A RANDOMIZED CONTROLLED TRIAL OF THE EFFECTS OF
GUIDED IMAGERY ON BLOOD PRESSURE
IN HYPERTENSIVE PREGNANT WOMEN

By

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A thesis in conformity with the requirements
for the degree of Doctor of Philosophy
Graduate Department of Nursing Science
University of Toronto

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Abstract
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Hypertension occurs in nearly 10% of pregnancies, and is associated with infant and maternal morbidity and mortality. Prior studies of non-pregnant adults have demonstrated the effectiveness of a variety of relaxation therapies in reducing blood pressure. A pilot randomized controlled trial was conducted, the purposes of which were 1) to provide preliminary evidence regarding the usefulness of guided imagery (GI) in reducing blood pressure in hypertensive pregnant women, and 2) to answer feasibility questions for a larger trial.

Pregnant women with hypertension prior to 37 weeks gestation (n = 69) were randomized to either 15-minute periods of guided imagery (n = 34), or of quiet rest (QR) (n = 35), twice daily for four weeks or until delivery, whichever came first. Daytime ambulatory mean arterial pressure (MAP), systolic and diastolic blood pressures, anxiety, rest and GI use were measured weekly, to a maximum of four weeks. Sixty women completed at least one week in the study; 46.4% completed four weeks. Compliance was excellent.

Intention to treat analysis was used. In the unadjusted analysis, women allocated to GI had significantly lower average daytime ambulatory mean MAP elevations from baseline to their
last week of study participation than women allocated to quiet rest (GI: M = 1.58 mmHg, SD = 7.63; QR: M = 5.93 mmHg, SD = 6.55; t = 2.36, p = .02). However, the effect was no longer statistically significant (p = 0.14) when adjusted for baseline mean arterial pressure and gestation. There was no statistically significant difference in the numbers of women who were prescribed antihypertensive medication after randomization (GI: n = 16, QR: n = 13, X^2 = 0.74, p = .46). There was also no evidence of an effect of guided imagery on anxiety.

Nearly 90% (n = 26) of the guided imagery group indicated they would use it again, either in a subsequent pregnancy or during stressful life events. Given the ease of use, low cost, acceptability to women, and lack of risk of guided imagery, an adequately-powered randomized controlled trial is warranted.
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CHAPTER 1: INTRODUCTION AND PROBLEM STATEMENT

Hypertensive disorders occur in approximately ten percent of all pregnancies, and are identified as a significant health issue (World Health Organization, 1988). Hypertension in pregnancy is associated with fetal/infant morbidity and mortality and is a leading cause of maternal death in Canada (Health Canada, 2000).

Although hypertensive disorders in pregnancy have different etiologies, with diagnosis either predating or occurring during the pregnancy, clinical management tends to be similar and related to type and/or worsening of symptoms, and time of onset. Measures such as exercise programs, salt intake reduction, and weight loss, used outside of pregnancy to reduce hypertension (Campbell et al., 1999), are not recommended in hypertensive pregnancy, due to inadequate evidence of their benefit for this population group. Current recommendations for clinical management of hypertension in pregnancy are limited: careful assessment of maternal blood pressure and blood values, fetal growth and other indicators of wellbeing, increased maternal rest, along with hospitalization and /or medication as warranted (Moutquin et al., 1997).

Most of the maternal health risk is related to severe hypertension (Botting, 2001; Magee, 2001). Therefore, lowering of severe maternal hypertension is recommended (Botting, 2001). However, for mild to moderate hypertension, the effectiveness of antihypertensive drug therapy in limiting poor perinatal outcomes is unclear (Abalos, Duley, Steyn, & Henderson-Smart, 2001; Magee, 2001). Although antihypertensive medication use has been associated with decreased severe maternal hypertension, fewer prenatal admissions to hospital, and fewer instances of respiratory distress syndrome in the newborn, these medications have also been associated with small-for-gestational-age (SGA) infants (Abalos et al., 2001; Magee, Ornstein, & von Dadelszen, 1999; von Dadelszen & Magee, 2002; von Dadelszen et al., 2000). Magee (2001)
has described a “continuum of risk” in which perinatal mortality and intrauterine growth restriction increases incrementally with increases in maternal blood pressure. However, as there are concerns about potential fetal risks in association with antihypertensive medication use, pharmacological approaches to management of hypertension in pregnancy may not be desirable. Therefore, other less potentially harmful approaches to blood pressure reduction have appeal, either alone, or in combination with pharmacological management of hypertension in pregnancy.

