the duration of the first stage of labour in the hypnosis group to be significantly shorter ($p < 0.001$) than the control group by over two hours (Harmon et al 1990). One study (Freeman et al 1986) reported a longer mean duration of labour in the hypnosis group than in the control group (12.4 versus 9.7 hours, $P < 0.05$).

Neonatal outcome

Limited neonatal outcomes were reported in three trials. No difference between groups in admission to neonatal intensive care (RR 0.18, 95% CI 0.02 to 1.43 [42 babies]) was observed (Martin et al 2001). Apgar scores at five minutes were reported by one study (Harmon et al 1990); the mean score for the hypnosis group was 9.30 (standard deviation [SD] 0.65), and the control group's mean score was 8.7 (SD 0.50). No difference was seen in neonatal resuscitation between groups in one study (RR 0.67, 95% CI 0.11 to 3.96) (Mehl-Madrona 2004).

Systematic Review discussion

Despite the increasing use of hypnosis, numerous case series and a small number of RCTs, a lack of well-designed randomised controlled trials remains in order to evaluate the effectiveness of many of these therapies for pain management in labour. Apart from the research

on the effects of continuous support during labour (Hodnett et al 2007), hypnosis has been studied more frequently than any other non-pharmacological intervention. All but one trial (Mehl-Madrona 2004) studied the effects of hypnosis on only small numbers of women. All but one trial (Harmon et al 1990) were of poor methodological quality or inadequately reported. The insufficient reporting made the assessment of methodological quality and data extraction difficult. The heterogeneity reported for the hypnosis trials may be explained by variation in the design of the treatment interventions, including techniques and the duration of the intervention. Overall, the clinical implications of the studies are limited by the inclusion of few clinical outcomes.

Limitations of the systematic review

The evidence of the effectiveness of hypnosis as an adjunct to analgesia during childbirth to date is limited by only four small trials and one large trial of poor methodology (Smith et al 2006). Only one trial (Mehl-Madrona 2004) investigated women who had access to an "on demand" epidural service for labour analgesia, which is widely available in many developed countries. Neither the intervention nor the number of sessions were standardised in this study, which was performed by a single practitioner over a ten-year period. The intervention was unstructured and delivered with a very wide range in the number of sessions. Such features of previous studies limit the reproducibility of the intervention and decreases external validity.

Current available evidence appears to show that hypnosis reduces the need for pharmacological pain relief, including epidural analgesia in labour. Maternal satisfaction with pain management in labour may be greater among women using hypnosis (Rock et al 1969).

Other promising benefits from hypnosis appear to be an increased incidence of vaginal birth and a reduced use of oxytocin augmentation (Cyna et al 2004; Smith et al 2006). There was no evidence of any adverse effects on the mother or neonate. Potentially, clinical hypnosis could be used alone for pain relief as part of a woman's care during childbirth. In practice, however, hypnosis may be best seen as an adjunct to facilitate and enhance other analgesics.

Personnel delivering the hypnosis intervention during childbirth

A wide variety of personnel administered the hypnosis intervention under study in the various trials included in this review including medical students (Rock et al 1969), psychologists (Harmon et al 1990; Martin et al 2001) and obstetricians (Freeman et al 1986).

Number of hypnosis sessions

Although most clinical hypnotherapists use three or more sessions in the antenatal period when training women with hypnosis preparation for childbirth (Harmon et al 1990), others (Rock et al 1969) found hypnosis effective in untrained mothers during their labour. Clinical experience at our own institution suggests that the intervention is optimally delivered when three sessions are scheduled in late pregnancy (Cyna et al 2006). Interestingly, despite differences between trials in the timing and number of hypnosis interventions reported, outcomes are consistently in favour of hypnosis (Cyna et al 2004). However, the possibility of publication bias cannot be excluded.

Timing of the intervention

Previous research suggests that, as pregnancy progresses, responsiveness to hypnosis and suggestion increases(Tiba 1990). The largest hypnosis study to date (Mehl-Madrona 2004) has

shown that antenatal hypnosis training, when commenced in the first trimester, effectively reduces analgesia requirements. Most workers begin training women in the use of hypnosis later on in pregnancy, usually in the third trimester (Irving & Pope 2002).

Groups versus individual administration of hypnosis

One report (Leeb 1996) suggests that hypnosis can be successfully used in groups of up to 20 women when preparing for childbirth, while Harmon demonstrated a range of beneficial outcomes following antenatal hypnosis training in groups of 15 women (Harmon et al 1990). Anecdotal 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 (Fuchs et al 1980).

Multiparous versus 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 (Cyna et al 2005; Jenkins & Pritchard 1993).

Reproducibility of the hypnosis intervention

None of the studies have provided sufficient detail to reproduce the hypnosis intervention. However, four of the studies attempted to standardise the intervention, although few details were provided (Freeman et al 1986; Harmon et al 1990; Martin et al 2001; Rock et al 1969).

Supplementing hypnosis using an audio compact disc (CD) at home and during labour

Several workers ask patients to listen to an audio recording of hypnosis suggestions at home as practice in their preparation for childbirth, re-enforcing the techniques learned in the classroom (McCarthy 1998; Harmon et al 1990). The heterogeneity seen in our systematic review (Cyna et al 2004) can be explained by the use of supplemental recordings of suggestions, in one of the studies, in addition to live preparation (Harmon et al 1990). This appears to support the view that it is beneficial for subjects to practice the intervention using audio-recorded suggestions at home (McCarthy 2001). However, no randomised studies exist that 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 using a crossover design with the Stanford Hypnotic Clinical Scale. This study showed no difference in response to suggestions in these two conditions (Van Der Does et al 1989).

Conclusions

Implications for practice

The data available suggest hypnosis reduces the need for pharmacological pain relief in labour, reduces the requirements for drugs to augment labour and increases the incidence of

spontaneous vaginal birth. Women should not be discouraged from using hypnosis in this setting, as it may be effective.

Implications for research

Although solid preliminary evidence exists for the effectiveness of hypnosis for labour analgesia, too few women have been rigorously investigated in late pregnancy to provide strong recommendations; further adequately powered, well-designed trials are required. To date, no well-designed trials have been conducted with a large enough sample size to provide clear evidence of the effects of hypnosis in this setting. Further randomised controlled trials of hypnosis for pain management in labour are needed. These studies should be adequately powered and include clinically relevant outcomes such as those described in this review. The quality and reporting of future trials need to be improved. In particular, no trial reported satisfactory randomisation and allocation concealment. Future research in this setting should ensure adequate methods of randomisation and allocation concealment and its reporting. Only one study reported that an epidural analgesia service was available (Mehl-Madrona 2004). None of the included studies have investigated the effects of hypnosis on multiparous women. In addition, further research is required that includes data measuring neonatal outcomes and the effects on analgesia requirements in institutions with and without an ‘on demand’ epidural service. A cost-benefit analysis should be incorporated into the design of future studies.

Investigation is required of the timing and specific aspects of delivery of hypnosis such as the following: group versus individual training in hypnosis; the number of sessions of hypnosis; use of an audio recording on hypnosis versus live hypnosis; longer-term follow up for postnatal

depression (at least four months) and anxiety; the relative effects of hypnosis administered before and after the third trimester; whether different hypnotherapists delivering a similar intervention produce similar clinical outcomes.

Conclusions for this review

This systematic review suggested that hypnosis could be an effective intervention for: reducing the need for pharmacological pain relief in labour; reducing the requirements for drugs to augment labour; and increase the incidence of spontaneous vaginal birth. Too few women have been rigorously investigated in late pregnancy to provide strong recommendations suggesting that further adequately powered, well-designed trials are required. Such studies should include clinically relevant outcomes such as those described in this review.

Chapter 3 – The HATCh Trial Study Aims and Rationale

Introduction and Background to the HATCh Trial

The relief of pain and suffering associated with childbirth has been one of the long sought goals of the medical profession. Although medical interventions play an important role in preserving lives and maternal comfort, they have increasingly become part of the routine in normal childbirth. Labour pain and anxiety about childbirth and concerns regarding medical interventions have considerable implications for intra- and post-partum care. The conventional medical approach to the management of pain in labour and delivery has increasingly come to rely on the use of anaesthetic and analgesic drugs even when labour and childbirth are proceeding uneventfully. This trend has evolved in spite of reservations from within the medical community, midwives and mothers.

An antenatal program for women to train in hypnosis for pain relief during childbirth

Since April 2002, we have been developing an antenatal hypnosis training program for women after 36 weeks of gestation to be utilised for anxiolysis and as an analgesia adjunct during childbirth. Initially, women were planned to be attended to on an individual basis. However, increasing demand for this intervention from mothers, midwives and obstetricians at our institution has led us to the current practice of training groups of 5–10 women a week in self-

hypnosis techniques described previously (Waxman 1990; McCarthy 1998; Bejenke 1996). The hypnosis training program continued to develop over the three years prior to commencing the HATCh trial, 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 were held on a weekly basis for three consecutive weeks. Seventy-seven antenatal women were taught hypnosis in preparation for childbirth between January 2003 and August 2004. A comparison of birth outcomes of women experiencing antenatal hypnosis with parity-matched controls delivering after 37 weeks of gestation during 2003 at the largest referral centre for maternity care in South Australia showed that primiparous women receiving hypnosis preparation used fewer epidurals than controls. The ratios were 18/50 (36%) versus 765/1436 (53%) (RR 0.68, 95% CI 0.47, 0.98) and less augmentation 9/50 (18%) versus 523/1436 (36%) (RR 0.48, 95% CI 0.27, 0.90) (Cyna et al 2005). These findings were consistent with those of the systematic review (Cyna et al 2004).

Number of hypnosis sessions

Although most clinical hypnotherapists use three or more sessions in the antenatal period when training women with hypnosis preparation for childbirth, one group of workers (Rock et al 1969) found hypnosis effective in untrained mothers during their labour. Our clinical experience suggests that the intervention was optimally delivered when three sessions were provided to women.

Development of the structured intervention delivered by audio CD on hypnosis

The audio CDs 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, sat in on our Hypnosis Group sessions for several weeks and took notes of the types of suggestions utilised during each session. Our practice is based on published scripts of suggestions by experts in the administration of hypnosis in childbirth combined with anecdotal clinical experience. A final written script for each session based on our current clinical practice in training women in hypnosis in preparation for childbirth was finally agreed upon by the hypnotherapist members of the research team. These scripts were used to produce the 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 29 minutes (Cyna et al 2007; Cyna et al 2008; Cyna et al 2008a). A fourth audio CD lasting 14 minutes has also been developed for use during labour and childbirth (Cyna et al 2007). Multiple copies were made by our institution's digital media department. The CDs are labelled with a caution that they should not be used while operating machinery or driving. The lead investigators' names and contact phone numbers are also shown on each CD label. Participants are also advised that the CDs are for their use alone as part of the Hypnosis Antenatal Training for Childbirth (HATCh) Trial.

Timing of the intervention

One study (Tiba 1990) found that as pregnancy progressed, responsiveness to hypnosis and suggestion increased. Our clinical 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 versus individual administration of hypnosis

One study (Leeb 1995) successfully used hypnosis in groups of up to 20 women in preparation for childbirth, while another (Harmon et al 1990) demonstrated a range of beneficial outcomes following antenatal hypnosis training in groups of 15 women. Our own experience suggests that group hypnosis may be effective and allows more women to receive the intervention than would be the case with individual administrations.

Rationale for a clinical hypnosis study in childbirth

Pain and the fear of pain associated with childbirth are nearly universal. Currently utilised pharmacological methods of pain relief have limitations, and well-recognised complications are associated with their use. Reducing pharmacological analgesia requirements in labour will reduce the incidence of their complications and potentially improve the childbirth experience. Use of hypnosis during childbirth has a long history. It is claimed to be one of the most useful settings in which to utilise hypnosis (Scott 1974; August 1960; Spiegel 1963).

Systematic review evidence to date presented in Chapter 2 and our use of hypnosis as antenatal preparation for labour at the Women's and Children's Hospital (Cyna 2003a; Cyna et al 2005) suggest benefits in reducing analgesia requirements, oxytocin administration and an

increased incidence of spontaneous birth. However, the existing evidence from small or poorly designed trials is inadequate to confirm these effects. Renewed interest in this topic and the call for more research is as relevant today as it was 30 years ago (Davenport-Slack 1975).

The hypnosis intervention used in the author's institution appears to be easy to administer and relatively simple and inexpensive means of preparing women for labour and childbirth. This is the first randomised trial investigating the effects of antenatal hypnosis preparation for childbirth in late pregnancy in both nulliparous and multiparous women. It had a structured defined intervention, the capability to be reproduced easily, excellent external validity, clearly described adequate allocation concealment and the incidence of postnatal depression as a key endpoint.

The perioperative use of hypnosis has been shown to increase the incidence of beneficial outcomes and lower costs. This is very likely to be translated into the childbirth setting. Although interventions such as epidural analgesia have been shown to be an effective form of pain relief in labour, they can deprive the mother of an optimal birth experience (Morgan et al 1982) and are associated with adverse effects such as post-dural puncture headache and neurological injury (Weeks 1999; Bromage 1999). The increasing medicalisation of childbirth (Johanson et al 2002) has led many women to look for alternative means of relieving labour pain.

The systematic review evidence presented in Chapter 2 suggested that learning hypnosis techniques for use in childbirth would allow mothers to reduce their need for pharmacological analgesia and other interventions, such as intravenous oxytocic, and increase their chance of having a spontaneous vaginal birth (Cyna et al 2004; Huntley et al 2004; Smith et al 2006). Also,

as presented in Chapter 1, several reports indicate a low incidence of postnatal depression associated with women preparing for childbirth using hypnosis techniques, although comparative data is lacking (August 1960; McCarthy 1998). Convincing evidence in the perioperative setting has shown that the use of hypnosis decreases patient anxiety and reduces overall costs (Lang & Rosen 2002; Lang et al 2000; Faymonville et al 1997). A large, randomized, well-designed study with a hypnosis intervention that could be easily implemented, should it be shown to be effective, was clearly needed.

Study Aims of the HATCh Trial

The HATCh Trial aimed to determine the efficacy, or otherwise, of antenatal group hypnosis preparation for childbirth. If effective, this intervention would be a relatively simple and inexpensive way to improve the childbirth experience, reduce side effects and complications associated with pharmacological interventions, yield cost savings in maternity care and provide evidence to guide clinical practice.

Specific aims

The specific aims of this study are to assess whether antenatal hypnosis preparation for childbirth

- is an effective way of reducing a mother's use of pharmacological analgesia
- reduces the incidence of adverse outcomes on the mother
- reduces the incidence of adverse effects on the baby
- impacts the mother's emotional well-being

Additional specific aims

Additional aims of the HATCh trial were to compare two methods of delivering antenatal group hypnosis in a double-blind fashion. One method used a hypnotherapist to deliver the intervention followed by an audio CD on hypnosis for re-enforcement of the techniques learned. The other method was to use an audio CD on hypnosis alone to deliver the intervention.

Hypotheses

The primary hypothesis of the study was to investigate whether antenatal hypnosis, when compared with cases where no intervention was made, reduces the use of pharmacological analgesia during labour in mothers planning a normal vaginal birth, as measured by documentation of analgesia techniques used in the birth register or maternal medical record.

The null hypothesis

Antenatal hypnosis has no effect on maternal pharmacological analgesia requirements when compared with cases where no intervention is made.

Secondary hypotheses

Antenatal hypnosis when compared with no intervention:

- decreases the maternal perception of the overall pain experienced during labour and childbirth as measured by a 0–10 numerical rating scale in the postnatal period within one week and at 6 weeks;
- increases the incidence of mothers reporting that they received adequate pain relief during childbirth as measured by a postnatal maternal questionnaire;

- increases the incidence of spontaneous vaginal birth as measured by documentation in the birth register or medical record;
- decreases the use of oxytocic as documented in the birth register or medical record;
- decreases the duration of labour as measured by documentation in the birth register or medical record;
- increases maternal satisfaction with the birth experience as measured by maternal questionnaires that include a 0–10 numerical rating scale in the postnatal period within the first week and at 6 weeks;
- increases a perceived sense of maternal control during labour and during the birth as measured by maternal questionnaires that include a 0–10 numerical rating scale within one week of the birth;
- increases the mother's subjective ability to cope with labour and childbirth as measured by maternal questionnaires that include a 0–10 numerical rating scale in the postnatal period within one week of the birth;
- increases the incidence of a positive birth experience as measured by maternal questionnaires that include a 3-point verbal descriptor scale within one week of the birth;
- decreases the incidence of the baby's admission to the neonatal unit as measured by the medical and nursing notes;
- decreases the baby's length of stay in the hospital as measured by the medical and nursing notes;
- decreases the maternal length of stay in the hospital as measured by the maternal record;

- increases the incidence of breast feeding post-partum as measured by the mother's response to the postnatal questionnaires at 6 weeks;
- decreases the incidence of postnatal depression as measured by the mother's response to the EPDS and specific questions about being treated for postnatal depression in the postnatal questionnaires at 6 weeks; and
- decreases post partum anxiety as measured by the mother's response to the Spielberger State/Trait Anxiety Scale in postnatal questionnaires at 6 weeks.

Other secondary outcomes

(1) Antenatal hypnosis guided by a hypnotherapist has a greater treatment effect on primary and secondary outcomes when compared with an audio CD on hypnosis administered by a nurse with no hypnotherapy training, as measured by the maternal/birth record and the mothers' responses to our postnatal questionnaires.

(2) Hypnotisability as measured by the CIS is predictive of analgesia requirements in childbirth, and other maternal/neonatal/birth outcomes.

(3) Antenatal expectations of the need for epidural analgesia and predicting a spontaneous vaginal birth, as measured by maternal response to a baseline antenatal questionnaire, is predictive of analgesia requirements in childbirth, and other maternal/neonatal/birth outcomes.

A trial was proposed that was the most comprehensive yet put forth, and its expanded scope covers many of the criticisms of previous attempts to evaluate the effects of hypnosis in childbirth (Irving & Pope 2002). In addition, the trial design has solid

external validity, as the techniques used are structured to include many of the features reported previously by experts in the field using antenatal hypnosis as preparation for childbirth. In addition, the structure of the sessions is fixed, using audio CDs based on our live intervention. This simple structured delivery of the intervention was expected to allow other workers to deliver the intervention should the expected benefits be realised. The possible confounding of outcomes was minimised by the use of stratification of parity at randomisation. Proposed sub-group analyses were planned a priori so that other possible unavoidable confounders in a study of this type could be accounted for. It was considered likely that many unanswered questions related to this topic would be answered upon completion of this trial.

Chapter 4 – HATCh Methods & Research Plan

Experimental Design

A single-centre, randomised, controlled trial using a 3-arm parallel group design to assess the effects of hypnosis preparation for childbirth in late pregnancy as a means of reducing analgesia requirements in labour and improving other birth outcomes.

Interventions

Group 1: Hypnosis administered by a hypnotherapist plus audio CD on hypnosis for re-enforcement and consolidation.

Group 2: Audio CD on hypnosis administered by a nurse without training in hypnotherapy

Group 3: No intervention control; participants were asked to continue with their usual preparation for childbirth

Setting

The largest tertiary maternity unit in South Australia

Participants – inclusion criteria

Women > 34 to 39 weeks gestation, with a 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 are planning a vaginal birth.

Participants – Exclusion Criteria

- Previous hypnosis preparation for childbirth
- Poor understanding of English, requiring a translator
- Women who were 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

Pain caused by specific pathological entities such as

- congenital neuromuscular disorders
- spina bifida
- metastatic disease
- osteoporosis
- rheumatoid arthritis
- fractures

Trial entry

Potentially eligible women > 34 weeks of gestation were identified during their attendance at the antenatal clinic, antenatal classes, or midwifery group practice, or while an in-patient of the antenatal ward. Posters advertising the trial were placed around the hospital in

these areas. An 'expression of interest' form was made available where mothers could obtain contact information from our research coordinator and be advised on further information regarding participation in the trial.

All women approached for eligibility had a structured explanation regarding participation in the trial and were numbered according to the consort statement (Begg et al 1996). Potential trial participants were informed that they had a 66% chance of being allocated to one of the hypnosis interventions and a 33% chance of proceeding with their childbirth preparation following the usual practice of our institution. Eligible women who declined to enter the trial were asked for consent to allow us to collect routine birth outcome data without any other intervention. Reasons for declining to participate were recorded as among the following: 'not interested', 'against my religion', 'too busy', 'don't believe in it', 'declined randomisation', or 'other'. Other reasons for leaving the study prior to randomisation were noted. For safety considerations, the consent process included permission from participants to inform their GP and obstetrician if further clinical assessment or treatment for postnatal depression was indicated. Baseline demographic data about study participants was collected, including parity, health insurance status, highest level of formal education, marital status and the use of any complementary therapies such as acupuncture or yoga. At this time, participants were asked to complete the Spielberger State/Trait Anxiety Measure (Barber & Wilson 1978) and EPDS. Women were tested for hypnotisability using the CIS which unlike other scales avoids a formal induction of hypnosis and therefore was less likely to contaminate the control group during baseline testing. We delivered the scale by asking participants to listen to a standardised audio

CD of the CIS in the presence of a researcher. Participants then completed an answer sheet detailing their imaginative experience on a 5-point Likert-scale (Spielberger 2004).

Randomisation

Biomedical statisticians at our institution's Department of Public Health have arranged for a computer-generated random number sequence of unspecified block size stratified for parity to produce study arms of approximately equal size. This method allowed for similar numbers of nulliparous and multiparous participants to be allocated to each study group at any time point.

Allocation concealment

After baseline testing was completed, we were provided with the group allocation for each individual participant via telephone at the Department of Public Health for the first 6 months of the study and then by a password-protected computer database program. The randomization sequence was inaccessible to research assistants involved in recruiting potential trial participants. Allocation concealment was assured as participant ID, parity and eligibility for trial entry were confirmed and recorded on a password-protected computer database prior to revealing the participant's group assignment. Participants assigned to hypnosis groups were given appointments by our research assistant to commence antenatal group hypnosis training as closely as possible to 37 weeks of gestation.

Blinding

The nature of the intervention made it difficult to double blind comparisons between hypnosis groups and non-intervention controls. However, every attempt was made to conceal group allocations from the treating obstetricians, anaesthetists, midwives and those personnel

collecting and analysing data. All participants were informed that they may or may not appreciate which group they are in, as we believed that some women might think that the baseline testing for hypnotisability was the intervention. However, we did expect that most women allocated to usual care would probably realise they were not in an intervention group. Although it was not possible to blind the administration of our intervention, all data was collected and analysed by researchers who were unaware of the participants' group allocation. Any comparisons between participants receiving an intervention in Groups 1 and 2 were made in a truly double-blind fashion with both participants and outcome assessors blinded to allocation.

Our primary outcomes and key secondary outcomes were designed to be as objective as they could be for a study of this type. An assessment of blinding was determined by asking participants if they thought they were in a control or intervention group in the final post-partum questionnaire.

Trial registration: The trial was registered with the Australian Controlled Clinical Trials Register (ACTRN012605000018617) in November 2005 prior to commencing recruitment for the study.

CONSORT criteria: All eligible women were numbered according to the consort statement (see the section titled 'Trial Flow' below).

Ethics approval: Local Regional Ethics Committee approval was obtained prior to recruitment in 2005 with a further three-year extension obtained in 2008 (Approval No: REC1600/6/2010). Recruitment commenced in December 2005 and was completed by the end of June 2009.

Treatment schedules

A researcher was responsible for base line data management, collection and co-coordinating of appointments with the hypnotherapist and nurse supervising Group 1 and 2 participants respectively and directing women to their allocated interventions. Following baseline demographic data collection, which included the administration of the EPDS, Spielberger and CIS, trial participants were informed of where and when to attend their allocated sessions. The two interventions were administered in groups of up to ten women in the hospital's group physiotherapy room. Participants allocated to an intervention were requested to attend sessions, scheduled as closely as possible to 37 weeks of gestation and held at weekly intervals for three consecutive weeks. Those women having a planned induction of labour were allocated to their hypnosis sessions as quickly as possible to commence within three weeks of the induction date rather than the original expected date of confinement (EDC).

The intervention

Group 1: Antenatal hypnosis plus hypnosis audio CD (hypnotherapist guided)

Session 1

Fears and anxieties were discussed, questions about hypnosis answered and expectancy of success seeded. Basic hypnosis was taught using progressive relaxation with a self-hypnosis component at the end. Women were asked to listen to the session 1 audio CD on a daily basis until the next session (Cyna et al 2007).

Session 2

After a hypnosis induction, suggestions were given for confidence, coping and strength during contractions. Women were asked to focus on breathing for analgesia and relaxation. Suggestions for time distortion were given to allow contractions to seem shorter and rest periods between contractions to seem longer than they really were. Standardised suggestions were given for a labour rehearsal involving recurrent fractionation and staircase imagery (McCarthy 2001). Women were asked to listen to the session 2 audio CD on a daily basis until the next session (Cyna et al 2008).

Session 3

In terms of pain control techniques, amnesia was suggested for unhelpful comments and utilisation of helpful suggestions. Dissociation and lower body anaesthesia were elicited using the lignocaine spa imagery (McCarthy 2001). Suggestions were given for uterine contraction after delivery and relaxation to facilitate breastfeeding. The Session 3 audio CD was played and women were asked to practice hypnosis while listening to the whole CD on a daily basis until the birth (Cyna et al 2008a). Women were told that they could listen to the labour audio CD during labour if they wished (Cyna et al 2007).

Group 2: Antenatal hypnosis audio CD (Nurse guided)

Session 1

Participants were given structured information to help them draw as much as possible value from the audio CDs. It was suggested that not trying to pay conscious attention and going along with any instructions would provide optimal benefit. Questions were answered and

Session 1 audio CD was played (Cyna et al 2007). Participants were asked to listen to the CD at least on a daily basis until the next session.

Session 2

Questions from study participants were answered. The Session 2 audio CD was played (Cyna et al 2008). Participants were asked to listen to the audio CD at least on a daily basis until the next session.

Session 3

Questions from study participants were answered. The Session 3 audio CD was played. Participants were asked to listen to the CD at least on a daily until the birth (Cyna et al 2008a)

Group 3: No intervention control

Women allocated to usual care were not asked to attend any further sessions at the hospital other than those required for their usual antenatal care. These mothers were further involved by responding to a maternal questionnaire in the early postnatal period.

Compliance with Treatment Schedules

Those women allocated to attend either of the two intervention groups were asked to listen to each session audio CD on a daily basis between the weekly sessions. Those participants who were unable to attend one or more sessions in person were contacted by telephone to confirm all was well. We then asked if we could post the audio CD(s) of the missed session so that the participant may listen to its prior to their next hospital visit. Trial participants were able to withdraw from the trial at any stage. All randomised participants and their babies received post partum followed up regardless of the treatment actually received.

Care during labour and the postnatal stay

Care of the woman during labour and postnatal stay was managed by the trial participants' attending midwife, obstetrician and neonatal team consistent with the usual practice of our institution.

Sample size calculation

It was proposed that a sufficient number of women be randomised to provide reliable evidence of the effects of antenatal hypnosis regarding the primary outcome measure of this study: the incidence of not using pharmacological pain relief during labour and childbirth. An audit of 100 consecutive mothers birthing in the largest tertiary referral centre for maternity care in South Australia was performed in May 2004. This audit showed an incidence of using one or more pharmacological interventions in 80% of birthing women. In order to show a clinically relevant fall of 20% in the number of women requiring pharmacological analgesia, that means from 80% to 64%, a power calculation was performed using a 2-tailed calculation (nQuery advisor computer program V.5). ***A study with 80% power would require each group to contain 135 women to detect this difference at the 0.05 level***.

Complete collection of the primary endpoint was assured as all analgesia techniques used, such as Entonox, pethidine and epidural analgesia were documented routinely in the labour ward birth register and medical record by each participant's treating midwife. We planned to recruit 150 women per group to accommodate for unforeseen reasons such as incomplete or unusable data. The findings of our case-matched control study at our institution (Cyna et al 2005) were consistent with those of our systematic review of the literature on this topic (Cyna et al 2004).

No comparative trials have investigated the effects of hypnosis on postnatal depression, although acknowledged experts in the field report a low incidence in women taught hypnosis; < 1% (McCarthy 2001). Currently, postnatal depression affects one in seven women (approximately 14%) giving birth in Australia. Our study had a power of 80% at the 0.05 level of significance to show a reduction from 16% to 5.4% for this secondary outcome. For normally distributed continuous measures (e.g., EPDS), we would be able to detect shifts of 0.4 SD with a power of 80% between individual arms of the study (n = 135 per group). Comparisons that exploited the two treatment groups (assuming a conservative estimate of postnatal data in 270 subjects in Groups 1 and 2) had an 80% power to detect a shift of only 0.28 SD. A sample size of 135 per group gave us an 80% power to detect the following differences in specified primary and key secondary endpoints at the 0.05-level.

Key endpoints

Significant rate differences calculated in treatment and control groups with a sample size of 135 per group Nullip. = Nulliparous, Multip. = Multiparous

Table 4.1: Key endpoints calculated on sample size for various key outcomes

Key endpoints	Rate for usual care %	Expected % change detectable by sample size	Expected rate for hypnosis women given this % change
Pharmacological analgesia (Nullip)*	80	20	64
Epidural rate**	Total 39 Nullip. = 62 Multip. = 33	Total = 41 Nullip. = 27 Multip. = 45	Total = 23 Nullip. = 45 Multip. = 18
Use of oxytocics**	Total = 31 Nullip. = 36 Multip. = 18	Total = 48 Nullip. = 45 Multip. = 65	Total = 16 Nullip. = 20 Multip. = 6
Spontaneous vaginal birth**	Total = 57 Nullip. = 47.5 Multips = 77	Total 26 Nullip. 35 Multip.18	Total 73 Nullip. 65 Multip. 91
Postnatal depression	16	69	5
EPDS	Unknown		
Spielberger	Unknown		

* *Data collected from the birth register at our institution for the month of May 2004*
* * *Clinical Information Service 2004 data for our institution*

Based on these estimates, a total recruitment of 450 women would have detected significant differences of clinical relevance for the primary outcome and for some key secondary outcomes. We recognized that a trial of this size was likely to be too small to detect differences in the risk of some of our secondary endpoints. This information will allow comparisons of women in other studies of hypnosis in a systematic review or suggest other beneficial outcomes or adverse effects that require further controlled evaluation.

Data Collection and Outcomes

Assessment of primary outcomes

Data on our primary outcome, the use of pharmacological analgesia during labour and childbirth, was collected from the birth register and medical record where all analgesia was documented by the attending midwife. Any unclear entries were clarified by referring further to additional notes in the medical and midwifery record of the birth.

The definition of each specific primary outcome is designated below:

(1) The field "No pharmacological analgesia" was defined to contain the number of women in each group where no pharmacological analgesia was used during labour or childbirth whether or not they had a caesarean section or other intervention.

(2) The field "Nitrous oxide" was defined to indicate the use of nitrous oxide inhalational analgesia at any time during labour and childbirth.

(3) The field "Use of opioids analgesia" was defined to indicate the use of parental opioids analgesia such as intravenous, intramuscular, or subcutaneous pethidine, morphine or fentanyl but excluding neuraxial opioids.

(4) The field "Use of epidural" for analgesia was defined to indicate one of the following: combined spinal epidural (CSE) or spinal for labour analgesia or assisted vaginal or operative birth.

Assessment of key secondary outcomes

Data on most of our key secondary endpoints, such as the use of oxytocics, the mode of delivery, neonatal Apgar score at 5 minutes < 7 and maternal admission to the High Dependency Unit (HDU) or the Intensive Care Unit (ICU), were obtained from the birth summary record in the medical notes. These outcomes were documented by a midwife who was unaware of the respective parturients' group allocation.

Maternal events during labour and delivery

Maternal side effects, such as PPH= > 600 ml, blood transfusion, death, ICU admission, meconium stained liquor and babies admitted to the neonatal unit, were documented from maternal, nursing and medical records.

Other secondary outcome data collection following delivery

A second researcher who was blinded to group allocations managed the data collections on the ward and from post-natal questionnaires. Mothers were asked to complete a postpartum questionnaire while in the hospital and asked to rate the overall pain experienced during labour and childbirth, whether the birth experience was worse/better/same as expected, whether they felt in control during the labour and during the birth and whether the birth was rated as a positive or negative experience. We also asked mothers how well they coped with labour/childbirth, whether hypnosis training was obtained outside of the trial and whether hypnosis will be used in future pregnancies. The length of the neonatal nursery stay, length of the maternal stay in the hospital and number of women breast-feeding at discharge from the hospital were also recorded.

Further follow-up

Postnatal questionnaires were sent to each participant at 6 weeks and 6 months after the birth; the EPDS and Spielberger anxiety scales were repeated. Women were asked whether they were still breast-feeding and were invited to make comments about any problems or difficulties with the intervention. Two weeks after posting the postnatal questionnaires, non-responders were contacted by telephone call at home.

Assessment of hypnotisability during intervention sessions (Groups 1 & 2)

A variety of phenomena accompany the hypnotic state. The extent to which these phenomena are experienced or observed are traditionally thought to be associated with the depth of the hypnotic state (Burrows & Stanley 2001). Any hypnotic phenomena demonstrated during the delivery of the intervention, such as eye catalepsy, arm levitation or time distortion, were also documented.

Data Management

The EDC of each participant recruited was entered on an Excel spreadsheet, and a register of trial participants was accessed from our hospital patient database (OACIS) on a daily basis on order to identify when a trial participant had delivered. The date of delivery was entered on the spreadsheet, which utilised formulas to indicate when the 6-week and 6-month postnatal surveys were due. Data entry into a computer database, data verification and completion of all data fields were finalised as early as possible at each time point when the data became available. All data was accounted for and reasons were given for why any data was missing.

Analyses

All primary and secondary outcomes of trial participants fulfilling all eligibility criteria were analysed using the "Intention to treat" principle. A comparison of key endpoints was made for mothers in all three groups. Analyses were performed with a researcher blinded to group allocations. Initial analyses examined baseline characteristics of all randomised participants according to the "intention to treat" principle. Chance differences in baseline data found between treatment groups were taken into account in subsequent analyses. The population was characterised by maternal age, highest level of education and maternal expectations of a normal delivery. Subsequent analyses took into account parity, whether labour was induced, number of sessions participants attended, whether each session CD was used at least once, hypnotisability as measured by the CIS and the number of sessions attended.

We tailored the hypnosis intervention so that most of the skills were learned in the first session and nearly all the skills were delivered by the second session. The third session was designed for re-enforcement and consolidation of the teachings. All women giving birth prior to completing all three sessions were analysed both on an "intention to treat" basis and with total session exposure as a predictor. All eligible women approached who decided to continue their preparation for childbirth outside of the trial were asked for permission that we may collect birth outcome data in order to compare primary outcomes of non-participants with those participants randomised to our "no intervention" control group.

Statistical tests

Descriptive statistics mean/SD for parametric data, median and inter-quartile range for non-parametric data were reported. For dichotomous outcomes: Chi squared and/or Relative Risks with 95% CIs were reported. Regression analysis was utilised to examine the influence of potential confounders on our outcomes of interest. Kruskal-Wallis equality-of-populations rank test was used for non-parametric comparisons and ANOVA for parametric analyses. The Number Needed to Treat (NNT) was used for benefit and harm where appropriate and were calculated using Stat calc and the SPSS computer program. On the basis of data from previous studies, we hypothesized that the intervention would decrease the use of analgesia during labour by 20%. To detect a significant difference between the groups with a type I error of 0.05 and a power of 0.80, 417 women had to be recruited, 139 in each group. We decided to include 150 women in each group to allow for women lost to follow-up or missing the full intervention. Continuous variables of non-parametric data were reported as medians and interquartile ranges and categorical variables as proportions. Comparisons of continuous non-parametric variables between the two randomized groups were performed with the Wilcoxon rank-sum test, whereas comparisons of categorical variables were performed with the Pearson chi-square test or Fisher's exact test, as appropriate. Parametric data are presented as means and standard deviation with ANOVA or Student's t-tests utilised to compare the groups as appropriate. All tests were two-sided, and P-values of less than 0.05 were considered to indicate statistical significance. Statistical tests were performed using the SPSS™ software package.

Sub-group analyses

Sub-group analyses of primary outcomes were performed for women regarding induced versus spontaneous labour, attendance at all three sessions, listening to the audio CD between sessions and during labour, women's hypnotisability, women's beliefs on whether they were in the experimental group, women's beliefs of the efficacy of hypnosis prior to labour, women's expectations of requiring an epidural, women's expectations of having a normal spontaneous birth, and previous experience of non-childbirth hypnosis or yoga.

Interim sequential analyses

As described previously (Whitehead 1992), interim sequential analyses were planned for all primary and main secondary outcomes when 150 and 300 participants had been recruited, Our independent data monitoring committee (DMC) had clear stopping rules in their terms of reference when reviewing data and performed analyses as Group A versus B versus C, without knowing which groups were assigned to intervention or control.

Stopping rules

Significant differences in serious adverse events between groups, or clear differences ($p < 0.01$) between groups shown in primary outcome, and futility in continuing the trial were planned reasons for stopping the trial early that did not eventuate. Following primary and key secondary outcomes assessments, the steering committee were advised to continue the trial by the DMC at two pre-planned time points. The first interim analysis was done around August 2007 with an N=150; the second interim analysis was done around June 2008 with an N=336. These interim analyses were taken into consideration when looking for differences between groups.

Safety Concerns

Hypnosis is an extremely safe intervention in pregnancy with only two previous case reports of associated adverse effects in pregnancy (Cyna 2003). Women scoring > 12 on the EPDS, or where otherwise indicated, were advised to see their GP for advice. All participants gave consent for treating clinicians to be informed of any clinical concerns and/or the need for further clinical assessments during the trial.

Confidentiality and data security

All patient data was de-identified during analyses. All trial documentation and participant identifiers will be kept in a locked cabinet and stored for 25 years after publication of the trial results. Trial data on a computer database will be protected by password.

Protocol violations at enrolment to the HATCh Trial

After completing two years of recruitment, we became aware that 137 women had been randomised who were ineligible for participation as their gestation fell below the pre-specified requirement for > 34 weeks of gestation at trial entry. We therefore planned to continue to recruit women to the study until our initial planned sample size of 450 eligible women had been reached and to perform our planned analyses of only those women who met all eligibility criteria for inclusion (Figure 5.1).

Chapter 5 – HATCh Trial Results

The HATCh Trial results are presented in four sections:

Section I: **Trial flow** and aspects of recruitment during the course of the HATCh Trial

Section II **Baseline data**, relative risks and 95% CIs, and P-values where significant differences between groups were found;

Section III **Primary and key secondary outcomes** for both mothers and their babies

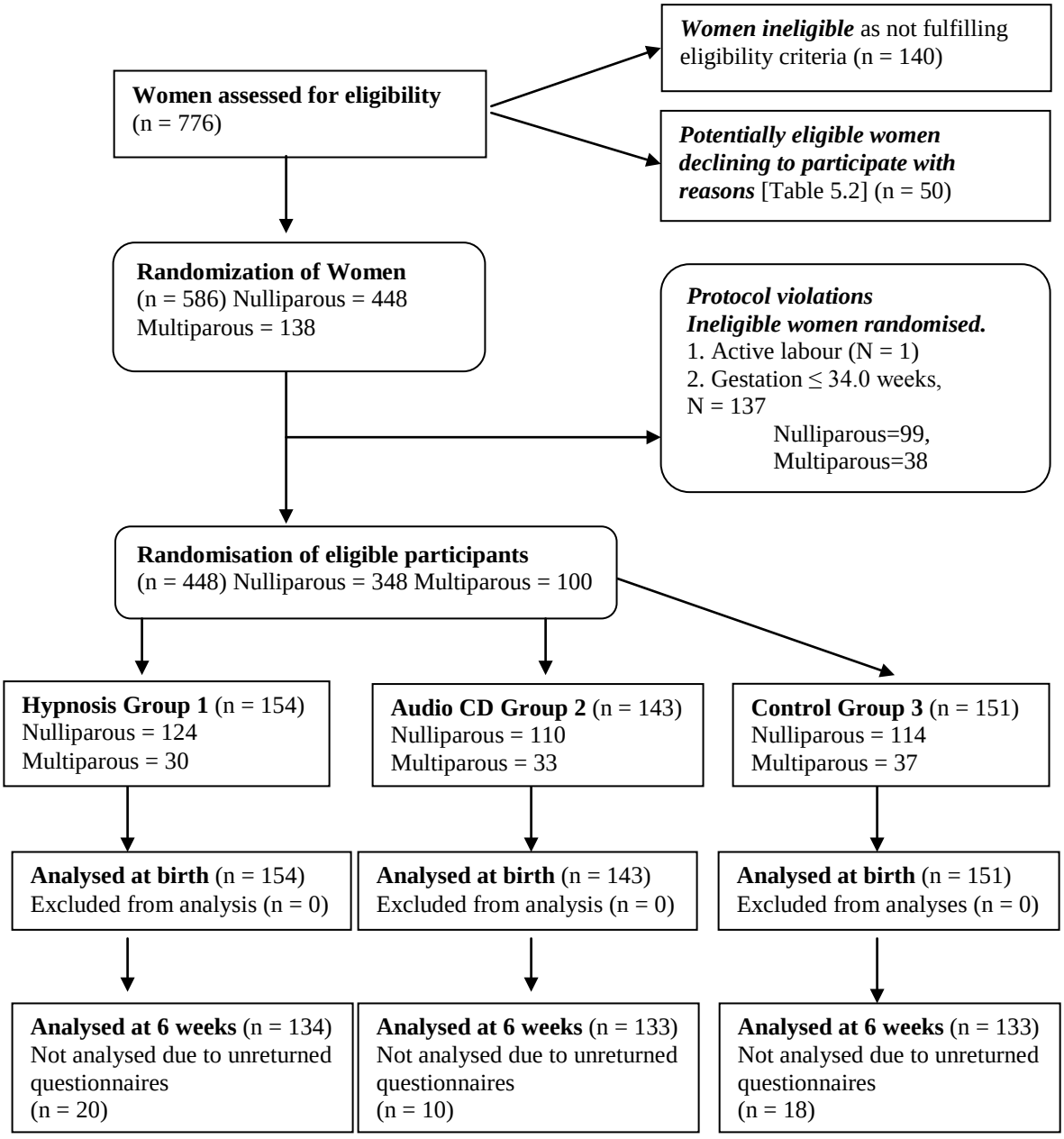
Section IV **Outcomes for our 6-week follow-up** questionnaires of HATCh Trial participants

Section I Trial Flow

Eligibility for trial entry was assessed in 776 women between December 2005 and July 2009 as shown in Figure 1. Of the assessed women, 278 women did not meet the eligibility criteria (140 prior to randomisation and 138 post randomisation), and 50 eligible women declined to participate (Figure 5.1).