Women with pregnancy complications, including hypertension, tend to have higher anxiety than women during healthy pregnancies (Da Costa, Larouche, Dritsa, & Brender, 1999; Hatmaker & Kemp, 1998; Heaman, 1998). Associations between stress and significant blood pressure elevations are documented in both normotensive and hypertensive pregnancies (Nisell, Hjemdahl, Linde, Beskow, & Lunell, 1986; Nisell, Hjemdahl, Linde, & Nunell, 1985; Nisell & Nunell, 1985), as well as outside of pregnancy (Habib, Gold, & Chrousos, 2001). The pathology of either pre-eclampsia, primary hypertension or both, can diminish utero-placental perfusion, and anxiety may result in further vasoconstriction and maternal blood pressure elevation (White & Porth, 2000), thereby exacerbating perfusion problems. Both release of catecholamines and vasoconstriction can restrict oxygen and nutrients to the fetus (Copper et al., 1996), and there is evidence that fetal exposure to high levels of stress hormones may contribute to low birth weight babies and preterm birth (Challis, Matthews, Gibb, & Lye, 2000; Sandman et al., 1994; Wadwha, Dunkel-Schetter, Chicz-DeMet, Porto., & Sandman, 1996). Therefore, interventions to lower blood pressure through decreases in stress responses in the pregnant hypertensive woman could be a valuable addition to the repertoire of clinical management strategies for these women.

Psychophysiologic (mind-body) methods of blood pressure management are appealing because they may reduce the need for medication and thus incidence of unpleasant and harmful side effects, are simple to use, are often low-cost, and have other benefits such as decreasing
anxiety (Schwartz, 1995). Psychophysiologic techniques are theorized to reduce maternal blood pressure through direct and indirect pathways by reduction of sympathetic nervous system activation and/or enhancement of parasympathetic nervous system responses. Although psychophysiologic interventions would not address the underlying etiology of hypertensive disorders in pregnancy, they do appear to impact neural pathways (Freeman, 2001), and may reduce the sympathetic nervous system overactivity reported to occur in pregnancy hypertension (Greenwood, Scott, Stoker, Walker, & Mary, 2001; Sander, Hansen, & Sander, 1995; Schobel, Fischer, & Heuszer, 1996), possibly resulting in more normal maternal blood pressures.

Psychophysiological therapies such as biofeedback (Yucha et al., 2001), meditation (Infante, Peran, Martinez, & Roldan, 1998; Infante, Torres-Avisbal, Pinel, & Vallejo, 2001), and guided imagery (Crowther, 1983; Young, 1999) have been used successfully in reducing blood pressure in non-pregnant adults, although the study of guided imagery as a single therapy has been quite limited (Manyande et al., 1995; Salmore & Nelson, 2000; Young, 1999). Many psychophysiologic therapies require considerable practice by the patient, and/or the expertise of a skilled technician, and since use in pregnancy precludes a long, involved technique, the simple and inexpensive strategy of guided imagery provides a reasonable therapy to test for effectiveness in reducing blood pressure levels in hypertensive pregnancy. Guided imagery (GI), in which an individual is guided to form mental images to accomplish a therapeutic goal (Bazzo & Moeller, 1999; Johnsen & Lutgendorf, 2001), can elicit both psychological and physiologic relaxation (Achterberg, 1985; Baider, Peretz, Hadani, & Koch, 2001; Baider, Uziely, & De-nour, 1994; Butcher & Parker, 1988; Esplen, Garfinkel, Olmstead, Gallop, & Kennedy, 1998; Hammer, 1996; McCaffery, 1990; Sheikh, Kunzendorf, Sheikh, & Baer, 2002).
Medline and PsycInfo database searches for 1975 to 2004 revealed only two published evaluations of psychophysiologic therapies for pregnancy hypertension. The first reported study of primiparous and multiparous women with elevated blood pressure (n = 60) compared six weekly sessions of relaxation training alone, with six weekly sessions of relaxation training combined with biofeedback, and a control of routine care (Little et al., 1984). Both intervention groups also were asked to undertake daily home practice, using audiotaped relaxation instructions. The means of all diastolic and systolic blood pressures in the last month of pregnancy were found to be lower for each intervention group than the control group, but only the single relaxation-therapy group showed a statistically significant difference in systolic blood pressure values (M for study readings = 118.0 mmHg vs. 125.9 mmHg, p < .05; M = for clinical readings = 128.7 mmHg vs. 134.5 mmHg, p < 0.05). Routine prenatal diastolic blood pressure readings, but not diastolic blood pressure readings done as part of the research protocol, were significantly different between relaxation training and control groups (84.0 mmHg vs. 88.5 mmHg, p < 0.05). Generalizability of findings is limited due to sequential, rather than randomized allocation to groups (Little et al., 1984).