All original eligibility and inclusion criteria for the HATCh Trial were met by 448 randomised women: 154 were allocated to receive the hypnosis intervention; 143 women were allocated to the CD group and 151 women were allocated to the control group (Figure 1). Data from all these participants were available for inclusion in the primary analysis at birth for both mothers and their babies. At six weeks post-partum, 400 women (89.3%) returned questionnaires with data suitable for analyses. Of these, 134 women (87.0%) were allocated to receive hypnosis, 133 (93.0%) were allocated to the CD group, and 133 women allocated to control (88.1%).

Figure 5.1: The HATCh Trial Flow Chart



Referral sources of women considering participating in the HATCh Trial

HATCh Trial participants were referred from a variety of sources (Table 5.1). Overall, there were 75 referrals from midwives, 61 phone calls from women, and 179 patients were self-referred having heard about the trial from advertising at the hospital, talks given by a researcher, from the antenatal clinic, and media reports of the trial. A total of 133 women submitted an expression of interest form. Referral to the HATCh Trial occurred largely by self-referral via a phone call or a submission of an expression of interest form to a researcher. Midwives were more likely to refer patients than obstetricians. Several women who were otherwise eligible, declined to participate in the HATCh Trial (Table 5.2).

Table 5.1: Referral sources of trial participants and their treatment group allocation*

Source of recruitment of HATCh Trial participants	Allocation		
	Hypnosis	CD only	Control
Midwife referral	23 (14.9)	25 (17.5)	27 (17.9)
Obstetrician referral	4 (2.6)	0 (0.0)	1 (0.7)
Patient phone call to a researcher	23 (14.9)	22 (15.4)	16 (10.6)
Patient submitted an expression of interest form	51 (33.1)	34 (23.8)	48 (31.8)
Other	53 (34.4)	62 (43.4)	59 (39.1)
Total	154 (100)	143 (100)	151 (100)

**Data are shown as numbers (%)*

Reasons for declining to participate in the HATCh Trial

Most eligible women declining to participate in the HATCh Trial did not report their reasons (Table 5.2). Most women that gave a reason reported that pregnancy was too far advanced for them to participate while a small minority did not wish to be in a trial that might randomise them to a non-hypnosis group. Knowing the reasons for declining to participate in this trial may help researchers recruit some additional women in future studies. Firstly, by recruiting at an earlier stage and, secondly, by explaining that being allocated to a non-hypnosis group does not necessarily mean women will use less analgesia than being in a control group.

Table 5.2: Reasons eligible women gave for declining to participate in the HATCh Trial

Reasons for declining to participate	**Potentially eligible women** (%) N = 50
Pregnancy felt to be too advanced to attend sessions	12 (24)
Definitely wanted hypnosis	7 (14)
Too tired to attend all sessions	2 (4)
Reason not stated	29 (58)

Section II Baseline Data

We performed our analyses on the 448 eligible randomised participants who fulfilled all our inclusion criteria (Figure 1). Our analyses of baseline data shows that the randomisation with stratification for parity produced comparable groups with the exception of the incidence of women with a history of depression, and an EPDS score > 12 being increased in the Hypnosis Group (Tables 5.3 and 5.4). The distribution of all other participants' baseline demographic data across the three groups, such as mothers' use of complementary therapies during their pregnancy, age, weight and country of birth, were also comparable (Table 5.3). Over 55% of women had a tertiary education, which is substantially higher than the average among the South Australian pregnant population as a whole. There is an association with a higher incidence of women allocated to the Hypnosis Group with a history of depression compared to controls, although this did not reach statistical significance. Apart from a possible higher incidence of a history of depression in the Hypnosis Group, baseline data between groups was comparable in all other respects. This study population was more highly educated and older than the general pregnant population of South Australia which may have affected the generalisability of our study findings (Table 5.3).

Table 5.3: Maternal baseline demographic data *

Baseline demographic data	Hypnosis N=154	CD N = 143	Control N = 151	Total N = 448	P value
Age**	30.5, 5.1	31.4, 4.4	31.2, 4.7	31.0, 4.7	0.282
Nulliparity	124 (80.5)	110 (76.9)	114 (75.5)	348 (77.7)	0.551
Height (cms)†	166, 10 (N = 152)	167, 8.5 (N = 140)	166, 8.2 (N = 150)	166, 9 (N = 442)	0.798
Weight (kgs) †	63.3, 16.6 (N = 153)	62, 13 (N = 142)	62, 14 (N = 151)	63, 14 (N = 446)	0.278
BMI†	22.9, 5.5 (N = 151)	22.9, 4.4 (N = 140)	22, 4.2 (N = 150)	22.7, 4.7 (N = 441)	0.169
Gestational age (mean, sd)	35.1 (1.4)	35.3 (1.6)	35.0 (1.3)	35.1 (1.6)	0.281
Tertiary Ed.	86 (55.8)	84 (58.7)	83 (55.0)	253 (56.5)	0.793
High School completion	137 (89)	120 (83.9)	126 (83.4)	383 (85.5)	0.305
Australia born	112 (72.7)	107 (74.8)	111 (73.5)	330 (73.7)	0.918
Married/de facto	139 (90.3)	134 (93.7)	142 (94.0)	415 (92.6)	0.350
Previous caesarean	7 (4.6)	5 (3.5)	6 (4.0)	18 (4.0)	0.899
Previous epidural	20 (13.0)	20 (14.0)	18 (11.9)	58 (13.0)	0.870
Midwife Antenatal Care	102 (66.2)	102 (71.3)	101 (66.9)	305 (68.1)	0.333
h/o depression §	43 (27.9)	26 (18.2)	27 (17.9)	96 (21.4)	0.057
h/o Medical hypnosis	9 (5.8)	16 (11.2)	10 (6.6)	35 (7.8)	0.250
h/o Non-medical hypnosis	12 (7.8)	5 (3.5)	13 (8.6)	30 (6.7)	0.142
Complementary therapy in pregnancy	86 (55.8)	75 (52.5)	83 (55.0)	244 (54.5)	0.832
Yoga	65 (42.2)	68 (47.6)	70 (46.4)	203 (45.3)	0.620
Meditation	19 (12.3)	21 (14.7)	21 (13.9)	61 (13.6)	0.832
Acupuncture	13 (8.4)	11 (7.7)	11 (7.3)	35 (7.8)	0.930
Fish Oil	24 (34.3)	25 (38.5)	24 (32.4)	73 (34.9)	0.630

** Numbers of women (%) are shown unless otherwise stated ** Mean, SD*

† Median, interquartile range (numbers of women with data); one woman planned for a home birth. h/o=history of

§ Hypnosis versus control borderline significance

Psychological assessments of depression, anxiety and hypnotisability

Baseline psychological assessments of the HATCh participants at recruitment showed similar baseline hypnotisability and anxiety assessments (Table 5.4). In contrast, depression as measured by the EPDS showed increased scores in the Hypnosis Groups compared to the other two groups with more women allocated to this group with an EPDS > 12 (Table 5.4). One woman did not complete her EPDS form, one woman missed two items of the EPDS, another woman missed one item from the State Spielberger and one woman omitted to answer one item from the Trait Spielberger. Fifty-eight women (13.0%) failed to score the entire CIS form after listening to the CD and stated they either did not remember hearing the item or they reported "falling asleep" near the end of the CD. The CIS median was 23. Sixty-eight participants allocated to the Hypnosis Group were above this median and 60 below; 58 were above and 60 below in the CD group; and 64 women were above and 63 below in the control group. A total of 58 women (13.0%) had missing responses to their CIS assessments. The group allocations for this missing data were 17, 19 and 22 women, distributed across hypnosis, CD and control groups respectively. EPDS median scores at baseline were significantly increased in women allocated to receive hypnosis compared with controls (Table 5.4). Similarly, an increased incidence of women with a baseline EPDS > 12 were allocated to the Hypnosis Group when compared with the control group, although this difference did not reach statistical significance. These differences were not found when the CD group was compared with control. Baseline differences in the possible incidence of depression existed that needed to be corrected for and are presented, alongside uncorrected data, in subsequent outcome analyses.

Table 5.4: Baseline psychological testing of HATCh participants at recruitment*

Hypnotisability, as measured by the CIS, anxiety, as measured by the Spielberger and depression as measured by the EPDS according to allocated group.

Psychological assessment	Hypnosis N = 154	CD N = 143	Control N = 151	Total N = 448	P value
EPDS	6, 6	5,6	4.5, 6 n = 150	5, 5 N = 447	0.097
EPDS > 12	15 (9.7)[§§]	9 (6.3)	6 (4.0)	30 (6.7)	0.058
Spielberger State	30.0, 13 (N=153)	29, 13	30, 11	30, 12 N = 447	0.448
Spielberger Trait	32.5, 12	31, 12	30, 10	31, 12	0.108
CIS n = 390	23, 11 (N=137)	23,10.5 (N=124)	23, 11 (N=129)	23,11 (N=390)	0.981

** Data is complete unless otherwise stated, median, interquartile range*
[§§] Hypnosis versus control p = 0.058 – borderline statistical significance

Expectations regarding mode and place of birth, need for epidural analgesia and beliefs about hypnosis

Baseline expectations may affect outcomes, and their distribution across group allocation is important. HATCh Trial participants' baseline beliefs and expectations were similar across the three groups (Table 5.5). Only 4 women (0.9%) indicated that they did not intend to breast-feed after the birth and 4 were unsure.

Table 5.5: Expectations regarding mode and place of birth, need for epidural analgesia, and beliefs about hypnosis by HATCh participants at trial entry*

Expectations / Beliefs	Hypnosis n = 154	CD n = 143	Control n = 151	Total n = 448
Will have spontaneous vaginal birth	139 (90.3)	131 (91.6)	135 (89.4)	405 (90.4)
Planned site of birth BC/LWD ††	73 (47.4)/81 (52.6)	86 (60.1)/57 (39.9)	74 (49.0)/77 (51.0)	233 (52.0)/215 (48.0)
Will need an epidural	2 (1.3)	4 (2.8)	3 (2.0)	9 (2.0)
Women planning for epidural analgesia	2 (1.3)	2 (1.4)	4 (2.7)	8 (1.8)
Hypnosis will help in labour	103 (66.9)	95 (66.4)	113 (74.8)	311 (69.4)
Hypnosis is sleep/unconsciousness	37 (24.0)	21 (14.7)	34 (22.5)	92 (20.5)
Under hypnotherapist's control	22 (14.3)	16 (11.2)	28 (18.5)	66 (14.7)
Hypnosis is role-playing/acting	2 (1.3)	0 (0.0)	8 (5.3)	10 (2.2)
Can get stuck in hypnosis	3 (2.0)	3 (2.1)	4 (2.7)	10 (2.2)
Must be relaxed to be in hypnosis	126 (81.8)	107 (74.8)	133 (88.1)	366 (81.7)
Allows accurate recall	51 (33.1)	45 (31.5)	53 (35.1)	149 (33.3)
Hypnotherapist must be present	1 (0.7)	4 (2.8)	3 (2.0)	8 (1.8)
Helpful in childbirth	89 (57.8)	83 (58.0)	72 (47.7)	244 (54.5)
Effects explained by brain research	50 (32.5)	38 (26.6)	30 (19.9)	118 (26.3)
Decreases maternal control	4 (2.6)	6 (4.2)	5 (3.3)	15 (3.4)
Useful for pain relief	142 (92.2)	124 (86.7)	140 (92.7)	406 (90.6)
Useful for reducing anxiety	152 (98.7)	137 (95.8)	145 (96.0)	434 (96.9)

** Numbers of women (%) BC = Birthing centre; LWD =labour ward*

Compliance with treatment allocation and scheduling

The attendance of HATCh Trial participants according to their allocated group and self-reported compliance with listening to the audio CD on at least one occasion is shown according to their allocated group (Table 5.6).

Less than 50% of women allocated to an intervention attended all three allocated hypnosis sessions and even fewer attended the CD sessions. Only 26.0% of women in the Hypnosis Group and 30.8% in the CD group actually complied with all parts of the intervention, – i.e. they attended all sessions and listened at least once to each of the four CDs. HATCh Trial participants' compliance with their allocated intervention was poor. Hypnosis training outside the trial was reported by 17 HATCh Trial participants (3.9%): two allocated to the Hypnosis Group (1.3%), seven participants to the Audio CD Group (5.0%) and eight to the Control Group (5.6%). There was a non-significant association in this regard as trial participants were less likely to seek additional training if they were allocated to the Hypnosis Group ($p = 0.06$) when compared to controls.

Table 5.6: Number of sessions attended by trial participants and self-reported compliance with listening to audio CD on hypnosis according to allocated group*

Sessions Attended	Hypnosis	Audio CD Only	Control
0	24 (15.6)	18 (12.6)	151
1	28 (18.2)	24 (16.8)	0
2	34 (22.1)	44 (30.8)	0
3	68 (44.2)	57 (39.9)	0
Attended 3 sessions and listened to all CDs at least once	40 (26.0)	44 (30.8)	0 (0.0)

**Data are as shown as numbers (%)*

Section III Primary and Secondary Birth Outcomes

Maternal primary birth outcomes

There was no difference in our primary outcome – **pharmacological analgesia use,** found between groups when comparing:

Hypnosis with control (81.2% versus 76.2%; unadjusted RR 1.07, 95% CI 0.95, 1.20);

CD versus control (76.9% versus 76.2% unadjusted RR 1.01, 95% CI 0.89, 1.15).

After adjusting for differences at baseline in the Hypnosis Group for 'a history of depression' and 'EPDS score >12', there was similarly no difference in pharmacological analgesia use when comparing:

Hypnosis with control (RR 1.06, 95% CI 0.94, 1.19 P = 0.348) or

CD with control (RR 1.01, 95% CI 0.89, 1.15, P = 0.881).

HATCh Trial Hypnosis and CD interventions were ineffective in changing analgesia pharmacological requirements during labour and childbirth (Table 5.7). Unadjusted risk ratios (RR) for the primary outcome (unadjusted), and those adjusted for differences in 'a history of depression' and an 'EPDS > 12' at baseline in the Hypnosis Group for each comparison (adjusted) are shown as data for Hypnosis versus Control† and CD versus control§.

Table 5.7: Maternal primary outcome according to group allocation

Primary outcome	Hypnosis n = 154	CD n = 143	Control n = 151	Total n = 448	RR (95%CI) unadjusted	RR (95% CI) adjusted	P value
Childbirth Analgesia	125 (81.2)	110 (76.9)	115 (76.2)	350 (78.1)	†1.07 (0.95, 1.20) §1.01 (0.89, 1.15)	†1.06 (0.94, 1.19) §1.01 (0.89, 1.15)	0.348 0.881

Data are shown as numbers (%).
RR (95% CI) = Risk Ratio and 95% CIs, † Hypnosis versus control, §Audio CD versus control
Adjusted data is for differences in baseline EPDS and incidence of h/o of depression between groups.

Key secondary outcomes

There was no difference found between groups in pharmacological analgesia or epidural analgesia use, the use of oxytocin labour augmentation, and the incidence of spontaneous vaginal birth when comparing the Hypnosis Group with the Control Group or the CD Group with the Control Group. After adjusting for a history of depression and EPDS scores at baseline, no differences in the relative risks of these outcomes were found when comparing the Hypnosis Group with controls and, the CD Group with controls. The hypnosis and the CD intervention

were ineffective as a means of changing analgesia requirements during labour and childbirth, the use of oxytocics during labour or the incidence of spontaneous vaginal birth (Table 5.8).

Table 5.8: Key secondary outcomes according to group allocation

Unadjusted risk ratios (RR) for all key secondary outcomes, and those adjusted for a history of depression and an EPDS > 12 for each comparison – Hypnosis versus Control[†] and CD versus control[§]

Key outcomes	Hypnosis n = 154	CD n = 143	Control n = 151	Total n = 448	RR (95%CI) unadjusted	RR (95% CI) adjusted[$$]	P value
Analgesia except Entonox	98 (64.1)	81 (56.6)	85 (56.3)	264 (59.1)	[†]1.14 (0.95, 1.37) [§]1.01 (0.82, 1.23)	[†]1.12 (0.93, 1.35) [§]1.02 (0.83, 1.24)	0.222 0.883
Epidural labour analgesia	78 (51.0)	63 (44.1)	71 (47.0)	212 (47.4)	[†]1.08 (0.86, 1.36) [§]0.94 (0.73, 1.20)	[†]1.07 (0.85, 1.35) [§]0.94 (0.74, 1.21)	0.548 0.653
Oxytocin	57 (37.3)	53 (37.1)	56 (37.1)	166 (37.1)	[†]1.00 (0.75, 1.35) [§]1.00 (0.74, 1.35)	[†]1.00 (0.74, 1.34) [§]1.00 (0.74, 1.35)	0.976 1.000
Spontaneous Vaginal birth	85 (55.2)	84 (58.7)	92 (60.9)	261 (58.3)	[†]0.91(0.75, 1.10) [§]0.96 (0.80, 1.16)	[†]0.92 (0.76, 1.12) [§]0.97 (0.81, 1.17)	0.410 0.745

Data are shown as numbers (%).
RR (95% CI) = Risk Ratio and 95% CIs, [†] Hypnosis versus control, [§]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups.

Other maternal secondary outcomes

After adjusting for a history of depression and an EPDS > 12, there was an increased incidence of induced labour when the Hypnosis Group was compared with controls: 40.9% versus 31.1% (adjusted RR = 1.39, 95% CI 1.02, 1.89 P = 0.04). An increased use of prostaglandins for induction in women allocated to the Hypnosis Group was also noted when compared with controls (35.7% versus 23.2%; adjusted RR 1.57, 95% CI, 1.09, 2.25; P = 0.01).

After adjusting for the effects of the other predictors, the relative risk of spontaneous labour was 0.80 times lower in the Hypnosis Group compared to the Control Group ($p = 0.02$).

The fact that a greater proportion of those in the Hypnosis Group experienced induced labour, and used prostaglandins, when compared to the other two groups, suggests that hypnosis had an effect on the spontaneous onset of labour. There were no differences between groups on mode of delivery, admission to HDU, incidence of episiotomy, or need for blood transfusion (Table 5.9).

Table 5.9: Maternal secondary outcomes according to group allocation with unadjusted and adjusted relative risks and 95% CIs.

Key outcomes	Hypnosis n = 154	CD n = 143	Control n = 151	Total n = 448	RR (95%CI) unadjusted	RR (95% CI) adjusted[$$]	P value
Induced Labour	63 (40.9)	43 (30.1)	47 (31.1)	153 (34.2)	[†]1.31 (0.97, 1.78) [§]0.97 (0.69, 1.36)	[†]1.39 (1.02, 1.89) [§]0.99 (0.70, 1.40)	0.036 0.963
Induction with Prostaglandins	55 (35.7)	32 (22.4)	35 (23.2)	122 (27.2)	[†]1.54 (1.08, 2.21) [§]0.97 (0.63, 1.47)	[†]1.57 (1.10, 2.25) [§]0.96 (0.63, 1.47)	0.014 0.866
Augmentation	66 (42.9)	66 (46.2)	66 (43.7)	198 (44.2)	[†]0.98 (0.76, 1.27) [§]1.06 (0.82, 1.36)	[†]0.95 (0.74, 1.23) [§]1.06 (0.83, 1.36)	0.717 0.647
Caesarean section	38 (24.7)	25 (17.5)	29 (19.2)	92 (20.5)	[†]1.29 (0.84, 1.97) [§]0.91 (0.56, 1.48)	[†]1.30 (0.84, 2.01) [§]0.94 (0.58, 1.53)	0.247 0.804
Forceps / vacuum	31 (21.3)	34 (23.8)	30 (19.9)	95 (21.2)	[†]1.01 (0.65, 1.59) [§]1.20 (0.78, 1.85)	[†]0.99 (0.63, 1.55) [§]1.18 (0.76, 1.82)	0.954 0.463
Episiotomy	24 (15.6)	25 (17.5)	26 (17.2)	75 (16.7)	[†]0.91 (0.55, 1.50) [§]1.02 (0.62, 1.67)	[†]0.86 (0.52, 1.43) [§]1.00 (0.61, 1.65)	0.565 0.990
Intact perineum	94 (61.4)	71 (49.7)	91 (60.3)	256 (57.3)	[†]1.02 (0.85, 1.22) [§]0.82 (0.67, 1.02)	[†]1.01 (0.84, 1.21) [§]0.83 (0.67, 1.02)	0.945 0.077
PPH	24 (15.6)	22 (15.4)	14 (9.3)	60 (13.4)	[†]1.68 (0.91, 3.12) [§]1.66 (0.88, 3.12)	[†]1.70 (0.91, 3.16) [§]1.64 (0.87, 3.09)	0.097 0.123
Blood transfusion	4 (2.6)	7 (4.9)	1 (0.7)	12 (2.7)	[†]3.92 (0.44, 34.69) [§]7.39 (0.92, 59.33)	[†]3.17 (0.36, 28.32) [§]7.03 (0.88, 56.19)	0.301 0.066
Admission to HDU/ICU	3 (2.0)	7 (4.9)	2 (1.3)	12 (2.7)	[†]1.47 (0.25, 8.68) [§]3.70 (0.78, 17.50)	[†]1.24 (0.21, 7.24) [§]3.51 (0.75, 16.41)	0.811 0.111

**Data are as shown as numbers of women (%). RR (95% CI) = Risk Ratio and 95% CIs*
[†]Hypnosis versus control [§]Audio CD versus control

Hospital stay

There was no difference between groups in the median number of days women stayed in hospital after the birth – 4, with an IQR of 2. There was also no difference in the incidence of breast-feeding at hospital discharge – 140 mothers breast-fed in the Hypnosis Group (91.5%), 139 in the CD group (97.2%) and 140 (92.7%) in the control.

Maternal perceptions of their birth experience

There were no differences between groups with regard to the mother perceiving that she had received adequate pain relief. Also, there were no differences between groups in maternal perceptions of the birth being better than expected or a positive experience (Table 5.10).

Table 5.10: Secondary outcomes: Maternal perceptions of the birth experience

Key outcomes	**Hypnosis** n = 154	**CD** n = 143	**Control** n = 151	**Total** n = 448	**RR** (95%CI) unadjusted	**RR** (95% CI) adjusted[$$]	**P value**
Received adequate pain relief	112 (82.4) N = 136	92 (70.2) N = 131	99 (77.3) N= 128	303 (76.7) N = 395	[†]1.07 (0.94, 1.20) [§]0.91 (0.79, 1.05)	[†]1.06 (0.94, 1.20) [§]0.91 (0.79, 1.05)	0.326 0.206
Birth a positive experience	108 (72.5)	105 (75.5)	118 (81.9)	331 (76.6)	[†]0.89 (0.78, 1.00) [§]0.92 (0.82, 1.04)	[†]0.92 (0.82, 1.04) [§]0.95 (0.84, 1.06)	0.188 0.353
Birth better than expected	59 (41.0) N = 144	44 (32.1) N = 137	46 (32.2) N = 143	149 (35.1) N = 424	[†]1.27 (0.94,1.73) [§]1.00 (0.71, 1.40)	[†]1.30 (0.96,1.78) [§]1.01 (0.72, 1.42)	0.096 0.940

**Data are as shown as numbers of women (%). RR (95% CI) = Risk Ratio and 95% CIs*
[†]Hypnosis versus control [§]Audio CD versus control

Neonatal outcomes

Approximately 15% of babies had meconium-stained liquor across the groups, and one third of babies were admitted to the baby unit. After adjusting for a history of depression and an EPDS > 12, there was no difference in the incidence of meconium-stained liquor, babies with an Apgar < 7 at 5 minutes and admissions to the SCBU. Neonatal outcomes were not influenced by the intervention (Table 5.11).

Table 5.11: Neonatal outcomes

Key outcomes	**Hypnosis** n = 154	**CD** n = 143	**Control** n = 151	**Total** n = 448	**RR** (95% CI) unadjusted	**RR** (95% CI) adjusted[$$]	**P value**
Meconium stained liquor	23 (15.0)	24 (16.8)	19 (12.6)	66 (14.8)	[†]1.20 (0.68, 2.10) [§]1.33 (0.76, 2.33)	[†]1.15 (0.65, 2.03) [§]1.32 (0.76, 2.31)	0.635 0.321
Neonatal Apgar <7 at 5 minutes	1 (0.7)	1 (0.7)	2 (1.3)	4 (0.9)	[†]0.49 (0.05, 5.32) [§]0.53 (0.05, 5.72)	[†]0.50 (0.05, 5.48) [§]0.53 (0.05, 5.82)	0.567 0.606
Admitted to SCBU	53 (34.4)	45 (31.5)	51 (33.8)	149 (33.3)	[†]1.02 (0.75,1.39) [§]0.93 (0.67, 1.30)	[†]1.03 (0.75,1.41) [§]0.95 (0.68, 1.32)	0.849 0.751

**Data are as shown as numbers of women (%). RR (95% CI) = Risk Ratio and 95% CIs*
[†]Hypnosis versus control [§]Audio CD versus control

Section IV – Six-Week Follow-Up

Follow-up at six weeks showed no difference in postpartum anxiety and depression scores between intervention and control groups (Table 5.12). Differences in the number of women with an EPDS score > 12 at baseline are no longer evident at six weeks for the comparison between the Hypnosis Group versus the Control Group (RR adjusted 0.95, 0.64–1.42, p = 0.814) and the CD Group versus the Control Group (RR adjusted 0.80, 0.51-1.25, P = 0.325).

Table 5.12: Maternal outcomes according to allocated group for EPDS, Spielberger Anxiety, VAS Pain during childbirth and satisfaction with birth experience scales at 6 weeks post-partum.

Psychological 6 week assessment	**Hypnosis** n = 134	**CD** n = 133	**Control** n = 133	**Total** n = 400	**P value**
EPDS	6, 6	5, 5	5, 6	5,6	0.243
EPDS > 12	37/154 (24.0)	24/143 (16.8)	31/151 (20.5)	92/448 (20.5)	0.301
Spielberger State	33, 14	29, 13	30, 12	30.5, 14	0.130
Spielberger Trait	34.5, 14	31, 14	30, 11	31, 13.5	0.070
Pain score median (IQR)	8 (2)	8 (2) (N=132)	8 (2) (N=132)	8 (2) (N=398)	0.419
Satisfaction median (IQR)	8 (4)	8 (3)	8 (3)	8 (3)	0.446

** Data is complete unless otherwise stated, median, interquartile range*

Those women exposed to the hypnosis or audio CD intervention were more likely to state that they would use hypnosis, in future pregnancies, than those in the control group. Nearly 50% of women in intervention groups believed that hypnosis was helpful during the birth. There were no differences in the incidence of maternal readmission to hospital or problems related to the use of hypnosis between groups (Table 5.13),

Table 5.13: Maternal outcomes at 6 weeks post-partum

Key outcomes	**Hypnosis** n = 134	**CD** n = 133	**Control** n = 133	**Total** n = 400	**RR** (95%CI) unadjusted	**RR** (95% CI) adjusted	**P Value**
Readmitted to hospital	11 (8.2)	8 (6.0)	7 (5.3)	26 (6.5)	1.56 (0.62, 3.90) 1.14 (0.43, 3.06)	1.58 (0.63, 4.01) 1.13 (0.42, 3.01)	0.332 0.815
Believed hypnosis allocation	110 (82.1)	98 (73.7)	0 (0.0)	208 (52.5)	-	-	<0.001
Any problems using hypnosis	3 (2.3)	1 (0.8)	1 (0.9)	5 (1.3)	2.50 (0.26, 23.65) 0.83 (0.05, 13.04)	2.21 (0.23, 21.28) 0.78 (0.05, 12.19)	0.492 0.859
Hypnosis helpful for the birth	51/109 (46.8)	51/110 (46.4)	9/35 (25.7)	111/254 (43.7)	1.82 (1.00, 3.31) 1.80 (0.99, 3.28)	1.80 (0.99, 3.28) 1.81 (0.99, 3.28)	0.054 0.052
Willing to use hypnosis in future pregnancies	104/134 (77.6)	111/133 (83.5)	78/133 (58.7)	293/400 (73.3)	-	-	<0.001
Used hypnosis since the birth	40/134 (29.9)	33/132 (25.0)	6/127 (4.7)	79/393 (20.1)	6.32 (2.78, 14.39) 5.29 (2.30, 12.20)	6.56 (2.88, 14.95) 5.29 (2.29, 12.19)	<0.001 <0.001

**Data are as shown as numbers of women (%). RR (95% CI) = Risk Ratio and 95% CIs*
[†]Hypnosis versus control [§]Audio CD versus control
- *Numbers too small for analysis*

No differences were reported with respect to, breastfeeding, incidence of baby readmissions to hospital, and whether the baby was settled or not, between groups (Table 5.14).

Table 5.14: Neonatal outcomes at 6 weeks post-partum

Key outcomes	**Hypnosis** n = 134	**CD** n = 133	**Control** n = 133	**Total** n = 400	**RR** (95% CI) unadjusted	**RR** (95% CI) adjusted	**P value**
Baby's age*	6.6 (1.86)	6.7 (3.14) (N=132)	6.9 (5.71)	6.7 (3.43)	-	-	0.229
Baby settled	90 (67.2)	88 (66.2)	85 (63.9)	263 (65.8)	1.05 (0.88, 1.25) 1.04 (0.87, 1.23)	1.07 (0.90, 1.27) 1.06 (0.89, 1.26)	0.462 0.538
Baby readmitted to hospital	14 (10.5)	9 (6.8)	10 (7.5)	33 (8.3)	1.39 (0.64, 3.02) 0.90 (0.38, 2.14)	1.55 (0.71, 3.38) 0.92 (0.39, 2.19)	0.270 0.847
Exclusive Breast-feeding	94/133 (70.7)	107 (80.5)	108 (81.2)	309/399 (77.4)	†0.87(0.76,1.00) §0.99 (0.88,1.11)	†0.88(0.77,1.01) §1.00 (0.89,1.12)	0.072 0.998

**Median IQR*

- *Numbers too small for analysis*

Conclusions for the HATCh Trial Main Results

Primary outcome

No difference was observed in our primary outcome – the use of pharmacological analgesia or anaesthesia during childbirth when comparing the Hypnosis Group with the Control Group or the CD Group versus the Control Group. Both the hypnosis and audio CD interventions used in the HATCh Trial were ineffective in changing analgesia and anaesthesia pharmacological requirements during labour and childbirth.

Secondary outcomes

The hypnosis and the CD intervention did not affect analgesia requirements – including epidural analgesia during labour and childbirth – the use of oxytocics during labour, or the incidence of spontaneous vaginal birth.

The use of hypnosis was associated with an increased incidence of induced labour.

Six-week follow-up

There were no differences in depression or anxiety between groups at the six-week assessments. More women in the Hypnosis Group, 104/134 (77.6%), and the CD group, 111/133 (83.5%), stated that they would use hypnosis in future pregnancies than those women allocated to control, 78/133 (58.7%), ($P < 0.001$).

Chapter 6 – Sub-group Analyses

During initial subgroup analyses calculations there was found to be insufficient reliability in the accuracy of subgroup calculated relative risks. We have therefore presented subgroup analyses as Odds Ratios with 95% confidence intervals (OR, 95% CI).

Primary and Key Secondary Outcomes in Sub-Group Analyses

This chapter reports a number of a priori planned sub-group analyses including the effects of primary and key secondary outcomes for parity, induction versus spontaneous labour, high versus low hypnotisability, compliance with the intervention, use of yoga, expectations of having a normal birth, and expectations of having an epidural (Tables 6.1–6.10).

Parity sub-group analyses

As expected, multiparous women used less pharmacological analgesia than nulliparous women. However there were no clinically relevant differences with respect to use of pharmacological analgesia or anaesthesia between groups whether the women were multiparous or nulliparous with respect to the use of pharmacological analgesia including epidural analgesia, oxytocin, or the incidence of spontaneous birth between hypnosis, cd and control groups (Table 6.1).

Table 6.1: Nulliparous (N) and Multiparous (M) women sub-group analyses of primary and key secondary outcomes according to group allocation

Key outcomes	**Parity**	**Hypnosis** n = 154	**CD** n = 143	**Control** n = 151	**Total** n = 448	**OR** (95%CI) unadjusted	**OR** (95% CI) adjusted[$$]
Any analgesia/ anaesthesia for childbirth	N	105/124 (84.7)	90/110 (81.8)	93/114 (81.6)	288/348 (82.8)	[†]1.25 (0.63, 2.46) [§]1.02 (0.52, 2.00)	[†]1.19 (0.60, 2.37) [§]1.00 (0.51, 1.97)
	M	20/30 (66.7)	20/33 (66.6)	22/37 (59.5)	62/100 (62.0)	[†]1.36 (0.50, 3.72) [§]1.05 (0.40, 2.73)	[†]1.33 (0.48, 3.66) [§]1.08 (0.41, 2.83)
Analgesia except Entonox	N	83/123 (67.5)	66/110 (60.0)	71/114 (62.3)	220/347 (63.4)	[†]1.26 (0.74, 2.14) [§]0.91 (0.53, 1.56)	[†]1.17 (0.68, 2.02) [§]0.90 (0.52, 1.54)
	M	15/30 (50.0)	15/33 (45.5)	14/37 (37.8)	44/100 (44.0)	[†]1.64 (0.62, 4.36) [§]1.37 (0.53, 3.56)	[†]1.61 (0.61, 4.31) [§]1.39 (0.53, 3.62)
Epidural for labour analgesia	N	70/123 (56.9)	51/110 (46.4)	63/114 (55.3)	184/347 (53.0)	[†]1.07 (0.64, 1.79) [§]0.70 (0.41, 1.18)	[†]1.01 (0.60, 1.70) [§]0.69 (0.40, 1.17)
	M	8/30 (26.7)	12/33 (36.4)	8/37 (21.6)	28/100 (28.0)	- -	- -
Oxytocin	N	51/123 (41.5)	49/110 (44.6)	48/114 (42.1)	148/347 (42.7)	[†]0.97 (0.58, 1.63) [§]1.11 (0.65, 1.87)	[†]1.02 (0.60, 1.73) [§]1.13 (0.66, 1.92)
	M	6/30 (20.0)	4/33 (12.1)	8/37 (21.6)	18/100 (18.0)	- -	- -
Spontaneous Vaginal birth	N	62/124 (50.0)	60/110 (54.6)	64/114 (56.1)	186/348 (53.5)	[†]0.78 (0.47, 1.30) [§]0.94 (0.55, 1.59)	[†]0.83 (0.49, 1.39) [§]0.95 (0.56, 1.62)
	M	23/30 (76.7)	24/33 (72.7)	28/37 (75.7)	75/100 (75.0)	- -	- -

**Data are shown as numbers (%). OR (95% CI) = Odds Ratio and 95% CIs*
[†] Hypnosis versus control, [§]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups
- Too few numbers to perform Odds Ratios

Induced versus spontaneous labour

As expected, women who had an induced labour received more analgesia than those women having a spontaneous labour. However, sub-group analysis for primary and key secondary outcomes in participants according to group allocation for induced and spontaneous labour revealed no differences between groups with respect to, analgesia or oxytocin use, or the incidence of spontaneous vaginal birth (Table 6.2).

Table 6.2: Primary and key secondary outcomes according to group allocation for induced (I) versus spontaneous (S) labour

Key outcomes	**Labour Onset**	**Hypnosis** n = 154	**CD** n = 143	**Control** n = 151	**Total** n = 448	**OR** (95%CI) unadjusted	**OR** (95% CI) adjusted[$$]
Any analgesia/ anaesthesia for childbirth	I	59/63 (93.7)	39/43 (90.7)	45/47 (95.7)	143/153 (93.5)	- -	- -
	S	60/85 (70.6)	68/97 (70.1)	67/101 (66.3)	195/283 (68.9)	[†]1.22 (0.65, 2.27) [§]1.19 (0.65, 2.17)	[†]1.12 (0.59, 2.10) [§]1.17 (0.64, 2.13)
Analgesia except Entonox	I	52/62 (83.9)	35/43 (81.4)	36/47 (76.6)	123/152 (80.9)	- -	- -
	S	40/85 (47.1)	43/97 (44.3)	46/101 (45.5)	129/283 (45.6)	[†]1.06 (0.60, 1.90) [§]0.95 (0.54, 1.67)	[†]0.95 (0.52, 1.72) [§]0.93 (0.53, 1.64)
Epidural for labour analgesia	I	43/62 (69.4)	30/43 (69.8)	34/47 (72.3)	107/152 (70.4)	[†]0.87 (0.38, 2.00) [§]0.88 (0.35, 2.20)	[†]0.86 (0.36, 2.01) [§]0.91 (0.36, 2.28)
	S	35/85 (41.2)	33/97 (34.0)	37/101 (36.6)	105/283 (37.1)	[†]1.21 (0.67, 2.19) [§]0.89 (0.50, 1.60)	[†]1.07 (0.59, 1.97) [§]0.87 (0.48, 1.56)
Oxytocin	I	37/62 (59.7)	29/43 (67.4)	29/47 (61.7)	95/152 (62.5)	[†]0.92 (0.42, 2.00) [§]1.29 (0.54, 3.06)	[†]1.02 (0.46, 2.26) [§]1.31 (0.54, 3.17)
	S	20/85 (23.5)	24/97 (24.7)	27/101 (26.7)	71/283 (25.1)	[†]0.84 (0.43, 1.64) [§]0.90 (0.48, 1.71)	[†]0.76 (0.38, 1.50) [§]0.87 (0.46, 1.66)
Spontaneous Vaginal Birth	I	28/63 (44.4)	22/43 (51.2)	21/47 (44.7)	71/153 (46.4)	[†]0.99 (0.46, 2.12) [§]1.30 (0.57, 2.97)	[†]0.99 (0.45, 2.15) [§]1.25 (0.54, 2.91)
	S	57/85 (67.1)	62/97 (63.9)	71/101 (70.3)	190/283 (67.1)	[†]0.86 (0.46, 1.60) [§]0.75 (0.41, 1.36)	[†]0.94 (0.50, 1.78) [§]0.77 (0.42, 1.39)

**Data are shown as numbers (%). OR (95% CI) = Odds Ratio and 95% CIs*
[†] Hypnosis versus control, [§]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups
- Too few numbers to perform Odds Ratios

The effects of hypnotisability

After adjusting for history of depression and EPDS score, the odds of using analgesia was higher in the Hypnosis Group compared to the Control Group for those women of low hypnotisability with a CIS score < 23 but not for women of high hypnotisability.

The key finding in this sub-group analysis was that women with low hypnotisability had an increased use of pharmacological analgesia (excluding Entonox alone) in the Hypnosis Group as compared with controls – 70% versus 46% OR 2.87 (95% CI 1.34, 6.13). This difference was not seen in women with a CIS score above the median of 23, i.e. women of high hypnotisability used less analgesia than those of low hypnotisability – 59.2% versus 62.1% OR 0.82 (95% CI 0.41, 1.63) (Table 6.3).

For each of the other three outcomes: odds of epidural, oxytocin use or the incidence of spontaneous vaginal birth – there were no differences between groups whether the woman was of high or low hypnotisability. The difference in analgesia use in the sub-group analysis of women of high hypnotisability compared to women of low hypnotisability was in the direction expected – that is women of high hypnotisability in hypnosis and CD groups used less analgesia than those of low hypnotisability. It is difficult to explain why women of low hypnotisability allocated to receive hypnosis showed an increased use of pharmacological analgesia compared with controls, although this could be related to the increased incidence of labour induction in women allocated to the Hypnosis Group.

Table 6.3: Primary and key secondary outcomes according to Women's hypnotisability CIS median score ≥ 23 versus those with a CIS score < 23

Key outcomes	CIS Score	Hypnosis n = 154	CD n = 143	Control n = 151	Total n = 448	**OR** (95%CI) unadjusted	**OR** (95% CI) adjusted[$$]
Any analgesia/ anaesthesia for childbirth	**< 23**	50/60 (83.3)	48/60 (80.0)	45/63 (71.4)	143/183 (78.1)	[†]2.00 (0.84, 4.78) [§]1.60 (0.69, 3.69)	[†]2.08 (0.85, 5.06) [§]1.69 (0.73, 3.92)
	≥ 23	63/77 (81.8)	47/64 (73.4)	52/66 (78.8)	162/207 (78.3)	[†]1.21 (0.53, 2.77) [§]0.74 (0.33, 1.67)	[†]1.16 (0.50, 2.67) [§]0.74 (0.33, 1.67)
****Analgesia except Entonox**	**< 23**	42/60 (70.0)	36/60 (60.0)	29/63 (46.0)	107/183 (58.5)	[†]2.74 (1.30, 5.74) [§]1.76 (0.86, 3.60)	[†]2.87 (1.34, 6.13) [§]1.86 (0.90, 3.82)
	≥ 23	45/76 (59.2)	33/64 (51.6)	41/66 (62.1)	119/206 (57.8)	[†]0.86 (0.45, 1.74) [§]0.65 (0.32, 1.31)	[†]0.82 (0.41, 1.63) [§]0.64 (0.32, 1.31)
Epidural for labour analgesia	**< 23**	33/60 (55.0)	26/60 (43.3)	27/63 (42.9)	86/183 (47.0)	[†]1.63 (0.80, 3.32) [§]1.02 (0.50, 2.08)	[†]1.60 (0.77, 3.32) [§]1.09 (0.53, 2.24)
	≥ 23	36/76 (47.4)	27/64 (42.2)	32/66 (48.5)	95/206 (46.1)	[†]0.96 (0.49, 1.85) [§]0.78 (0.39, 1.55)	[†]0.88 (0.45, 1.71) [§]0.73 (0.36, 1.47)
Oxytocin	**< 23**	21/60 (35.0)	22/60 (36.7)	22/63 (34.9)	65/183 (35.5)	[†]1.00 (0.48, 2.11) [§]1.08 (0.52, 2.26)	[†]1.01 (0.47, 2.16) [§]1.16 (0.55, 2.44)
	≥ 23	31/76 (40.8)	24/64 (37.5)	27/66 (40.9)	82/206 (39.8)	[†]1.00 (0.51, 1.95) [§]0.87 (0.43, 1.75)	[†]0.99 (0.50, 1.96) [§]0.83 (0.41, 1.69)
Spontaneous Vaginal birth (SVB)	**< 23**	32/60 (53.3)	34/60 (56.7)	38/63 (60.3)	104/183 (56.8)	[†]0.75 (0.37, 1.54) [§]0.86 (0.42, 1.76)	[†]0.67 (0.32, 1.42) [§]0.79 (0.38, 1.64)
	≥ 23	43/77 (55.8)	40/64 (62.5)	41/66 (62.1)	124/207 (59.9)	[†]0.77 (0.39, 1.51) [§]1.02 (0.50, 2.07).	[†]0.84 (0.43, 1.67) [§]1.05 (0.51, 2.16)

**Data are shown as numbers (%). OR (95% CI) = Odds Ratio and 95% CIs*
[†] Hypnosis versus control, [§]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups
*** Note that different results were obtained by the CIS < 23 and CIS >= 23 groups for analgesia use.*

Women's beliefs regarding the efficacy of hypnosis prior to labour

No differences were found in any of the key outcomes in relation to whether or not women believed hypnosis was effective. Sub-group analyses show that women's beliefs regarding hypnosis did not affect primary and key secondary outcomes (Table 6.4).