The second study used randomization to allocate 50 women between 30 and 36 weeks gestation with pregnancy-induced hypertension to twice-daily biofeedback plus relaxation with guided imagery and self-monitoring of blood pressure, an educational intervention to enhance compliance with bed rest, or to bed rest (usual care). Mean arterial pressure measured at the last prenatal visit before delivery was significantly lower in the relaxation group than in the education and control groups (F 2, 42 = 9.30, p < .001). Six of 15 women in the experimental group had post-intervention mean arterial blood pressure < 95 mmHg, compared with only one in each of the other groups. (Somers, Gevirtz, Jasin, & Chin, 1989).
The evidence that psychophysiological therapy may reduce blood pressure, the current lack of useful clinical approaches to the problem of hypertension in pregnancy, and concerns about antihypertensive medication all pointed to the need for a controlled evaluation of the effectiveness and feasibility of guided imagery for blood pressure management in hypertensive pregnant women.

The primary purpose of this pilot RCT was to provide preliminary indicators of the effects of guided imagery compared to a quiet rest intervention on a) blood pressure and b) anxiety. Additional objectives were: (1) to determine the appropriateness of measuring the primary outcome at four weeks by examining patterns of weekly daytime mean arterial pressure across the intervention period for both groups; (2) to provide an estimate of recruitment rates; (3) to assess compliance with allocated treatment; (4) to determine participants’ satisfaction with allocated treatment; and; (5) to determine the degree of relationship between standard prenatal measurements and average daytime ambulatory measurement of blood pressure during the study period.
CHAPTER 2: REVIEW OF LITERATURE

The following literature review has been organized into three general categories: physiology of blood pressure control; hypertension in pregnancy; and mind-body communication and psychophysiologic therapies, under which guided imagery as clinical intervention for blood pressure and anxiety is specifically addressed.

Physiology of Blood Pressure Control

Blood pressure is the product of cardiac output (CO) and peripheral vascular resistance (PVR), both influenced by a variety of factors (Kaplan, 2002), including when in pregnancy measurement occurs (Brown et al., 1998; Halligan et al., 1993; Hermida, Ayala, & Iglesias, 2001). Cardiac output is a function of heart contractility and heart rate, while vascular resistance relates to resistance to blood flow in the blood vessels. Depending on the etiology of the hypertension in pregnancy and how long it has been present, cardiac output or peripheral vascular resistance or both may be elevated (Beevers, Lip, & O'Brien, 2001; Bosio, McKenna, Conroy, & O’Herlihy, 1999).

The autonomic nervous system regulates blood flow by dilating or constricting blood vessels. Its sympathetic branch is responsible for innervation of the adrenal medulla and secretion of catecholamines into the circulation, as well as direct innervation of the heart and blood vessels (Kaplan, 2002). Blood vessels contain smooth muscle that regulates tone in vessel walls, influencing peripheral vascular resistance (Brocklesby, Kieran, & Baker, 1999). Thus the sympathetic nervous system can influence cardiovascular tissue directly, or alternately via catecholamine release (Guyton, 1991).

The parasympathetic system can enhance sympathetic nervous system activity by withdrawing and can antagonize it by increasing its own activity. It down-regulates blood pressure through baroreflexes via the vagus nerve (Guyton, 1991). When BP increases, vascular...
signals stimulate the vasomotor centre of the brain and trigger parasympathetic activation and sympathetic inhibition, slowing the heart rate, slightly reducing heart contractility, and signaling blood vessel walls to relax. These effects decrease cardiac output, and to a lesser extent, vascular resistance (Guyton, 1991), thus reducing blood pressure (Kaplan, 1998a). The vasomotor centre can also be influenced from other parts of the nervous system, particularly the limbic cortex, via the hypothalamus (Guyton, 1991).

Chemicals produced by the endothelial lining of blood vessels also help regulate blood pressure. Nitric oxide (NOS), for example, plays a role in dilating blood vessels and has both vascular and neural signaling capacities (De Swiet, 1998). When the vascular endothelial lining is damaged as in pre-eclampsia or chronic hypertension, endothelial relaxing factors such as NOS may be decreased and blood vessels become less able to relax (Kaplan, 1998a), further increasing blood pressure. Acute rises in BP can also damage endothelial function, potentially adding to BP elevations (Millgard & Lind, 1998).