Table 6.4: Primary and key secondary outcomes according to women's beliefs regarding the efficacy of hypnosis prior to labour Y = yes, U = unsure

Key outcomes	**Belief**	**Hypnosis** n = 154	**CD** n = 143	**Control** n = 151	**Total** n = 448	**OR** (95%CI) unadjusted	**OR** (95% CI) adjusted[$$]
Any analgesia / anaesthesia for childbirth	**Y**	82/103 (79.6)	73/95 (76.8)	87/113 (77.0)	242/311 (77.8)	[†]1.17 (0.61, 2.23) [§]0.99 (0.52, 1.90)	[†]1.12 (0.58, 2.16) [§]0.99 (0.52, 1.89)
	U	43/51 (84.3)	37 (77.1)	28/38 (73.7)	108/137 (78.8)	- -	- -
****Analgesia except Entonox**	**Y**	63/103 (61.2)	53/95 (55.8)	63/113 (55.8)	179/311 (57.6)	[†]1.25 (0.73, 2.15) [§]1.00 (0.58, 1.74)	[†]1.20 (0.69, 2.08) [§]1.00 (0.58, 1.74)
	U	35/50 (70.0)	28/48 (58.3)	22/38 (57.9)	85/136 (62.5)	[†]1.70 (0.70, 4.11) [§]1.02 (0.43, 2.41)	[†]1.63 (0.67, 4.00) [§]1.01 (0.43, 2.40)
Epidural for labour analgesia	**Y**	47/103 (45.6)	44/95 (46.3)	51/113 (45.1)	142/311 (45.7)	[†]1.02 (0.60, 1.74) [§]1.05 (0.61, 1.81)	[†]0.98 (0.57, 1.70) [§]1.04 (0.60, 1.81)
	U	31/50 (62.0)	19/48 (39.6)	20/38 (52.6)	70/136 (51.5)	[†]1.47 (0.62, 3.45) [§]0.59 (0.25, 1.39)	[†]1.32 (0.55, 3.15) [§]0.57 (0.24, 1.36)
Oxytocin	**Y**	36/103 (35.0)	34/95 (35.8)	40/113 (35.4)	110/311 (35.4)	[†]0.98 (0.56, 1.72) [§]1.02 (0.58, 1.80)	[†]0.97 (0.55, 1.71) [§]1.02 (0.57, 1.81)
	U	21/50 (42.0)	19/48 (39.6)	16/38 (42.1)	56/136 (41.2)	[†]1.00 (0.42, 2.34) [§]0.90 (0.38, 2.14)	[†]1.04 (0.44, 2.49) [§]0.91 (0.38, 2.17)
Spontaneous Vaginal birth	**Y**	58/103 (56.3)	58/95 (61.1)	67/113 (59.3)	183/311 (58.8)	[†]0.89 (0.52, 1.52) [§]1.08 (0.62, 1.88)	[†]0.92 (0.53, 1.59) [§]1.07 (0.61, 1.88)
	U	27/51 (52.9)	26/48 (54.2)	25/38 (65.8)	78/137 (56.9)	[†]0.59 (0.25, 1.39) [§]0.62 (0.26, 1.48)	[†]0.58 (0.24, 1.40) [§]0.61 (0.25, 1.48)

**Data are shown as numbers (%). OR (95% CI) = Odds Ratio and 95% CIs*
[†] Hypnosis versus control, [§]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups
- Too few numbers to perform Odds Ratios

Women's expectations of requiring an epidural

Women's expectations of having an epidural did not show any differences in any of the key outcomes (Table 6.5).

Table 6.5: Primary and key secondary outcomes according to women's expectations of requiring an epidural N = no, U = unsure

Key outcomes	Belief	Hypnosis n = 154	CD n = 143	Control n = 151	Total n = 448	OR (95%CI) unadjusted	OR (95% CI) adjusted[$$]
Any analgesia/ anaesthesia for childbirth	**N**	51/65 (78.5)	50/74 (67.6)	56/82 (68.3)	157/221 (71.0)	[†]1.69 (0.80, 3.59) [§]0.97 (0.49, 1.90)	[†]1.56 (0.73, 3.35) [§]0.96 (0.49, 1.90)
	U	72/87 (82.8)	56/65 (86.2)	56/66 (84.9)	184/218 (84.4)	[†]0.86 (0.36, 2.05) [§]1.11 (0.42, 2.94)	[†]0.88 (0.36, 2.13) [§]1.13 (0.43, 2.99)
Analgesia except Entonox	**N**	38/65 (58.5)	36/74 (48.7)	39/82 (47.6)	113/221 (51.1)	[†]1.55 (0.81, 2.99) [§]1.04 (0.56, 1.96)	[†]1.46 (0.75, 2.84) [§]1.04 (0.55, 1.96)
	U	58/86 (67.4)	42/65 (64.6)	43/66 (65.2)	143/217 (65.9)	[†]1.11 (0.56, 2.18) [§]0.98 (0.48, 2.00)	[†]1.12 (0.56, 2.23) [§]1.00 (0.49, 2.06)
Epidural for labour analgesia	**N**	26/65 (40.0)	29/74 (39.2)	31/82 (37.8)	86/221 (38.9)	[†]1.10 (0.56, 2.14) [§]1.06 (0.56, 2.02)	[†]1.03 (0.52, 2.02) [§]1.05 (0.55, 2.01)
	U	50/86 (58.1)	31/65 (47.7)	38/66 (57.6)	119/217 (54.8)	[†]1.02 (0.54, 1.96) [§]0.67 (0.34, 1.34)	[†]1.01 (0.52, 1.95) [§]0.69 (0.34, 1.37)
Oxytocin	**N**	20/65 (30.8)	26/74 (35.1)	29/82 (35.4)	75/221 (33.9)	[†]0.81 (0.41, 1.63) [§]0.99 (0.51, 1.91)	[†]0.76 (0.37, 1.55) [§]0.97 (0.50, 1.88)
	U	35/86 (40.7)	24/65 (36.9)	26/66 (39.4)	85/217 (39.2)	[†]1.06 (0.55, 2.03) [§]0.90 (0.45, 1.82)	[†]1.18 (0.60, 2.31) [§]0.94 (0.46, 1.92)
Spontaneous Vaginal birth (SVB)	**N**	40/65 (61.5)	47/74 (63.5)	53/82 (64.6)	140/221 (63.4)	[†]0.88 (0.45, 1.72) [§]0.95 (0.50, 1.83)	[†]0.92 (0.46, 1.81) [§]0.96 (0.50, 1.85)
	U	44/87 (50.6)	35/65 (53.9)	37/66 (56.1)	116/218 (53.2)	[†]0.80 (0.42, 1.53) [§]0.91 (0.46, 1.82)	[†]0.82 (0.43, 1.59) [§]0.89 (0.45, 1.79)

**Data are shown as numbers (%). OR (95% CI) = Odds Ratio and 95% CIs*
[†] Hypnosis versus control, [§]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups

Women's expectation of having a spontaneous vaginal birth

Women's expectations of having a spontaneous vaginal birth did not affect any primary or key secondary outcomes (Table 6.6).

Table 6.6: key outcomes according to women's expectations of having a normal spontaneous birth Y = yes, U = unsure

Key outcomes	**Belief**	**Hypnosis** n = 154	**CD** n = 143	**Control** n = 151	**Total** n = 448	**OR (95%CI) unadjusted**	**OR (95% CI) adjusted[$$]**
Any analgesia/ anaesthesia for childbirth	**Y**	113/139 (81.3)	99/131 (75.6)	100/135 (74.1)	312/405 (77.0)	[†]1.52 (0.86, 2.70) [§]1.08 (0.62, 1.88)	[†]1.48 (0.83, 2.63) [§]1.09 (0.62, 1.90)
	U	12/15 (80.0)	11/12 (91.7)	15/15 (100.0)	38/42 (90.5)	- -	- -
Analgesia except Entonox	**Y**	88/138 (63.8)	72/131 (55.0)	72/135 (53.3)	232/404 (57.4)	[†]1.54 (0.95, 2.50) [§]1.07 (0.66, 1.73)	[†]1.49 (0.91, 2.42) [§]1.08 (0.67, 1.76)
	U	10/15 (66.7)	9/12 (75.0)	13/15 (86.7)	32/42 (76.2)	- -	- -
Epidural for labour analgesia	**Y**	69/138 (50.0)	55/131 (42.0)	61/135 (45.2)	185/404 (45.8)	[†]1.21 (0.75, 1.95) [§]0.88 (0.54, 1.43)	[†]1.16 (0.72, 1.88) [§]0.89 (0.54, 1.44)
	U	9/15 (60.0)	8/12 (66.7)	10/15 (66.7)	27/42 (64.3)	- -	- -
Oxytocin	**Y**	51/138 (37.0)	47/131 (35.9)	50/135 (37.0)	148/404 (36.6)	[†]1.00 (0.61, 1.63) [§]0.95 (0.58, 1.57)	[†]1.00 (0.61, 1.65) [§]0.96 (0.58, 1.58)
	U	6/15 (40.0)	6/12 (50.0)	6/15 (40.0)	18/42 (42.9)	- -	- -
Spontaneous Vaginal birth (SVB)	**Y**	76/139 (54.7)	79/131 (60.3)	81/135 (60.0)	236/405 (58.3)	[†]0.80 (0.50, 1.30) [§]1.01 (0.62, 1.66)	[†]0.82 (0.50, 1.33) [§]1.00 (0.61, 1.65)
	U	9/15 (60.0)	5/12 (41.7)	10/15 (66.7)	24/42 (57.1)	- -	- -

**Data are shown as numbers (%). OR (95% CI) = Odds Ratio and 95% CIs*
[†] Hypnosis versus control, [§]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups
- Too few numbers to perform Odds Ratios

Previous experience of non-childbirth (medical) hypnosis

Sub-group analyses of previous experience of non-childbirth (medical) hypnosis did not show any differences in any of our primary or key secondary outcomes (Table 6.7).

Table 6.7: Primary and key secondary outcomes according to previous experience of non-childbirth (medical) hypnosis Y = Yes, N = No

Key outcomes	Belief	Hypnosis n = 154	CD n = 143	Control n = 151	Total n = 448	OR (95%CI) unadjusted	OR (95% CI) adjusted[$$]
Any analgesia/ anaesthesia for childbirth	**Y**	8/12 (66.7)	3/5 (60.0)	9/13 (69.2)	20/30 (66.7)	-	-
						-	-
						[†]1.39 (0.79, 2.44)	[†]1.37 (0.78, 2.41)
	N	117/142 (82.4)	107/138 (77.5)	106/138 (76.8)	330/418 (79.0)	[§]1.18 (0.67, 2.08)	[§]1.19 (0.67, 2.09)
Analgesia except Entonox	**Y**	6/12 (50.0)	3/5 (60.0)	5/13 (38.5)	14/30 (46.7)	-	-
						-	-
						[†]1.41 (0.87, 2.26)	[†]1.36 (0.84, 2.20)
	N	92/141 (65.3)	78/138 (56.5)	80/138 (58.0)	250/417 (60.0)	[§]1.07 (0.66, 1.74)	[§]1.08 (0.67, 1.76)
Epidural for labour analgesia	**Y**	3/12 (25.0)	2/5 (40.0)	4/13 (30.8)	9/30 (30.0)	-	-
						-	-
						[†]1.12 (0.70, 1.79)	[†]1.07 (0.67, 1.72)
	N	75/141 (53.2)	61/138 (44.2)	67/138 (48.6)	203/417 (48.7)	[§]0.88 (0.55, 1.43)	[§]0.89 (0.55, 1.45)
Oxytocin	**Y**	2/12 (16.7)	1/5 (20.0)	3/13 (23.1)	6/30 (20.0)	-	-
						-	-
						[†]0.98 (0.61, 1.59)	[†]0.97 (0.60, 1.57)
	N	55/141 (39.0)	52/138 (37.7)	53/138 (38.4)	160/417 (38.4)	[§]1.07 (0.65, 1.75)	[§]1.08 (0.66, 1.77)
Spontaneous Vaginal birth	**Y**	7/12 (58.3)	2/5 (40.0)	9/13 (69.2)	18/30 (60.0)	-	-
						-	-
						[†]0.77 (0.48, 1.24)	[†]0.79 (0.49, 1.27)
	N	78/142 (54.9)	82/138 (59.4)	83/138 (60.1)	243/418 (58.1)	[§]0.85 (0.52, 1.39)	[§]0.84 (0.51, 1.37)

**Data are shown as numbers (%). OR (95% CI)= Odds Ratio and 95% CIs*
[†] Hypnosis versus control, [§]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups
- Too few numbers to perform Odds Ratios

Use of yoga

There were no differences between groups in any of the key outcomes whether or not women used yoga during the pregnancy. Of interest women who used yoga and who were allocated to receive hypnosis used less analgesia than women who did not use yoga and were allocated to receive hypnosis 70.8% vs 88.8% ($P<0.01$). This difference was not seen in control group women who used and did not use yoga 74.3% vs 77.8% . This finding suggests that women using yoga who received the hypnosis intervention reduced their analgesia use while those women using yoga alone did not. Like hypnosis, yoga also involves the use of imagery, positive suggestion and the use of 'trance-like' states. The familiarity with these states may have primed this subgroup of women so that they enhanced their ability to learn the hypnosis techniques taught in this study over a shorter period and more effectively than women allocated to the control group (Table 6.8).

Table 6.8: Primary and key secondary outcomes according to use of yoga during the pregnancy Y = yes, N = No

Key outcomes	**Yoga**	**Hypnosis** n = 154	**CD** n = 143	**Control** n = 151	**Total** n = 448	**OR** (95%CI) unadjusted	**OR** (95% CI) adjusted[$$]
Any analgesia/ anaesthesia for childbirth	**Y**	46/65 (70.8)	45/68 (66.2)	52/70 (74.3)	143/203 (70.4)	[†]0.84 (0.39, 1.79) [§]0.68 (0.33, 1.41)	[†]0.79 (0.37, 1.69) [§]0.62 (0.30, 1.31)
	N	79/89 (88.8)	65/75 (86.7)	63/81 (77.8)	207/245 (84.5)	[†]2.26 (0.97, 5.23) [§]1.86 (0.80, 4.33)	[†]2.24 (0.96, 5.26) [§]1.88 (0.81, 4.40)
Analgesia except Entonox	**Y**	33/65 (50.8)	34/68 (50.0)	38/70 (54.3)	105/203 (51.7)	[†]0.87 (0.44, 1.71) [§]0.84 (0.43, 1.64)	[†]0.80 (0.40, 1.59) [§]0.76 (0.38, 1.50)
	N	65/88 (73.9)	47/75 (62.7)	47/81 (58.0)	159/244 (65.2)	[†]2.04 (1.07, 3.91) [§]1.21 (0.64, 2.31)	[†]2.03 (1.05, 3.92) [§]1.23 (0.65, 2.35)
Epidural for labour analgesia	**Y**	28/65 (43.1)	26/68 (38.2)	30/70 (42.9)	84/203 (41.4)	[†]1.01 (0.51, 2.00) [§]0.83 (0.42, 1.63)	[†]0.94 (0.47, 1.87) [§]0.74 (0.37, 1.48)
	N	50/88 (56.8)	37/75 (49.3)	41/81 (50.6)	128/244 (52.5)	[†]1.28 (0.70, 2.35) [§]0.95 (0.51, 1.78)	[†]1.21 (0.65, 2.25) [§]0.98 (0.52, 1.85)
Oxytocin	**Y**	24/65 (36.9)	28/68 (41.2)	25/70 (35.7)	77/203 (37.9)	[†]1.05 (0.52, 2.13) [§]1.26 (0.63, 2.51)	[†]1.04 (0.51, 2.12) [§]1.20 (0.60, 2.42)
	N	33/88 (37.5)	25/75 (33.3)	31/81 (38.3)	89/244 (36.5)	[†]0.97 (0.52, 1.80) [§]0.81 (0.42, 1.56)	[†]0.97 (0.51, 1.82) [§]0.84 (0.44, 1.63)
Spontaneous Vaginal birth	**Y**	37/65 (56.9)	40/68 (58.8)	43/70 (61.4)	120/203 (59.1)	[†]0.83 (0.42, 1.65) [§]0.90 (0.45, 1.77)	[†]0.90 (0.45, 1.81) [§]1.00 (0.50, 2.00)
	N	48/89 (53.9)	44/75 (58.7)	49/81 (60.5)	141/245 (57.6)	[†]0.77 (0.42, 1.41) [§]0.93 (0.49, 1.76)	[†]0.74 (0.40, 1.39) [§]0.89 (0.47, 1.70)

**Data are shown as numbers (%). OR (95% CI) = Odds Ratio and 95% CIs*
[†] Hypnosis versus control, [§]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups

Audio CD use and key outcomes sub-group analyses

After adjusting for history of depression and EPDS score, no differences were observed between hypnosis and CD groups in the relative risk of analgesia or other key outcomes with respect to whether women did or did not listen to all CDs (Table 6.9).

Table 6.9 Primary and key secondary outcomes according to whether hypnosis CDs were each used at least once versus some/all CDs not listened to (controls excluded from this analysis) Y = Yes, N = No

Key outcomes	**CDs**	**Hypnosis** n = 154	**CD** n = 143	**Total** n = 297	**OR** (95%CI) unadjusted	**OR** (95% CI) adjusted[$$]
Any analgesia/ anaesthesia for childbirth	Y	45/58 (77.6)	45/66 (68.2)	90/124 (72.6)	1.62 (0.72, 3.62)	1.52 (0.66, 3.48)
	N	68/79 (86.1)	59/70 (84.3)	127/149 (85.2)	1.15 (0.47, 2.85)	1.14 (0.46, 2.84)
Analgesia except Entonox	Y	38/58 (65.5)	30/66 (45.5)	68/124 (54.8)	2.28 (1.10, 4.72)	2.03 (0.96, 4.29)
	N	51/79 (64.6)	46/70 (65.7)	97/149 (65.1)	0.95 (0.48, 1.87)	0.88 (0.44, 1.75)
Epidural for labour analgesia	Y	32/58 (55.2)	25/66 (37.9)	57/124 (46.0)	2.02 (0.99, 4.14)	1.71 (0.81, 3.58)
	N	39/79 (49.4)	33/70 (47.1)	72/149 (48.3)	1.09 (0.57, 2.08)	0.99 (0.51, 1.93)
Oxytocin	Y	22/58 (37.9)	19/66 (28.8)	41/124 (33.1)	1.51 (0.71, 3.21)	1.47 (0.67, 3.21)
	N	28/79 (35.4)	31/70 (44.3)	59/149 (39.6)	0.69 (0.36, 1.34)	0.67 (0.34, 1.32)
Spontaneous Vaginal birth	Y	31/58 (53.5)	43/66 (65.2)	74/124 (59.7)	0.61 (0.30, 1.27)	0.65 (0.31, 138)
	N	43/79 (54.4)	36/70 (51.4)	79/149 (53.0)	1.13 (0.59, 2.15)	1.15 (0.60, 2.23)

**Data are shown as numbers (%). OR (95% CI) = Odds Ratio and 95% CIs*
[†] Hypnosis versus control, [$]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups

Attendance of participants to hypnosis and CD sessions

There was no difference in key outcomes obtained by those attending three sessions and those attending less than three sessions for pharmacological analgesia. This finding suggests that attending all three sessions in the Hypnosis and CD group was no more likely to reduce analgesia use or affect other key outcomes when compared with those allocated to work with the CD only (Table 6.10).

Table 6.10: Primary and key secondary outcomes according to whether women completed all three sessions versus < 3 sessions of exposure to the intervention

Y = Yes, N = No

Key outcomes	**3 Sessions**	**Hypnosis** n = 154	**CD** n = 143	**Total** n = 448	**OR** (95%CI) unadjusted	**OR** (95% CI) adjusted[$$]
Any analgesia / anaesthesia for childbirth	**Y**	55/68 (80.9)	44/57 (77.2)	99/125 (79.2)	1.25 (0.53, 2.97)	1.22 (0.51, 2.95)
	N	70/86 (81.4)	66/86 (76.7)	136/172 (79.1)	1.33 (0.63, 2.77)	1.28 (0.61, 2.70)
Analgesia except Entonox	**Y**	42/68 (61.8)	29/57 (50.9)	71/125 (56.8)	1.56 (0.76, 3.18)	1.41 (0.68, 2.93)
	N	56/85 (65.9)	52/86 (60.5)	108/171 (63.2)	1.26 (0.68, 2.35)	1.22 (0.65, 2.28)
Epidural for labour analgesia	**Y**	33/68 (48.5)	25/57 (43.9)	58/125 (46.4)	1.21 (0.60, 2.45)	1.01 (0.48, 2.12)
	N	45/85 (52.9)	38/86 (44.2)	83/171 (48.5)	1.42 (0.78, 2.60)	1.41 (0.77, 2.58)
Oxytocin	**Y**	20/68 (29.4)	23/57 (40.4)	43/125 (34.4)	0.62 (0.29, 1.29)	0.50 (0.23, 1.10)
	N	37/85 (43.5)	30/86 (34.9)	67/171 (39.2)	1.44 (0.78, 2.67)	1.52 (0.81, 2.83)
Spontaneous Vaginal Birth	**Y**	36/68 (52.9)	33/57 (57.9)	69/125 (55.2)	0.82 (0.40, 1.66)	0.94 (0.45, 1.95)
	N	49/86 (57.0)	51/86 (59.3)	100/172 (58.1)	0.91 (0.50, 1.67)	0.89 (0.48, 1.64)

**Data are shown as numbers (%). OR (95% CI) = Odds Ratio and 95% CIs*
[†] Hypnosis versus control, [§]Audio CD versus control
[$$] Adjusted for differences in baseline EPDS and incidence of h/o of depression between groups

Conclusions of Sub-Group Analyses

Subgroup analyses with respect to parity, induced labour, hypnotisability, maternal beliefs and the use of yoga, did not reveal any differences in primary and key secondary outcomes between allocated groups. Interestingly, women using yoga reduced their use of pharmacological analgesia when using hypnosis (P=0.005) or listening to a CD (P=0.004) on hypnosis but not when receiving usual care (P=0.664). This finding suggests that yoga alone may not reduce analgesia use but, when combined with learning hypnosis may be effective. Such an effect may be due to the use of imagery, positive suggestion and 'trance like' states in yoga. The familiarity of which, may have enhanced the ability of this sub-group of women to learn the hypnosis techniques taught in this study over a shorter period and, more effectively than women not using yoga. Future research will confirm or refute this interpretation of our findings, which until then, should be used with caution.

Chapter 7 – Discussion and Conclusions of HATCh Trial

Introduction

The HATCh Trial represents one of the largest randomised controlled trials conducted to date investigating the effects of hypnosis on any outcome and in any setting. The trial setting was the largest tertiary hospital for maternity care in South Australia and showed that antenatal group hypnosis after 34 weeks of gestation did not affect women's analgesia or anaesthesia requirements during their labour and childbirth.

Trial Strengths

The HATCh Trial had several strengths. These included the health significance of the issue, a high level of originality, the comprehensive outcome assessment, the clinically meaningful nature of the key outcomes chosen, and the support of preliminary studies, meta-analyses and the investigators' experience with the interventions. A rigorous experimental design was used and, with the exception of a history of depression and EPDS scores, achieved similar groups at baseline by using balanced randomization stratified for parity. Careful monitoring of patient data resulted in the detection of an error in recruitment. Despite this, we achieved our planned sample size with 448 randomised participants fulfilling all inclusion eligibility criteria with minimal missing data.

Systematic reviews of the evidence prior to the HATCh trial (Cyna et al 2004; Huntley & Coon 2004; Smith et al 2006) and our use of hypnosis as antenatal preparation for labour (Cyna et al 2006) strongly suggested benefits in the use of hypnosis to reduce analgesia requirements and the incidence of oxytocin administration and to increase the incidence of spontaneous vaginal birth. The planned primary outcome of reduced pharmacological analgesic intervention was a reasonable objective as it was absolute and relatively easy to measure. The use of the CD was an innovative feature of the study, with which investigators attempted to standardise the suggestions component of the intervention. The planned outcomes of improved psychological effects were also reasonable objectives, although somewhat more difficult to measure objectively.

This trial has contributed to the renewed interest in this topic and has answered the call – at least in part – for more research, which remains as relevant today as it was 30 years ago (Davenport-Slack 1975).

Key Findings

The key finding of the HATCh Trial is that learning self-hypnosis in the third trimester, using the particular three-session regimen of this study, when compared with the care of non-hypnosis controls, did not influence the use of pharmacological analgesia during labour and childbirth. In addition, unlike previous studies, mode of delivery and the use of oxytocics were similarly unaffected even after adjusting for the differences between groups in the incidence of women with a history of depression and an EPDS score > 12 at baseline.

Exceptions to the key findings

An unexpected finding of our analyses was that women allocated to the Hypnosis Group had an increased incidence of having an induction of labour and prostaglandin (PG) administration. This difference was observed even after making a statistical correction for the increased incidence of women with EPDS scores > 12 at baseline and a history of depression allocated to the Hypnosis Group.

Possible reasons why hypnosis was ineffective in affecting key outcomes in the HATCh Trial

The lack of efficacy of the antenatal hypnosis intervention in this setting may be due to several reasons. Firstly, one has to consider the possibility that hypnosis, as an intervention, is ineffective. This is unlikely given the previous evidence supporting its effectiveness in other settings - particularly the more recent neuro-imaging findings associated with hypnotic analgesia (see Chapter 1). Furthermore, one cannot easily dismiss the many thousands of patients who have had major surgery performed comfortably under hypnosis without any anaesthesia or other pharmacological medication supplements (Faymonville et al 1995; Faymonville et al 1999; Defechereux et al 2000; Fredericks 2000), including caesarean hysterectomy (Kroger & De Lee 1957).

The failure of the hypnosis intervention to show the effects of some previous studies may be due to a combination of factors: selection bias; the number of sessions and their timing; the tertiary setting; and finally the effects of our primary outcome on the increased incidence of induction in women allocated to the hypnosis arm of the study.

Generalisability and external validity

A high proportion of HATCh Trial participants had a post-school qualification; 338 women (57.8%) had either, a higher degree, a postgraduate diploma or a bachelor's degree (Table 5.3). Only 64 women (10.9%) had no post-school qualification. It may be that this population may have reduced our ability to observe an effect from the intervention. Participants with a higher degree, who are highly educated, are likely not representative of the pregnant population of other studies investigating the effects of hypnosis.

Poor compliance of women allocated to a hypnosis intervention

Only a minority of women actually attended all three sessions and listened to all four CDs. However, our sub-group analyses do not support poor compliance as a reason for the lack of efficacy of the hypnosis intervention.

The number of hypnosis training sessions

Previous studies, where a beneficial effect, has been shown have used six or more sessions and administered the intervention *before* the third trimester (Harmon et al 1990; Mehl-Madrona 2004).

The timing of commencing hypnosis training sessions

Interestingly, the only previous childbirth RCT where hypnosis failed to reduce analgesia requirements during labour and childbirth also had a design that involved delivering the antenatal hypnosis training in the third trimester (Freeman et al 1986). Anecdotal experience suggested that women may be more receptive to hypnosis the nearer they were to giving birth. However, the findings of the HATCh study suggest that this assumption may either be erroneous or that this

effect was insufficient to allow women to learn the self-hypnosis techniques effectively in the time available. Given our side study findings (Alexander et al 2009) of increased hypnotisability when pregnant compared to when not pregnant, the latter is more likely.

The tertiary setting

Previous studies do not appear to have been conducted in a tertiary referral centre. There may have been rates of intervention, such as caesarean section or epidural use during labour and childbirth in this setting that were not amenable to be changed by the hypnosis intervention. The sub-group analyses of a study investigating the effects of continuous support in labour in a low risk population (Hodnett et al 2007), found that in general, greater benefits – such as, decreased operative delivery including, caesarean section and increased spontaneous vaginal delivery – were present when epidural analgesia was not routinely available.

The increased incidence of induction

It is difficult to explain why the hypnosis intervention was found to increase the use of prostaglandins and the incidence of women having inductions in this study. Hypnosis has been used as an intervention both to induce labour (Cyna & Andrew 2003) and, anecdotally, to stop preterm labour. It is possible that the effect of increasing inductions in those women allocated to the hypnosis intervention may explain the lack of effect on reducing analgesia use that has been found in other randomised controlled studies (Harmon et al 1990; Martin et al 2001; Mehl-Madrona 2004).

Limitations of the study

There were several limitations to our study. Firstly, there was a lack of blinding. No methods are known of fully blinding a hypnosis intervention, unless women in the study are not fully informed about the intervention. Although this has been the case in some earlier studies (Harmon et al 1990; Martin et al 2001; Mehl-Madrona 2004; Rock et al 1969), ethical requirements in more recent times demand that trial participants are fully informed regarding the interventions used when participating in a trial.

Although the nature of the intervention makes it difficult to double-blind comparisons between hypnosis groups and non-intervention controls, every attempt was made to conceal treatment allocations from obstetricians, anaesthetists, midwives and those personnel collecting and analysing data. Participants were informed that they might not appreciate which group they were in, but in fact usually appreciated if they were not in an intervention group. Although it was not possible to blind the administration of our intervention, data were collected by researchers who were unaware of the participants' group allocation. Our primary outcomes and key secondary outcomes were designed to be as objective as they could be for a behavioural study of this type. Blinding was assessed by asking participants if they thought they were in a control or intervention group in the final post-partum questionnaire.

The second limitation was the inadvertent randomisation of ineligible women at recruitment with a gestation $\leq$ 34 weeks. As soon as we became aware of this protocol violation, we compensated for it by continuing to recruit women until our original calculated sample size was achieved to include only eligible women who fulfilled all inclusion criteria.

Conclusions about the HATCh Trial

(1) The innovative nature of the HATCh study had great potential. It was a high quality randomised controlled study with a low risk of bias. Our results have provided some clear objective answers to one application of a relatively old therapy.

(2) Our main study findings have not been able to support previous research showing hypnosis interventions reduce pharmacological analgesia requirements during labour or childbirth.

(3) The three-session regimen provided to women of > 34 weeks of gestation has not been found to be an effective hypnosis intervention during childbirth and therefore cannot be recommended.

(4) Future areas of research that may prove fruitful might include

- yoga as part of the hypnosis training regimen
- an investigation of the utility of a hypnosis intervention as a non-pharmacological means of preventing or stopping preterm labour. It should be noted that the effect of hypnosis on labour induction was not an ‘a priori’ outcome of this trial.
- The effects of increasing the number of training sessions and timing the hypnosis training earlier in the pregnancy need further research (see also Chapter 8).

Chapter 8 – Updated Systematic Review Incorporating the Results of the HATCh Trial

Introduction

The completion of the HATCh Trial has added important new data to that already available and detailed in Chapter 2. Figures 8.1 and 8.2 show updated meta-analyses for the primary outcome of the HATCh Trial – namely the use of pharmacological analgesia or anaesthesia during labour and childbirth. A Risk of Bias Table for each included study is also shown (Table 8.1).

Description of studies

The HATCh Trial represents the most methodologically sound study performed to date with clearly described and adequate randomisation, allocation concealment, ITT analysis and no losses to follow-up. The HATCh Trial and the Mehl-Madrona studies are the largest performed to date. In contrast to HATCh, the Mehl-Madrona study commenced hypnosis training in the first trimester and did not use a fixed hypnosis intervention. The frequency of sessions averaged 5, but ranged up to 90 (Mehl-Madrona 2004).

Table 8.1: Risk of bias

RCT	Participants	Sample size calculation	Randomisation	Allocation Concealment	Blinding	ITT analyses	Losses to F/U Comments
HATCh 2011 **Australia**	448 women > 34 weeks	Yes	Computer generated	Adequate-telephone randomisation/ computer program	Outcome assessors	Yes	None for primary outcome
Freeman, et al 1986 **UK**	75 women, 3rd trimester	Not stated	Method not stated	Unclear	Not stated	No	13 withdrew 4 lost to F/U "Prolongation of pregnancy and labour, might ensue"
Harmon et al 1990a **USA**	60 nullipara.	Not stated	Method not stated	Unclear	Participants, care providers and outcome assessors	Yes	None
Martin et al 2001 **USA**	47 teenagers 20–24 weeks	Not stated	Method not stated	Unclear	Participants, care providers and outcome assessors	Unclear	5 (10%)
Mehl-Madrona 2004	520 women commenced training in 1st or 2nd trimester	Not stated	Method not stated	Unclear	Outcome assessor blinded	Yes	None
Rock et al 1969 **USA**	40 nullipara. in labour	Not stated	Method not stated	Inadequate	Outcome assessor blinded	Yes	Not stated

Apart from the HATCh trial, no previous study has reported calculating a sample size prior to commencement or reached the pre-specified sample size. The HATCh trial remains the only trial to date investigating the effects of hypnosis in childbirth that had adequate allocation concealment, randomisation and a power analysis of key outcomes. Interestingly the Freeman trial reported that pregnancy and labour might be prolonged in hypnosis groups but they did not report any results as to why they stated this.

Updated meta-analysis results

Primary outcome – the need for pharmacological pain relief during childbirth

The need for pharmacological pain relief in women allocated to the hypnosis groups was compared to the control groups (RR 0.61, 95% CI 0.35 to 1.06 [1032 women]). All six trials reported on the use of pharmacological pain relief in labour.

In one study (Rock et al 1969), there was a reduced incidence in the use of pain relief in those women allocated to the hypnosis intervention when compared with the control (RR 0.67, 95% CI 0.48 to 0.94).

In two studies (Freeman et al 1986) and the HATCh trial, there was no difference in the use of pain relief between women receiving hypnosis and the control group (RR 1.06, 95% CI 0.40 to 2.82 [65 women]) and RR 1.06, 95% CI 0.82, 1.37 [448 women] respectively. Women rated to have a good or moderate response to hypnosis had relatively fewer epidurals than those rated to have a poor responsive (4/24 versus 4/5, $P < 0.05$) in the Freeman study while those of high hypnotisability in the HATCh trial used less analgesia when using hypnosis than women of low hypnotisability (59% vs 70%, $P < 0.05$).

In one trial (Martin et al 2001), women receiving hypnosis used less anaesthesia than women in the control group (RR 0.65, 95% CI 0.38 to 1.11 [42 women]).

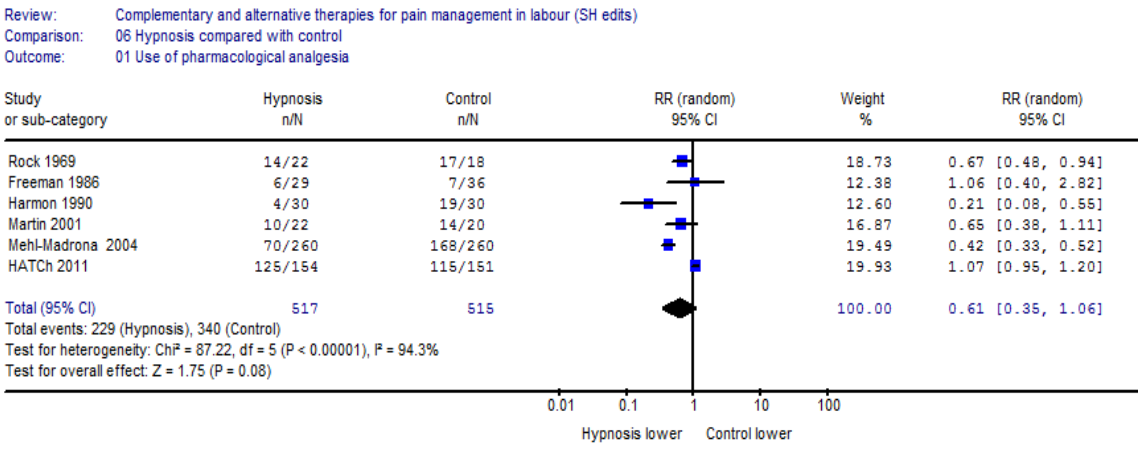
One trial (Harmon et al 1990) reported on the use of narcotics; fewer women in the hypnosis group used narcotics than in the control group (RR 0.21, 95% CI 0.08 to 0.55 [60 women]).

One study (Mehl-Madrona 2004) reported that women receiving hypnosis required less pharmacological pain relief (RR 0.42, 95% CI 0.33 to 0.52) and less use of epidural analgesia (RR 0.30, 95% CI 0.22 to 0.40 [520 women]).

The updated meta-analyses of all six trials no longer shows that hypnosis reduces pharmacological analgesia during childbirth (RR 0.61, 95% CI 0.35 to 1.06; P = 0.08) (Figure 8.1).

The I^2 statistic indicated significant heterogeneity at 94%; so a random-effects model was used for the meta-analyses of the six trials reporting this outcome (Figure 8.1).

Figure 8.1: Updated meta-analysis of the use of pharmacological analgesia or anaesthesia during labour and childbirth



When investigating possible reasons for the high degree of heterogeneity in the meta-analyses, one explanation for the different findings of the various studies investigating the use of pharmacological analgesia or anaesthesia when hypnosis is compared with controls, regards the timing when hypnosis training is administered.

Timing of commencing hypnosis training for reducing analgesia requirements during labour and childbirth

During labour

Only one RCT (Rock et al 1969) has attempted to use a hypnosis intervention during labour, RR 0.67 (0.48, 0.94) (Figure 8.2).

Third trimester training

Two studies have now investigated the use of hypnosis for childbirth by commencing training during the third trimester – the Freeman et al (1986) RCT and the HATCh Trial (RR 1.19 [0.98,1.20], P = 0.11, I^2 = 0%) (Figure 8.2).

First or second trimester training

Three RCTs – (Harmon et al 1990; Martin et al 2001; Mehl-Madrona 2004) commenced training before the third trimester

(RR 0.43 [0.27, 0.67], P=0.0002, I^2 = 57%) (Figure 8.2).

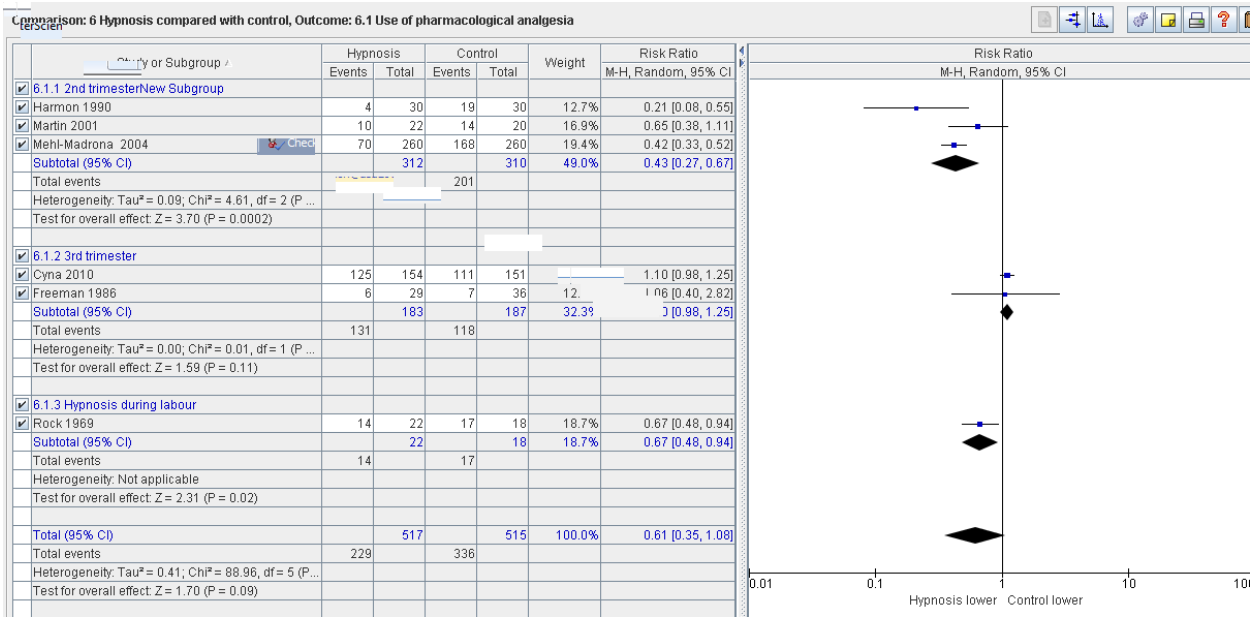


Figure 8.2: Updated meta-analysis of the use of pharmacological analgesia or anaesthesia during labour and childbirth grouped according to timing of the intervention (1st and 2nd trimester, 3rd trimester, in labour)

This updated systematic review appears to show that training pregnant women in self-hypnosis before the third trimester appears to decrease the use of pharmacological interventions for analgesia or anaesthesia, whilst training after the third trimester does not show these benefits (Figure 8.2). However the HATCh trial is the only study with a low risk of bias so these results need to be viewed with caution. Only one study investigated the effects of hypnosis during labour (Rock et al 1969), although the systematic review by Hodnett et al (2007) contains trials where ongoing support with positive suggestions and encouragement during labour has been shown to reduce analgesia requirements and increase the incidence of spontaneous vaginal birth.

Only two RCTs have investigated the effects of hypnosis on use of epidural analgesia during childbirth (Figure 8.3).

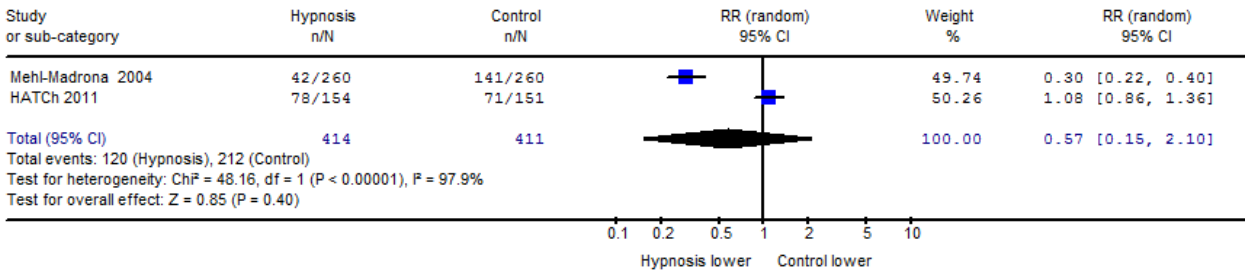


Figure 8.3: Use of epidural analgesia

Unlike the previous trials measuring this outcome, the HATCh Trial failed to demonstrate an increase in the incidence of spontaneous vaginal births, the meta-analysis, using a random effects model, no longer shows an increase in the incidence of spontaneous vaginal births (Figure 8.3).