In addition to maintaining blood pressure, the autonomic nervous system plays an important role in stress responses and in relation to physical exercise. Both the endocrine hypothalamic-pituitary-adrenal (HPA) axis and autonomic sympato-adrenal-medullary (SAM) system serve as pathways through which the brain influences body systems in response to physiological or psychological stressor stimuli. The hypothalamus stimulates the anterior pituitary to produce adrenocorticotropic hormone (ACTH), in turn stimulating the adrenal cortex to secrete stress hormones, including cortisol (Habib et al., 2001). The sympathetic branch can stimulate the adrenal medulla to secrete epinephrine, constricting blood vessels, limiting blood flow and elevating blood pressure, in a more sustained and more significant way than a limited fight or flight response (Kaplan, 1998a).
Hypertension in Pregnancy

Hypertension is generally defined as blood pressure greater than or equal to (≥) 140/90 mm Hg, using mercury sphygmomanometry and with diastolic pressure based on Korotkoff phase V sounds (Canadian Hypertension Education Program, 2003; World Health Organization-International Society of Hypertension [WHO-ISH], 1999). The presence of hypertension in pregnancy may be due to one or more conditions: pre-eclampsia/eclampsia, gestational hypertension, chronic hypertension, or pre-eclampsia superimposed on pre-existing chronic hypertension. Historically, research has been complicated by inconsistent definitions and categorizations of pregnancy hypertension. Standardization of classifications has been endorsed and use of internationally-accepted definitions encouraged by the International Society for the Study of Hypertension in Pregnancy (ISSHP) (Brown, Lindheimer, de Swiet, Van Assche, & Moutquin, 2001; Davey & MacGillivray, 1988). Acute blood pressure elevation may also occur in relation to cardiovascular reactivity or stress response, some of which is known as white-coat hypertension. Although blood pressure alone, at least via conventional means, is not a strong predictor of adverse pregnancy outcomes (Zhang, Klebanoff, & Roberts, 2001), it is still the most common sign clinicians use to monitor hypertensive pregnancy and is relied on as a surrogate clinical marker (Shennan & Halligan, 1999).

The extent to which the two branches of the autonomic nervous system play a role in hypertensive pregnancy is not clear. Early research of sympathetic nervous system activity in pre-eclampsia, using indirect measures such as catecholamine levels and hemodynamic changes, found conflicting results. It has since been demonstrated, with more rigorous research designs and direct microelectrode measures of sympathetic nerve output, that women with pregnancy hypertension have significantly higher peripheral sympathetic output than normotensive pregnant women (Greenwood et al., 2001; Sander et al., 1995; Schobel et al., 1996). A recent
study found similar peripheral sympathetic output levels in both pre-eclampsia and non-proteinuric gestational hypertension, suggesting that both these hypertensive entities may be similar, or one a precursor of the other, or that there was insufficient statistical power to discern differences (Greenwood, Scott, Walker, Stoker, & Mary, 2003). In pregnancy, parasympathetic responsiveness appears significantly lower than in non-pregnant women (Ekholm et al., 1992; Ekholm, Piha, Erkkola, & Antila, 1994; Molino et al., 1999; Silver, Tahvanainen, Kuusela, & Eckberg, 2001), and lower still in pre-eclampsia (Ekholm, Piha, Tahvanainen, Antila, & Erkkola, 1994; Eneroth-Grimfors, Westgren, Ericson, Ihrman-Sandahl, & Lindblad, 1994; Greenwood et al., 2003; Molino et al., 1999; Silver et al., 2001; Wasserstrum et al., 1989; Yang, Chao, Kuo, Yin, & Chen, 2000) and in gestational hypertension (Greenwood et al., 2003; Silver et al., 2001). However, discrepant findings of increases in both sympathetic and parasympathetic neural control in pre-eclampsia have been reported (Ekholm, Tahvanainen, & Metsala, 1997). Increased sympathetic nervous system activation and decreased vagal activity in chronic hypertension are also observed (Grassi, 1998).

**Pre-eclampsia /Eclampsia**

Pre-eclampsia is a multi-system disorder, characterized by abnormal vasoconstriction of maternal blood vessels and increased peripheral vascular resistance, leading to reduced organ perfusion, increased blood pressure, and proteinuria (Dekker & Sibai, 2001; Khalil & Granger, 2002); it may be mild to severe in character, and can result in such negative sequelae as hypertensive crisis, abruptio placentae, intravascular disseminated coagulopathy, liver or renal failure, cerebrovascular hemorrhage, coma and/ or eclampsia (seizures). Prevalence rates are reported as between 7% to 10%, with maternal mortality rates three times higher and perinatal mortality five times greater than in the general pregnant population (Witlin & Sibai, 2001).

Mechanisms of pre-eclampsia are not clearly understood (Dekker & Sibai, 2001; Khalil
& Granger, 2002). The etiology appears to be related to abnormal implantation of the placenta; normal invasion of trophoblastic placental cells into uterine spiral arteries early in placental development does not appear to occur to the same extent in women who later develop symptoms of pre-eclampsia (Cross, 2002). Maternal vascular endothelium cells appear to be activated or dysfunctional (Dekker & Sibai, 1998), vasodilators such as prostacyclin and nitric oxide appear to be lower than in healthy pregnancy (Granger, Alexander, Llinas, Bennett, & Kalil, 2002), and blood vessel relaxation is altered (Friedman, Lubarsky, Ahokas, Nova, & Sibai, 1995; Gillham, Kenny, & Baker, 2003).

The effectiveness of a number of potential preventive agents for pre-eclampsia has been investigated. Systematic reviews of clinical trials with at-risk pregnant women have concluded that: calcium supplementation slightly reduced occurrences of pre-eclampsia, but did not improve perinatal outcomes (Hofmeyr, Atallah, & Duley, 2003); maternal fish oil ingestion was associated with reductions in rates of pre-eclampsia, hypertension and preterm birth, but there is insufficient evidence to determine any decrease in perinatal mortality or morbidity (Enkin et al., 2000); and data are insufficient to determine whether salt has any effect (Duley & Henderson-Smart, 2003). A meta-analysis of 42 clinical trials of antiplatelet agents such as aspirin indicated a reduction in pre-eclampsia risk by 15% (relative risk (RR) = 0.85, 95% confidence interval (CI) 0.78 - 0.92), preterm birth 8% (RR = 0.92, 95% CI 0.82 - 0.97), and perinatal death by 14% (RR = 0.86, 95% CI 0.75 - 0.98), but with no difference in frequency of small for gestational age babies (RR = 0.92, 95% CI 0.84 - 1.01) (Knight, Duley, Henderson-Smart, & King, 2000). Aspirin dose, gestational age and study criteria varied widely between studies. However, a more recent double-blinded RCT of 560 pregnant women at risk of pre-eclampsia on the basis of impaired uterine arterial blood flow found no significant differences in pre-eclampsia rates between 150 mg aspirin daily from 22-24 weeks to 36 weeks of gestation and placebo (18% vs.
Early study reports of vitamins C and E for pre-eclampsia prevention suggest reductions in endothelial cell activation, measures of oxidative stress and placental function, and incidence of pre-eclampsia (Chappell et al., 1999; Chappell et al., 2002). Pre-eclampsia is cured only by birth of the baby and placenta, and timing of delivery is often based on balancing what is optimal for the mother’s health with what is optimal for fetal health.

**Gestational Hypertension**

Gestational hypertension is the presence of hypertension in pregnancy without proteinuria, and occurs in 5% to 6% of pregnancies (Saftlas, Olson, Franks, Atrash, & Pokras, 1990). It may be a precursor to proteinuric pre-eclampsia, indicative of previously undiagnosed chronic hypertension, or it may be a separate disorder (Greenwood et al., 2003). While the prevailing belief had been that women with non-proteinuric pregnancy hypertension had perinatal outcomes similar to those of normotensive women (Page & Christianson, 1976), recent reports found women with gestational hypertension were more likely to have small-for-gestational-age infants and significantly higher rates of preterm delivery (Allen, Joseph, Murphy, Magee, & Ohlsson, 2002; Buchbinder, Sibai, Caritis, & MacPherson, 2002).