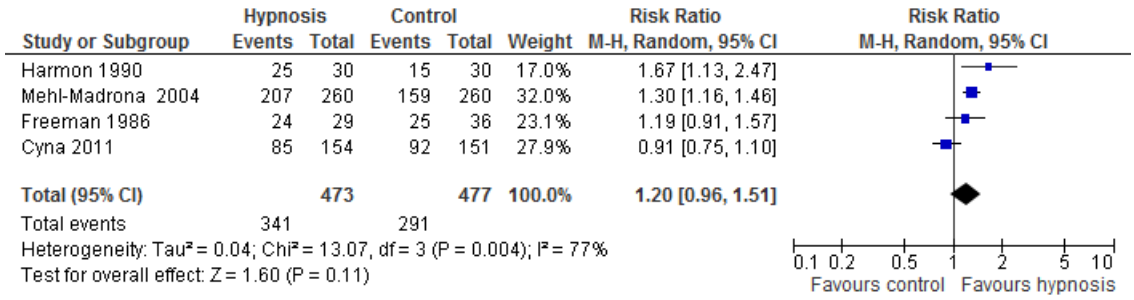


Figure 8.3: Updated meta-analysis of spontaneous vaginal birth

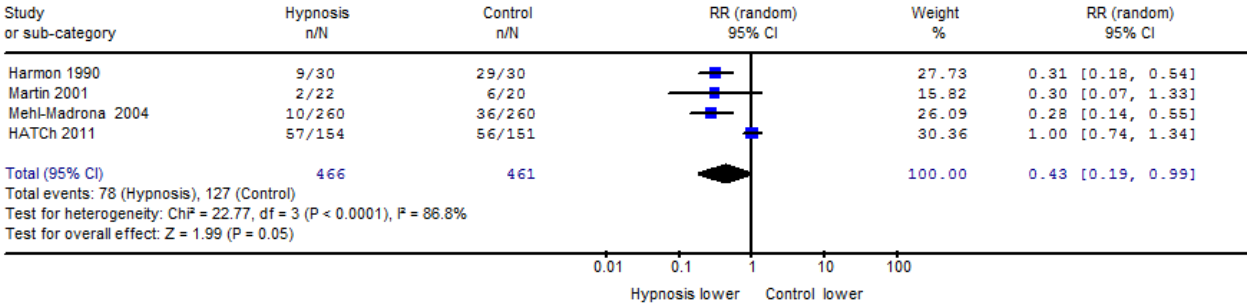


Figure 8.4: Updated meta-analysis for use of oxytocics

The original decrease in the use of oxytocics associated with hypnosis in childbirth is no longer significant in the meta-analysis when the HATCh trial findings are included (Figure 8.4).

Systematic review discussion

Despite the increasing use of hypnosis, numerous case series and a small number of RCTs, until the HATCh Trial, there was a lack of large, well-designed, randomised, controlled trials to evaluate the effectiveness of hypnosis in late pregnancy. With the inclusion of the HATCh Trial, the relative risk for use of pharmacological analgesia was identical to the only other trial (Freeman et al 1986) which commenced hypnosis training in the 3rd trimester This trial

commenced training at 32 weeks of gestation and continued on a weekly basis until the birth. The systematic review with respect to this outcome now strongly suggests that antenatal hypnosis training in the third trimester is ineffective, while hypnosis training that commences in the second or first trimester may be effective but the quality of trials investigating the effectiveness of hypnosis training before the 3rd trimester is poor. It appears that the timing of commencement of the antenatal hypnosis training may be an important factor on the efficacy of hypnosis. The clinical implications of these updated meta-analyses are that hypnosis training in late pregnancy cannot be recommended.

Limitations of the systematic review

Prior to the HATCh trial, the evidence of the effectiveness of hypnosis as an adjunct to analgesia during childbirth to date has been limited by only four small trials and one large trial of poor methodology (Smith et al 2006). Only two trials (Mehl-Madrona 2004, HATCh 2010) investigated women who had access to an "on demand" epidural service for labour analgesia, which is widely available in many developed countries. Neither the intervention nor the number of sessions were standardised in the earlier study, which was performed by a single practitioner over a ten-year period (Mehl-Madrona 2004). The intervention was unstructured and delivered with a very wide range in the number of sessions. Such features of previous studies have limited the reproducibility of the intervention and decreased the external validity.

Current available evidence appears to show that hypnosis reduces the need for pharmacological pain relief, including epidural analgesia in labour when antenatal hypnosis training commences before the third trimester. However, this finding needs to be made with

caution as all the studies have a high risk of bias. They will need to be confirmed in a study designed to investigate this hypothesis.

Personnel delivering the hypnosis intervention during childbirth

A wide variety of personnel administered the hypnosis intervention under study in the various trials included in this review. These included medical students (Rock et al 1969), psychologists (Harmon et al 1990; Martin et al 2001), obstetricians (Freeman et al 1986) and anaesthetists and a GP hypnotherapist (HATCh 2010).

Number of hypnosis sessions

Although most clinical hypnotherapists use three or more sessions in the antenatal period when training in hypnosis in preparation for childbirth (Harmon et al 1990), one group (Rock et al 1969) found hypnosis to be effective in untrained mothers during their labour. The HATCh trial has failed to show a decrease in analgesia use when three sessions were scheduled in late pregnancy.

Timing of the intervention

One previous study (Tiba 1990) suggests that, as pregnancy progresses, responsiveness to hypnosis and suggestion increases. One study has shown that antenatal hypnosis training, when commenced in the first trimester, effectively reduces analgesia requirements (Mehl-Madrona 2004). Most workers begin training women in the use of hypnosis later on in pregnancy, usually in the third trimester (Irving & Pope 2002). The latest meta-analysis including the HATCh trial

suggests that the commencement of hypnosis training before the third trimester is likely to be more effective than training that commences during the third trimester.

Groups versus individual administration of hypnosis

Hypnosis in groups of up to 20 women in preparation for childbirth has been used successfully (Leeb J 1995), while others (Harmon et al 1990) have demonstrated a range of beneficial outcomes following antenatal hypnosis training in groups of 15 women. The HATCh trial failed to show that group hypnosis was effective but this effect could be related to the timing of the intervention (see above). 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 (Fuchs 1980).

Multiparous versus nulliparous

Prior to the HATCh trial, randomised comparisons of hypnosis in childbirth 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 (Cyna et al 2005; Jenkins & Pritchard 1993). The HATCh trial has not shown these effects.

Reproducibility of the hypnosis intervention

Apart from the HATCh trial, none of the studies have provided sufficient detail to reproduce the hypnosis intervention. However, five of the studies (including HATCh) attempted

to standardise the intervention, although few details were provided in the four other trials (Freeman et al 1986; Harmon et al 1990; Martin et al 2001; Rock et al 1969).

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

Several workers asked patients to listen to an audio CD of hypnosis suggestions at home as practice in their preparation for childbirth, re-enforcing the techniques learned in the classroom (McCarthy 1998; Harmon et al 1990). The heterogeneity seen in our systematic review (Cyna et al 2004) can be explained by the use of supplemental audio recordings of suggestions, in one of the studies, in addition to live preparation (Harmon et al 1990). This appears to support the view that it is beneficial for subjects to practice the intervention using recorded suggestions at home (McCarthy 2001). The effectiveness of standardised over individualised suggestions during hypnosis has been studied using a crossover design with the Stanford Hypnotic Clinical Scale. This study showed no difference in response to suggestions in these two conditions (Van Der Does et al 1989). Until the HATCh trial, there were no randomised studies to assess whether listening to hypnotic suggestions on an audio recording is of additional value. However, the use of a recording for re-enforcing the suggestions is a simple, cheap supplement to hypnosis sessions that allows the intervention to be standardised and maximises external validity. The HATCh trial has failed to show audio CDs to be an effective intervention.

Conclusions

Implications for practice

The data available suggests hypnosis is ineffective at reducing the need for pharmacological analgesia when the antenatal training occurs in the third trimester. However it does appear to reduce the need for pharmacological pain relief in labour, reduce the requirements for drugs to augment labour and increases the incidence of spontaneous vaginal birth when the hypnosis intervention is administered prior to the 3rd trimester. Women should be warned of a possible effect on their need for an induction of labour but should not necessarily be discouraged from using hypnosis – especially when training commences before the 3rd trimester.

Implications for research

This updated systematic review suggests a clear need to assess whether the timing of the hypnosis intervention affects clinical outcomes. Other specific aspects of delivery of hypnosis is required, such as group versus individual training in hypnosis, the number of sessions of hypnosis, and use of an audio recording. As Schopenhauer remarked, 'All truth passes through three stages. First it is ridiculed. Second it is violently opposed. Third it is accepted as being self-evident'. The application of the rapid advances in cognitive neuroscience to hypnosis research is likely to make the reality of the third stage more likely (Gruzelier 1998). However, the timing and delivery method of an antenatal hypnosis intervention that can be shown to be effectively and, easily used in labour and childbirth is still awaited.

Chapter 9 – Thesis Summary

Literature review

The literature review, including our previously published systematic reviews (Cyna et al 2004; Smith et al 2006), identified a research gap that the HATCh Trial was designed to fill. The evidence appeared to suggest that the use of hypnosis in childbirth

(1) decreases analgesia requirements during labour

(2) decreases oxytocin requirements during labour

(3) increases the incidence of spontaneous vaginal birth

The HATCh Trial

The HATCh Trial was a comprehensive, high-quality, randomised trial that included 448 pregnant women in late pregnancy. It was designed to assess the efficacy of a short, three-session, standardised hypnosis intervention in late pregnancy. The HATCh study findings show that, unlike in all but one previous study, this hypnosis intervention in the third trimester was ineffective in reducing analgesia requirements during childbirth. The increased incidence of induction required in hypnosis groups when compared with controls was unexpected and suggests that hypnosis may have an effect in the non-pharmacological inhibition of spontaneous labour.

Sub-group analyses

Hypnosis may reduce analgesia requirements when supplemented by yoga and in those women of increased hypnotisability.

Updated systematic review

The addition of the HATCh Trial results has substantially increased the heterogeneity of the systematic review. Sub-group analyses, according to the timing of the hypnosis training during pregnancy, suggest that training in the third trimester is ineffective in reducing analgesia requirements. However, antenatal hypnosis training either during labour or commencing early in pregnancy, either in the first or second trimester, appears to decrease pharmacological analgesia use during childbirth.

Implications for practice

Antenatal group hypnosis training in the third trimester is likely to be ineffective in reducing analgesia requirements for childbirth. Training in hypnosis during pregnancy before the third trimester is likely to reduce pharmacological analgesia requirements during childbirth and increase the incidence of spontaneous vaginal birth.

Implications for research

Further research is required to investigate why hypnosis might inhibit the spontaneous onset of labour and how this effect might be negated, minimised or utilised. Further research is required to investigate the optimal timing to commence antenatal hypnosis training, the number of sessions and the types of suggestions that might be most effective. Yoga may be a useful

adjunct to the hypnosis intervention and should be researched further as a sole technique and together with antenatal hypnosis training during pregnancy. There appears to be a clear need for high quality trials where hypnosis training occurs before the 3rd trimester. Ideally, training after the 3rd trimester should be compared with hypnosis training before the 3rd trimester.

References

Abramson, M & Heron, WT 1950, 'An objective evaluation of hypnosis in obstetrics', *Am J Obst Gynecol*, vol 59, pp. 1069–74.

Alexander B, Turnbull D & Cyna A 2009. 'The effect of pregnancy on hypnotizability'. *Am J Clin Hypn*. Vol 52,1pp. 3-22.

Anderson, JA, Basker, MA & Dalton R 1975, 'Migraine and hypnotherapy', *Int J Clin Exp Hypn*, vol 23, no. 1, pp. 48–58.

ANZCA working party 2005, 'The pregnant patient', in P Macintyre (ed), *Acute pain management: Scientific evidence*, 2nd edn, Australian and New Zealand College of Anaesthetists and the Faculty of Pain Medicine, Melbourne, pp. 222–37.

Anim-Somuah, M, Smyth, R & Howell, C 2005, 'Epidural versus non-epidural or no analgesia in labour', *Cochrane Database Systematic Reviews*, 2005, Art. No. CD000331(4).

August, RV 1960, 'Obstetrical hypoanesthesia', *Am J Obstet Gynecol*, vol 79, pp. 1131–8.

Bailham, D & Joseph, S 2003, 'Post-traumatic stress following childbirth: a review of the emerging literature and directions for research and practice', *Psychological Health & Medicine*, vol 8, pp. 159–68.

Baier-Rogowski, V 1988 ['Anxiety, magic, suggestion, hypnosis and the role of the anesthesist'], *Anasth Intensivther Notfallmed*, vol 23, no. 2 pp. 73–6.

Barber, TX & Wilson, SC 1978, 'The Barber Suggestibility Scale and the Creative Imagination Scale: Experimental and clinical applications', *Am J Clin Hyp*, vol 21, no. 2,3, pp. 84–107.

Barnier, AJ & McConkey, KM 2003, 'Hypnosis, human nature, and complexity: integrating neuroscience approaches into hypnosis research', *Int J Clin Exp Hypn*, vol 51, no. 3, pp. 282–308.

Bejenke, CJ 1996, 'Obstetrics', in J Barber (ed), *Hypnosis and suggestion in the treatment of pain: A clinical guide*, WW Norton, London, pp. 250–55.

Begg, C Cho, M, Eastwood, S, Horton, R, Moher, D, Olkin, I, Pitkin, R, Rennie, D, Schulz, K, Simel, D & Stroup, D 1996, 'Improving the quality of reporting of randomized controlled trials: The CONSORT statement', *JAMA*, vol 276, no. 8, pp. 637–39.

Benedetti, F 2007, 'What do you expect from this treatment? Changing our mind about clinical trials', *Pain*, vol 128, no. 3, pp.193–4.

Benedetti, F, Lanotte, M, Lopiano, L & Colloca, L 2007, 'When words are painful: Unraveling the mechanisms of the nocebo effect', *Neuroscience*, vol 147, pp. 260–71.

BMA Working Party 1955, Medical use of hypnotism: BMA Subcommittee to Council, Supplementary report of BMJ, App X, pp. 190–93.

Bonica, JJ 1984, 'Labour Pain', in PD Wall Melzack R (ed,) *Textbook of Pain*, Churchill Livingstone, [NY], pp. 377–91.

Bromage, PR 1999, 'Neurologic complications of labor, delivery, and regional anesthesia', in DH Chestnut (ed), *Obstetric anesthesia*, Mosby, St. Louis, pp. 639–61.

Burrows, GD, Stanley R 2001, 'Introduction to clinical hypnosis and the hypnotic phenomena', in GD SR Burrows & PB Bloom (eds), *International handbook of clinical hypnosis*, John Wiley and Sons, Chichester, UK, pp. 1–17.

Chan, A, Scott, J, Nguyen, AM & Sage, L 2008, 'Pregnancy Outcome in South Australia 2007', in Pregnancy Outcome Unit, Adelaide: SA Health, Government of South Australia, p. 87.

Clawson, TA, Jr. & Swade, RH 1975, 'The hypnotic control of blood flow and pain: the cure of warts and the potential for the use of hypnosis in the treatment of cancer', *Am J Clin Hypn*, vol 17, no. 3, pp. 160–9.

Coldrey, J & Cyna, AM 2004, 'Anaesthetist's attitudes to hypnotherapy: a survey of South Australian anaesthetists', *Anaesthesia & Intensive Care*, vol 32, no. 5, pp. 676–80.

Cox, JL 1987, 'Detection of postnatal depression scale', *Brit J Psych*, vol 150, pp. 782–6.

Crawford, D (ed) 1914, *History of the Indian Medical Service*, Thacker and Co, London.

Cyna, AM 2003, 'A post-partum complication of hypnosis for analgesia during labour', *Aus J Clin Exp Hypn*, vol 31, no. 2, pp. 185–90.

Cyna, AM 2003a, 'Hypno-analgesia for a labouring parturient with contra-indications to central neuraxial block', *Anaesthesia*, vol 58, no. 1, pp. 101–2.

Cyna, AM & Andrew, MI 2003, 'Induction of labour using switchbox imagery during hypnosis', *Aus J Clin Exp Hypn*, vol 31, no. 1, pp. 74–87.

Cyna, AM, Andrew, MI, Robinson, JS, Crowther, CA, Baghurst, P, Turnbull, D, Wicks, G, and Whittle C 2006. Hypnosis Antenatal Training for Childbirth (HATCh): a randomised controlled trial [NCT00282204]. *BMC Pregnancy Childbirth,*. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1450315/

Cyna, AM, Andrew, MI & McAuliffe, GL 2005, 'Antenatal hypnosis for labour analgesia', *Int J Obstet Anesth*, vol 14, no. 4, pp. 365–6.

Cyna, AM, Andrew, MI & McAuliffe, GL 2006, 'Antenatal self-hypnosis for labour and childbirth: a pilot study', *Anaesth Int Care*, vol 34, no. 4, pp. 464–9.

Cyna, AM, Andrew, MI & Whittle, C 2007, 'Hypnosis Antenatal Training for Childbirth (HATCh): Intervention scripts 1 and 4', *Aus J Clin Exp Hypn*, vol 35, pp. 83–94.

Cyna, AM, Andrew, MI & Whittle, C 2008, 'Hypnosis Antenatal Training for Childbirth (HATCh): Intervention script 2', *Aus J Clin Exp Hypn*, vol 35, no. 2, pp. 234-42.

Cyna, AM, Andrew, MI & Whittle, C 2008a, 'Hypnosis Antenatal Training for Childbirth (HATCh): Intervention script 3', *Aus J Clin Exp Hypn*, vol 36, no. 1, pp. 80–86.

Cyna, A, McAuliffe, G & Andrew, M 2004, 'Hypnosis for pain relief in labour and childbirth: a systematic review', *Br J Anaesth*, vol 93, no. 4, pp. 505–11.

Cyna, AM & Dodd J 2007. Clinical update: obstetric anaesthesia. *Lancet*. vol 370, no. 9588, pp. 640-2.

Davenport-Slack, B 1975, 'A comparative evaluation of obstetrical hypnosis and antenatal childbirth training.' *Int J Clin Exp Hypn* vol 23, no. 4, pp. 266-281.

Decca, L, Daldoss, C, Fratelli, N, Lojacono, A, Slompo, M, Stegher, C, Stegher C, Valcamonico A, Frusca T 2004, 'Labor course and delivery in epidural analgesia: a case-control study', *J Mat Neonat Med*, vol 16, no. 2, pp. 116–18.

Defechereux, T, Degauque, C, Fumal, I, Faymonville, ME, Joris, J, Hamoir, E, Meurisse, M,et al. 2000, ['Hypnosedation, a new method of anesthesia for cervical endocrine surgery. Prospective randomized study'], *Ann Chir*, vol 125, no. 6, pp. 539–46.

De Costa, C & Robson, S 2004, 'Throwing out the baby with the spa water', *Med J Aus*, vol 181, no. 8, pp. 438–40.

Deltito, J & Baer, L 1986, 'Hypnosis in the treatment of depression: research and theory', *Psychol Rep*, vol 58, no. 3, pp. 923–9.

DeSousa, C & Wallace, RB 1977, 'Pain: a review and interpretation', *Int J Neurosci*, vol 7, no. 2, pp. 81–101.

Elias, J 2006, 'What is hypnosis?' in J Elias (ed), *True Magic*, 5 wisdom's press, Seattle, pp. 1–14.

Elbourne, D, & Wiseman, RA 2004. "Types of intra-muscular opioids for maternal pain relief in labour (Cochrane Review)." *The Cochrane Database of systematic reviews.* Chichester, UK: John Wiley & Sons, Ltd.(1): CD001237

Elliotson, J 1843, *Numerous cases of surgical operations without pain*, Lea and Blanchard, Philadelphia.

Elliotson, J 1849, *The Zoist: A journal of cerebral physiology and mesmerism and the applications of human welfare*, Balliere, London.

Eng, W & Cyna, A 2005, 'A comparison of midwives' knowledge of and attitudes to hypnosis in hospitals with and without a hypnotherapy service', *Aus J Clin Exp Hypn*, vol 33, no. 1, pp. 74–87.

Enqvist, B & Fischer, K 1997, 'Preoperative hypnotic techniques reduce consumption of analgesics after surgical removal of third mandibular molars: a brief communication', *Int J Clin Exp Hypn*, vol 45, no. 2, pp. 102–8.

Erickson, JC, 3rd 1994, 'The use of hypnosis in anesthesia: a master class commentary', *Int J Clin Exp Hypn*, vol 42, no. 1, pp. 8–12.

Faymonville, ME, Boly, M & Laureys, S 2006, 'Functional neuroanatomy of the hypnotic state', *J Physiol Paris*, vol 99, no. 4–6, pp. 463–9.

Faymonville, ME, Defechereux, T, Joris, J, Adant, JP, Hamoir, E & Meurisse, M 1998. [Hypnosis and its application in surgery], *Rev Med Liege*, vol 53, no. 7, pp. 414–8.

Faymonville, ME, Fissette, J, Mambourg, PH, Roediger, L, Joris, J & Lamy, M 1995. 'Hypnosis as adjunct therapy in conscious sedation for plastic surgery', *Reg Anesth*, vol 20, no. 2, pp. 145–51.

Faymonville, ME, Laureys, S, Degueldre, C, DelFiore, G, Luxen, A, Franck, G, Lam M, Marquet P. 2000, 'Neural mechanisms of antinociceptive effects of hypnosis' *Anesthesiology*, vol 92, no. 5, pp.1257-67 .

Faymonville, ME, Mambourg, PH, Joris, J, Vrijens, B, Fissette, J, Albert, A, & Lamy, M. 1997, 'Psychological approaches during conscious sedation. Hypnosis versus stress reducing strategies: a prospective randomized study', *Pain*, vol 73, no. 3, pp. 361–7.

Faymonville, ME, Meurisse, M, Fissette, J 1999, 'Hypnosedation: a valuable alternative to traditional anaesthetic techniques', *Acta Chir Belg*, vol 99, no. 4, pp. 141–6.

Faymonville, ME, Roediger, L, Del Fiore, G, Delgueldre, C, Phillips, C, Lamy, M, Luxen, A, Maquet, P, Laureys S. 2003, 'Increased cerebral functional connectivity underlying the antinociceptive effects of hypnosis', *Brain Res Cogn Brain Res*, vol 17, no. 2, pp. 255–62.