**Chronic Hypertension**

Chronic hypertension occurs more frequently with advancing age (Burt et al., 1995; Witlin & Sibai, 2001), and can be classified as hypertension secondary to other known causes or conditions, or as primary (essential) hypertension with no known cause. Primary hypertension accounts for 90% of chronic hypertension in pregnancy, while the remainder (10%) is secondary to underlying physiologic disorders such as renal disease (ACOG, 2001; National High Blood Pressure Education Program Working Group on High Blood Pressure in Pregnancy (NHBPEP),
Between 1991 and 2000, the Canadian birth rate among women 35 to 39 years increased from 25.6 live births per 1000 women to 30.6 per 1000, and from 3.5 per 1000 to 5.1 per 1000 women between 40 to 44 years of age (Canadian Perinatal Health Report, 2003). Meanwhile, survey data indicate that in 1998-1999, the prevalence of hypertension in Canadian women (all age groups) was 12.7%, while Nova Scotia had 20.9%, with rates in 2000-2001 at 13.9% for Canadian females and 17.9% of Nova Scotian females (Statistics Canada, 2003). The rate of pregnant women with pre-existing hypertension in 2000 in Nova Scotia was approximately 5% (Atlee Database, March 5, 2003). Collectively, these data point to chronic hypertension becoming a greater health problem in pregnant women. Chronic hypertension in pregnancy is associated with higher risk of preterm birth, low birth weight, and perinatal deaths (Allen et al., 2002; Ananth, Peedicayil, & Savitz, 1995; Rey & Couturier, 1994; Sibai et al., 1998). As many as 20% of pregnant women with chronic hypertension develop super-imposed pre-eclampsia (Sibai et al., 1998). Despite earlier reports indicating that women with chronic hypertension without superimposed pre-eclampsia had pregnancy outcomes similar to those in the general population (Rey & Couturier, 1994; Sibai, Abdella, & Anderson, 1983; Sibai, Mabie, Shamsa, Villar, & Anderson, 1990), recent cohort study findings contradict this (Allen et al., 2002; Haelterman, Breart, Paris-Llado, Dramaix, & Tchobroutsky, 1997), reporting significantly increased risk of small-for-gestational age infants (RR = 1.4, 95% CI 1.1-1.6), and stillbirth (RR 2.4, 95% CI 1.2-5.1) (Allen et al., 2002).

Blood Pressure Elevation in Pregnancy and Maternal Stress

Several studies have found that healthy primigravid pregnant women have significantly increased diastolic and systolic blood pressure and heart rate in response to standard laboratory cognitive stressors (Matthews & Rodin, 1992; McCubbin et al., 1996; Nisell et al., 1985; Shulte, Weisner, & Allolio, 1990), although to a lesser degree than when non-pregnant (Matthews &
Rodin, 1992). Daily emotional stress (Smith, Miller, & Rayburn, 2000) and work outside the home (Higgins, Walshe, Conroy, & Darling, 2002; Walker, Permezel, Brennecke, Ugoni, & Higgins, 2001) have also been demonstrated to significantly increase maternal ambulatory blood pressure in pregnancy outside laboratory settings. Pregnant hypertensive women, when compared with normotensive pregnant women, have been found to have higher blood pressure response to isometric handgrip and cold pressor tests (Nisell et al., 1985), while no significant BP differences were found in response to a standardized mental stressor (Nisell et al., 1986). However, mean response of the hypertension group was a systolic change from 154 ± 6 to 175 ± 7 mmHg and a diastolic change from 94 ± 3 to 106 ± 5 mmHg (Nisell et al., 1986), suggesting that stress in pregnancy elevates maternal blood pressure when it is already high due to pathological processes.

“White coat hypertension” was initially documented by Mancia and colleagues (1983) as a short-term rise in blood pressure in association with a physician or nurse approaching a patient and placing a blood pressure cuff on the patient’s arm. More recently, white coat hypertension is considered to exist when a person’s blood pressure is above normal in a clinic, but within normal range with ambulatory blood pressure monitoring (Bellomo et al., 1999; Brown, Robinson, & Jones, 1999; Pickering et al., 1988). Prevalence of white coat hypertension reported for late pregnancy varies from 3.2% for systolic and 4.2% for diastolic blood pressure (Brown et al., 1999) to 29% based on both systolic and diastolic pressures (Bellomo et al., 1999), as compared with 7.1% to 12% in the general population (Julius et al., 1990; Sega et al., 2001), and as high as 12.1% to 53.2% in hypertensive samples (Martinez et al., 1999; Verdecchia, Schillaci, Boldrini, Zampi, & Porcellati, 1992). A review of white-coat hypertension literature (Tsai, 2002) concluded that white coat hypertension in the general population has been associated with cardiovascular morbidity in some studies, and not in others. There is insufficient evidence on
which to draw conclusions about effects of white coat hypertension on mothers and unborn and newborn babies (Shennan & Halligan, 1999).

Women who are judged to have high-risk pregnancy report more stress and anxiety than do women with a low-risk pregnancy (Da Costa et al., 1999; Heaman, 1998; Leeners, Neumaier, Kuse, Bonzel, & Rath, 2002; Yali & Lobel, 1999). A combination of stressors, including the complication itself, heightened vigilance, a high-risk label, uncertainty, and additional health monitoring and surveillance all may serve as stressors in their own right, and can potentially raise anxiety (Kemp & Page, 1986; Mercer & Ferketich, 1988; Reading, 1983). Release of catecholamines and maternal vasoconstriction resulting from physiologic arousal can restrict oxygen and nutrients to the fetus (Copper et al., 1996), while fetal exposure to high levels of stress hormones via the hypothalamic-pituitary-adrenal axis may contribute to low birth weight and preterm birth (Challis et al., 2000; Sandman et al., 1994; Wadwha et al., 1996). This is especially important to consider when vasoconstriction is already an issue.

Although stress has also been suggested as a possible risk factor for pre-eclampsia (Dekker & Sibai, 2001), and is supported by animal research findings (Takiuti, Kahhale, & Zugaib, 2002), empirical evidence of any such relationship in humans is limited. There are few reports of studies investigating relationships between stress and subsequent development of pre-eclampsia, and findings conflict. Nisell, Larsson and Wager (1989) calculated total life stress scores for 345 women in their first trimester and found no significant differences in subsequent development of pre-eclampsia. However, a very small sample size may have led to insufficient statistical power to discern differences in outcome, and a non-standard instrument with no reported psychometrics was used to collect life events data. A study of maternal salivary cortisol levels and anxiety in early pregnancy and pre-eclampsia failed to identify any significant correlation between State-Trait Anxiety Inventory (STAI) scores, pregnancy-specific stress and
cortisol at 17-18 and 27-28 weeks gestation, and subsequent development of pre-eclampsia (Sikkema et al., 2001), when nine women with pre-eclampsia were compared with matched controls. Statistical power was low due to small sample size. Also, although salivary cortisol is considered a reliable measure outside of pregnancy (Meulenberg & Hofman, 1990), and levels increase as gestation advances (Allolio et al., 1990), its ability to reliably measure maternal stress in pregnancy is yet to be determined.

On the other hand, a body of recent epidemiologic research suggests that stressors related to pregnant women’s employment are associated with development of pre-eclampsia. For example, a prospective cohort study of 717 women (Landsbergis & Hatch, 2000) showed positive associations between psychosocial work stress and pregnancy-induced hypertension. In another study, women who worked outside the home were significantly more likely to develop pre-eclampsia than those who didn’t (odds ratio (OR) 4.1, 95% CI 1.1–15.2, p = 0.03) (Higgins et al., 2002). Even when confounders were controlled, the association remained significant (odds ratio 5.5, 95% CI 1.1–27.8, p = 0.04). This observation is supported by an analysis of survey data from 1397 German women indicating that women with a hypertensive disorder in pregnancy were significantly more likely to report having experienced acute emotional distress than women who had normal pregnancies (24% versus 17.7%, p < 0.01) (Leeners et al., 2002), and by a Canadian case-control study which found that women exposed to high job strain were more likely to develop pre-eclampsia (OR 2.1, 95% CI 1.1–4.1) (Marcoux, Berube, Brisson, & Mondor, 1999). These findings are limited by retrospective data collection and varying instruments to measure psychosocial stress, but a prospective study of 633 women expecting their first babies has also found associations between anxiety measured at 10 to 17 gestational weeks and subsequent development of pre-eclampsia (OR 3.2; 95% CI 1.4, 7.4) (Kurki, Hiilesmaa, Raitasalo, Mattila, & Ylikorkala, 2000). The limited number of studies, methodology
problems and conflicting findings suggest that further study is required to adequately determine the extent of any relationship between psychosocial stress and development of pre-eclampsia.

Management of Hypertension in Pregnancy

Primary goals of hypertension management in pregnancy are maternal safety and newborn health (Leveno & Cunningham, 1999). Since most maternal and perinatal risk appears to be associated with severe, rather than mild to moderate hypertension, the purpose of medical management of mild to moderate pregnancy hypertension is to prevent or postpone severe hypertension (Enkin et al., 2000). Standard clinical management includes limited physical activity and close supervision by health care providers to identify changes that would warrant intervention by early delivery, but may be influenced by hypertension severity, gestational age of the fetus, and risk factors. Antihypertensive medication may be introduced, or increased if it is already part of clinical management (Moutquin et al., 1997).