Fredericks, LE 2000, 'Hypnosis as a sole anaesthetic', In: LE Fredericks (ed), *The use of hypnosis in surgery and anaesthesiology*, Charles C Thomas, Springfield, IL, pp. 99–118.

Freeman, RM, Macaulay, AJ, Eve, L & Chamberlain, GVP, 1986, 'Randomised trial of self hypnosis for analgesia in labour', *British Medical Journal*, vol 292, pp. 657–8.

Fuchs, K, Paldi, E, Abramovici, H & Peretz, BA, 1980, 'Treatment of hyperemesis gravidarum by hypnosis', *Int J Clin & Exp Hypn*, vol 28, no. 4, pp. 313–23.

Fuge, C 1986, 'Bedford Square. A connection with mesmerism.' *Anaesthesia*, 41, pp. 726–30.

Gaffney, L & Smith, CA 2004, 'Use of complementary therapies in pregnancy: the perceptions of obstetricians and midwives in South Australia', *Aust N Z J Obstet Gynaecol*, vol 44, no. 1, pp. 24–9.

Gamsa, A 2003, 'Hypnotic analgesia', in R Melzack & PD Wall (eds), *Handbook of pain management*, Churchill Livingstone, London, pp. 521–31.

Goldman, L 1992, 'The use of hypnosis in obstetrics', *Psychiatr Med*, vol 10, no. 4, pp. 59–67.

Greenleaf, E 1974, 'Defining hypnosis during hypnotherapy', *Int J Clin Exp Hypn*, vol 22, no. 2, pp. 120–30.

Goldmann, L, Ogg, TW & Levey, AB 1988 'Hypnosis and daycase anaesthesia. A study to reduce pre-operative anxiety and intra-operative anaesthetic requirements', *Anaesthesia*, vol 43, no. 6, pp. 466–9.

Gonsalkorale, WM & Whorwell, PJ 2005, 'Hypnotherapy in the treatment of irritable bowel syndrome', *Eur J Gastroenterol Hepatol*, vol 17, no. 1, pp. 15–20. *Anesthesiology*, vol 92, no. 5, pp. 1257–67.

Greer, HS 1956, 'Hypnotic analgesia in childbirth', *Med J Aust*, vol 43, no. 22, pp. 819–20.

Gruzelier, JA 1998, 'Working model of the neurophysiology of hypnosis: a review of the evidence', *Contemporary Hypnosis*, vol 15, no. 1, pp. 3–21.

Hall, K & Giles-Corti, B 2000, 'Complementary therapies and the general practitioner- a survey of Perth GPs', *Australian Family Physician*, vol 29, no. 6, pp. 602–06.

Hammond, DC 2008, 'Hypnosis as sole anesthesia for major surgeries: historical & contemporary perspectives', *Am J Clin Hypn*, vol 51, no. 2, pp. 101–21.

Harmon, TM, Hynan, MT & Tyre, TE 1990, 'Improved obstetric outcomes using hypnotic analgesia and skill mastery combined with childbirth education', *J Consult Clin Psychol*, vol 58, no. 5, pp. 525–30.

Higgins, JPT & Green, S 2005, Formulating the problem. Cochrane Reviewer's Handbook 4.2.5 (updated May 2005). *The Cochrane Library*, John Wiley & Sons Ltd., Chichester, UK.

Hilgard, ER (ed) 1965, *Hypnotic susceptibility*, Harcourt, Brace & World, New York.

Hodnett, ED, Gates, S, Hofmeyr, GJ & Sakala, C 2007, 'Continuous support for women during childbirth (Cochrane Review)' *Cochrane Database of Systematic Reviews*, 2007, Art. No. CD003766(3).

Hoffman, G & Kipenhauer, D 1961, 'Medical hypnosis and its use in obstetrics', *American Journal of Medical Science*, vol 241, pp. 788.

Holroyd, J 1996, 'Hypnosis treatment of clinical pain: understanding why hypnosis is useful', *Int J Clin Exp Hypn*, vol 44, no. 1, pp. 33–51.

Huntley, AL, Coon, JT, & Ernst E 2004, 'Complementary and alternative medicine for labor pain A systematic review', *Am J Obstet Gynecol*, vol 191, pp. 36–44.

Irving, L & Pope, S 2002, 'Is the use of hypnosis during childbirth preparation associated with beneficial obstetric and psychological outcomes?' *Aus J Clin Exp Hypn*, vol 30, no. 1, pp. 24–34.

Jenkins, MW & Pritchard, MH 1993, 'Hypnosis: Practical applications and theoretical considerations in normal labour', *British Journal of Obstetrics and Gynaecology*, vol 100, pp. 221–26.

Johanson, R, Newburn, M & MacFarlane, A 2002, 'Has the medicalisation of childbirth gone too far?' *Brit med J*, vol 324, pp. 892–5.

Kihlstrom, J 2008, 'The domain of hypnosis, revisited', in MR Nash & AJ Barnier (eds), *The Oxford Handbook of Hypnosis*, Oxford University Press, New York, pp. 21–52.

Kosslyn, SM, Thompson, WL, Costantini-Ferrando, MF, Alpert, NM & Spiegel, D 2000, 'Hypnotic visual illusion alters color processing in the brain', *Am J Psychiatry*, vol 157, no. 8, pp. 1279–84.

Koyama, T, McHaffie, JG, Laurienti, PJ & Coghill, RC 2005, 'The subjective experience of pain: where expectations become reality', *Proc Natl Acad Sci*, vol 102, pp. 12950–55.

Kroger, WS & DeLee, ST 1943, 'The use of the hypnoidal state as an amnesic analgesic and anesthetic agent in obstetrics', *Am J Obst Gynec*, vol 46, pp. 655–61.

Kroger, WS & De Lee, ST 1957, 'Use of hypno-anaesthesia for Caesarian section and hysterectomy', *JAMA*, vol 163, pp. 442–4.

Lang, EV, Joyce, JS, Spiegel, D, Hamilton, D & Lee, KK 1996 'Self-hypnotic relaxation during interventional radiological procedures: effects on pain perception and intravenous drug use', *Int J Clin Exp Hypn*, vol 44, no. 2, pp. 106–19.

Lang, EV, Benotsch, EG, Fick, LJ, Lutgendorf, S, Berbaum, ML, Berbaum, KS, Logan H, & Spiegel D . 2000, 'Adjunctive non-pharmacological analgesia for invasive medical procedures: a randomised trial', *Lancet*, vol 355, no. 9214, pp. 1486–90.

Lang, EV, Berbaum, KS, Faintuch, S, Hatsiopoulou, O, Halsey, N, Li, X, Berbaum ML, Laser E, Baum J. 2006, 'Adjunctive self-hypnotic relaxation for outpatient medical procedures: a prospective randomized trial with women undergoing large core breast biopsy', *Pain*, vol 126, no. 1–3, pp. 155–64.

Lang, EV & Rosen, MP 2002, 'Cost analysis of adjunct hypnosis with sedation during outpatient interventional radiologic procedures', *Radiology*, vol 222, no. 2, pp. 375–82.

Leeb, J 1996, 'A protocol for training individual pregnant patients in self-hypnosis for labour', *European Journal of Clinical Hypnosis*, vol 3, no. 1, pp. 5–9.

Lucas-Polomeni, MM 2004, 'Hypnosis: a new anesthetic technique!' *Pediatric Anesthesia*, vol 14, pp. 975–6.

Maquet, P, Faymonville, ME & Degueldre, C 1999, 'Functional neuroanatomy of hypnotic state', *Biol Psychiat*, vol 45, no. 3, pp. 327–33.

Martin, AA, Schauble, PG, Rai, SH & Curry, RW 2001, 'The effects of hypnosis on the labor processes and birth outcomes of pregnant adolescents', *J Fam Pract*, vol 50, no. 5, pp. 441–3.

McCarthy, P 1998, 'Hypnosis in Obstetrics', *Australian Journal of Clinical and Experimental Hypnosis*, vol 26, no. 1, pp. 35–42.

McCarthy, P 2001, 'Hypnosis in obstetrics and gynecology', in LE Fredericks & C Thomas (ed), *The use of hypnosis in surgery and anesthesiology: Psychological preparation for the patient*, WW Norton, Springfield, IL, pp. 163–211.

McRobert, GR 1972, 'Anesthesia by acupuncture', *Br Med J*, vol 3, no. 5824, p. 472.

Mehl-Madrona, LE 2004, 'Hypnosis to facilitate uncomplicated birth', *Am J Clin Hypn*, vol 46, no. 4, pp. 299–312.

Melzack R 1984, 'The myth of painless childbirth', *Pain*, vol 19, pp. 321–37.

Millar, K, Jelicic, M, Bonke, B & Asbury, AJ 1995, 'Assessment of preoperative anxiety: comparison of measures in patients awaiting surgery for breast cancer', *British Journal of Anaesthesia*, vol 74, pp. 180–83.

Montgomery, GH, David, D, Winkel, G, Silverstein, JH & Bovbjerg, DH 2002, 'The effectiveness of adjunctive hypnosis with surgical patients: a meta-analysis', *Anesth Analg*, vol 94, no. 6, pp. 1639–45.

Montgomery, GH, DuHamel, KN & Redd, WH 2000, 'A meta-analysis of hypnotically induced analgesia: how effective is hypnosis?' *Int J Clin Exp Hypn*, vol 48, no. 2, pp. 138–53.

Morgan, BM, Bulpitt, CJ, Clifton, P & Lewis, PJ 1982, 'Analgesia and satisfaction in childbirth (the Queen Charlotte's 1000 Mother Survey)' *Lancet*, vol 2, no. 8302, pp. 808–10.

Mottershead, N 2006, 'Hypnosis: removing the labour from birth', *Pract Midwife*, vol 9, no. 3, pp. 26–7, 29.

Mushin, W 1973, 'Foreward', in D Scott (ed), *Modern Hospital Hypnosis Especially for Anaesthetists*, Lloyd-Luke, London, p. v.

Nash, M, & Barnier, A 2008, 'Introduction: a roadmap for explanation, a working definition', in MR Nash & AJ Barnier (eds), *The Oxford handbook of hypnosis*, Oxford University Press, New York, pp. 1–18.

Nash, M 2001, 'The truth and the hype of hypnosis', *Scientific American*, 2001, no. 7, pp. 47–53.

Piccione, C, Hilgard, ER & Zimbardo, PG 1989, 'On the degree of stability of measured hypnotizability over a 25-Year period', *Journal of Personality and Social Psychology*, vol 56, no. 2, pp. 289–95.

Pirotta, MV, Cohen, MM, Kotsirilos, V & Farish, SJ 2000, 'Complementary therapies: have they become accepted in general practice?' *Med J Aust*, vol 172, no. 3, pp. 105–9.

Ploghaus, A, Becerra, L, Borras, C & Borsook, D 2003, 'Neural circuitry underlying pain modulation: expectation, hypnosis, placebo', *Trends Cogn Sci*, vol 7, no. 5, pp. 197–200.

Pope, S, Watts, J, Evans, S, McDonald, S & Henderson, J 2000, 'Postnatal depression: A systematic review of published scientific literature to 1999', NH&MRC document, Australian Government, Canberra, p. 127.

Rainville, P, Bao, QV & Chretien, P 2005, 'Pain-related emotions modulate experimental pain perception and autonomic responses', *Pain*, vol 118, no. 3, pp. 306–18.

Reilly, D 1983, 'Young doctors' views on alternative medicine', *Brit Med J*, vol 287, pp. 337–39.

Review Manager 2003, [RevMan 4.2 for Windows program], The Cochrane Collaboration, Copenhagen.

Richardson, J, Smith, JE, McCall, G & Pilkington, K 2006. 'Hypnosis for procedure-related pain and distress in pediatric cancer patients: a systematic review of effectiveness and methodology related to hypnosis interventions', *J Pain Symptom Manage*, vol 31, no. 1, pp. 70–84.

Robertson, D 2009, 'De l'hypnotisme' (1860) ['On hypnotism'], *Int J Clin Exp Hypn*, vol 57, no. 2, pp. 133–61.

Robin, A 1962, 'The psychological changes of normal parturition', *Psychiatric Quarterly*, vol 36, no. 1, pp. 129–50.

Rock, NL, Shipley, TE & Campbell, C 1969, 'Hypnosis with untrained, nonvolunteer patients in labor', *Int J Clin Exp Hypn*, vol 17, no. 1, pp. 25–36.

Saadat, H, Drummond-Lewis, J, Maranets, I, Kaplan, D, Saadat, A, Wang, SM, Kain ZN. 2006, 'Hypnosis reduces preoperative anxiety in adult patients', *Anesth Analg*, vol 102, no. 5, pp. 1394–6.

Schulz-Stubner, S 1996, [‘Hypnosis--a side effect-free alternative to medical sedation in regional anesthesia’], *Anaesthesist*, vol 45, no. 10, pp. 965–9.

Schulz-Stubner, S 2000, ‘Clinical hypnosis and anesthesia: an historical review and its clinical implications in today's practice’, *Bull Anesth Hist*, vol 18, no. 1, pp. 1, 4–5.

Schulz-Stubner, S 2002, ‘Clinical hypnosis instead of drug-based sedation for procedures under regional anesthesia’, *Reg Anesth Pain Med*, vol 27, no. 6, pp. 622–3.

Scott, D 1983, ‘Anaesthetists' attitudes to hypnotherapy’, *Anaesthesia*, vol 38, no. 7, pp. 699–700.

Scott, D 1974, ‘Clinical uses of hypnosis in anaesthesia’, *Modern hospital hypnosis especially for anaesthetists*, Lloyd-Luke, London, 93–100.

Shapiro, A, Fredman, B & Zohar, E 1998 ‘Delivery room analgesia: An analysis of maternal satisfaction’, *Int J Obstet Anesth*, vol 7, pp. 226–30.

Shor, RE & Orne EC 1962. Harvard Group Scale of Hypnotic Susceptibility: Form A. Palo Alto, California, USA, Consulting Psychologists Press.

Smith, CA, Collins, CT, Cyna, AM & Crowther, CA 2006, ‘Complementary and alternative therapies for pain management in labour’, *Cochrane Database Syst Rev,* 2006, no. 4, Art. No. CD003521.

Snow, JS (ed) 2008, *Blessed days of Anaesthesia,* Oxford University Press, Oxford, UK.

Spiegel, D 2008, Intelligent design or designed intelligence? hypnotizability as neurological adaptation. In: Barnier, AJ, Nash, MR, (eds). *The Oxford Handbook of Hypnosis*. Oxford University Press, Oxford, pp. 179–99.

Spiegel, H & Greenleaf, M 1963, ‘Current perspectives on hypnosis in obstetrics’, *NY St J Med*, vol 63, pp. 2933–41.

Spielberger, CD, Gorsuch, RL, Lushene, RE, Vagg, PR, Jacobs GA 1983, *Manual for the State-Trait Anxiety Inventory*, Consulting Psychologists Press, Palo Alto, CA.

Spielberger, CD, 2004, *Stait Trait Anxiety Inventory*. Redwood, California: Mind Garden, 1690 Woodside Rd Suite 202,

Teissèdre, F & Chabrol, H 2004. Detecting women at risk for postnatal depression using the Edinburgh Postnatal Depression Scale at 2 to 3 days postpartum. *Can J Psychiatry*, vol 49, no. 1, pp. 51-4.

Tiba, J 1990, 'Clinical, research and organisational aspects of preparation for childbirth and the psychological diminution of pain during labour and delivery', *British Journal of Experimental and Clinical Hypnosis*, vol 7, no. 1, pp. 61–64.

Van Der Does, AJ, Van Dyck, R, Spinhoven, P & Kloosman, A 1989, 'The effectiveness of standardized versus individualized hypnotic suggestions: a brief communication', *Int J Clin Exp Hypn*, vol 37, no. 1, pp. 1–5.

Vickers, AJ & Cassileth, BR 2001, 'Unconventional therapies for cancer and cancer-related symptoms', *Lancet Oncol*, vol 2, no. 4, pp. 226–32.Fuge, C 1986, 'Bedford Square. A connection with mesmerism', *Anaesthesia* vol 41, pp. 726–30.

Vickers, A, & Zolman, C 1999, 'Hypnosis and relaxation therapies', *BMJ*, vol 319, pp. 1346–49.

Wainer, N 2000, 'HypnoBirthing. A radical change on our perspective of pain in childbirth', *Midwifery Today Int Midwife*, 2000, no. 55, pp. 36–8.

Warner, R, Appleby, L, Whitton, A & Faraghen, B 1996, 'Demographic and obstetric risk factors for postnatal psychiatric morbidity', *British Journal of Psychiatry*, vol 168, pp. 607–611.

Waxman, D 1990, 'Management of antenatal hypnotic training', in D Corydon Hammond (ed), *Handbook of hypnotic suggestions and metaphors*, WW Norton, London, 279–81.

Weeks, S 1999, 'Postpartum headache', in DH Chestnut (ed), *Obstetric anaesthesia*, Mosby, St. Louis, pp. 621–38.

Weir, EC 2000, 'The sharp end of the dural puncture', *BMJ*, vol 320, pp. 127.

Werner, WEF, Schauble, PG & Knudsen, MS 1982, 'An argument for the revival of hypnosis in obstetrics', *Am J Clin Hypn*, vol 24, no. 3, pp. 149–71.

Whitehead, J 1992, *The design and analysis of sequential clinical trials*, 2nd edn, John Wiley and Sons, Chichester, UK.

Woody, E & Sadler, P 2005, 'Some polite applause for the 2003 APA Division 30 definition of hypnosis', *Am J Clin Hypn*, vol 48, no. 2–3, pp. 99–106.

Yapko, MD 1990, *Trancework: an introduction to the practice of clinical hypnosis*, Bruner/Mazel, Florence, KY.

Yapko, MD (ed) 1992, *Hypnosis And The Treatment Of Depression: Strategies For Change*, Bruner/Mazel, Florence, KY.

Yapko, M 2001, ‘Hypnosis in treating symptoms and risk factors of major depression’, *Am J Clin Hypn*, vol 44, no. 2, pp. 97–108.

Zeltzer, L & LeBaron, S 1982, ‘Hypnosis and nonhypnotic techniques for reduction of pain and anxiety during painful procedures in children and adolescents with cancer’, *J Pediatr*, vol 101, no. 6, pp. 1032–5.

Publications related to the HATCh Trial

1. Alexander, B, Turnbull, D, & Cyna AM 2009, 'The effect of pregnancy on hypnotizability.' *Am J Clin Hypn*. Vol 52, no. 1, pp. 13-22.
2. Cyna AM, Andrew MI & Whittle (2008). 'Hypnosis Antenatal Training for Childbirth (HATCh): Intervention Script 3. '*Aus J Clin Exp Hypn*' vol 36, no. 1, pp. 80-86.
3. Cyna AM, Andrew MI, et al. (2007). 'Hypnosis Antenatal Training for Childbirth (HATCh): Intervention scripts 1 and 4. *Aus J Clin Exp Hypn* vol 35, pp. 83-94.
4. Cyna, AM, Andrew, MI, Robinson, JS, Crowther, CA, Baghurst, P, Turnbull, D, Wicks, G, & Whittle C 2006. Hypnosis Antenatal Training for Childbirth (HATCh): a randomised controlled trial [NCT00282204]. *BMC Pregnancy Childbirth*. Vol 5, no. 6 pp. 5.
5. Cyna, AM, Andrew, MI & McAuliffe, GL 2006. Antenatal self-hypnosis for labour and childbirth: a pilot study. *Anaesth Int Care*. Vol 34, no. 4, pp. 464-9.
6. Cyna, AM, & Andrew, MI 2006. "Antenatal self-hypnosis for labour and childbirth: a pilot study." *Anaesth Intensive Care* vol 34, no. 4, pp. 464-69.
7. Cyna, AM, Andrew, MI & Whittle, C 2005. "Antenatal hypnosis for labour analgesia.' *Int J Obstet Anesth,* vol 14, no. 4, pp. 365-6.
8. Cyna, AM, McAuliffe, GL & Andrew, MI 2004. "Hypnosis for pain relief in labour and childbirth: a systematic review." *Br. J. Anaesth*. Vol 93, no. 4, pp. 505-11.

Publication indirectly related to this research

1. Cyna, AM & Dodd, J (2007). 'Clinical update: obstetric anaesthesia.' *Lancet* vol 370, no. 9588, pp. 640-2.

Presentations at national and international meetings related to the HATCh Trial

- New Zealand Society of Hypnosis ASM, Wellington
- ASA Melbourne October 1–5, 2010, "Preliminary findings of the HATCh Trial"
- Australian Society of Hypnosis ASM Keynote speaker HATCh presentation Sydney, September 22, 2010
- New Zealand Society of Hypnosis Keynote, Wellington, New Zealand, 16–17, October 2010
- Side studies of the HATCh Trial
    - Knowledge and attitudes of pregnant women regarding the use of hypnosis in childbirth oral presentation by Dr. Irina Hollington and as an abstract at ANZCA ASM, May 2–6, 2009, Cairns
    - The effect of pregnancy on hypnotisability
        - Presented by Dr. AM Cyna at ASA Wellington, New Zealand
        - Thesis for Ms. Beth Alexander for Master's Psychology thesis under supervision of Dr. AM Cyna and Prof. D Turnbull, University of Adelaide
        - Prize paper 2009, Am J Clin Hyn Exp
    - The relationship between anxiety and hypnotisability in late pregnancy. Thesis for Ms. Divya Nair for Master's Psychology thesis under supervision of Dr. AM Cyna and Ms. S Blunden at the University of South Australia

International collaborations

- HATCh Denmark
- HATCh UK