Reduced Physical Activity, Bed Rest and Hospitalization

Reduction in maternal physical activity, including bed rest, has been intended to prevent or limit occurrence of severe hypertension and associated negative sequelae (Enkin et al., 2000), and/or enhance perfusion to the placenta and fetus (Sibai, 1996). In a nationwide survey, over one-quarter of Canadian obstetricians reported recommending bed rest for women with mild to moderate hypertension, while 61% advised these women to stop work (Caetano et al., 2002). However, systematic reviews conclude that insufficient evidence exists to support bed rest as being effective for pregnancy hypertension outcomes (Enkin et al., 2000), although blood pressure is elevated during physical activity in non-pregnancy (Guyton, 1991), and ambulation during healthy pregnancy has been associated with higher ambulatory blood pressure levels (Smith et al., 2000). Ambulatory blood pressure appears to be similar whether pregnant women
are at home or hospitalized (Walker et al., 2002), suggesting that location of prenatal care does not actually reduce blood pressure values, but hypertensive women may be hospitalized when disease is advancing or severe, to provide heightened maternal and fetal health surveillance (Cunningham, Gant, Leveno, et al., 2001).

**Anti-hypertensive Medication**

Antihypertensive medication is recommended for severe hypertension in pregnancy, if blood pressure is consistently equal to or greater than 170 mmHg systolic or greater than or equal to 110 mm Hg diastolic (Abalos, Duley, Steyn, & Henderson-Smart, 2001), as end organ damage such as cerebral hemorrhage is more likely when pressures reach these levels (Friedman, Lubarsky, & Lim, 2001). The lowest threshold of blood pressure at which benefit is conferred is controversial (Abalos et al., 2001), but mild to moderate hypertension in pregnancy (Rey, LeLorier, & Burgess, 1997) is widely treated in Canada with antihypertensive medication (Caetano et al., 2002).

All antihypertensive medication, for example, methyldopa and nifedipine, commonly used in pregnancy, modulates sympathetic nervous system activity in some way (de Champlain, 2001). Beta-blockers such as labetalol act by reducing cardiac output, but may not be ideal, as utero-placental perfusion is dependent on cardiac output (Enkin et al., 2000). Prenatal use of antihypertensive medications for mild to moderate chronic or late-onset hypertension in pregnancy has been associated with significant reductions in the rates of severe hypertension, use of additional antihypertensives, hospital admissions, proteinuria at delivery and respiratory distress syndrome (Abalos et al., 2001; Magee, Elran, Bull, Logan, & Koren, 2000; Magee et al., 1999). No significant differences have been found for super-imposed pre-eclampsia, preterm birth, or perinatal death (Abalos et al., 2001; Magee et al., 1999). Two systematic reviews found no differences in rates of small-for-gestational-age babies in mild to
moderately hypertensive pregnancies (Abalos et al., 2001; Magee et al., 1999), regardless of whether mothers received antihypertensive medication during pregnancy. A later analysis found a 10 mmHg reduction in mean arterial pressure (MAP) from oral antihypertensive to be associated with a 176 gram reduction in birth weight (slope 17.55, SD = 6.67, r² = 0.19, p = 0.031) (von Dadelszen & Magee, 2002).

The systematic reviews to date do not provide insights as to the period of time over which blood pressure reductions were accomplished. Also it is not known if the poorer fetal and neonatal outcomes seen in groups treated with medication (von Dadelszen & Magee, 2002; von Dadelszen et al., 2000) may result in part from the medication itself, excessive blood pressure reduction, or the condition being treated (Roberts, Pearson, Cutler, & Lindheimer, 2003; Sibai, 2002). Because a too rapid or dramatic BP drop may potentially exacerbate placental perfusion problems, maternal cerebral ischemia and renal function, no more than a 15 to 20% reduction of mean arterial blood pressure is recommended (Friedman et al., 2001; Sibai, 1996).

Mind-Body Communication, Psychophysiological Therapies, and Blood Pressure

Psychophysiological therapies, often referred to as biobehavioural or mind-body therapies, are psychological or cognitive methods used either alone or in some combination to alter and improve psychological and/or physiologic parameters (Barrows & Jacobs, 2002). Such therapies are based on relationships among thoughts, emotions, the physical body, and health (Jacobs, 2001; Straus, 2000).

One broad category of psychophysiological therapies includes techniques used to induce relaxation; in other words, to enhance feelings of calmness and reduce sympathetic nervous system arousal, resulting in relaxed musculature, lower respiration rate, pupil constriction,
decreased heart rate and/or blood pressure (Schwartz, 1995). Benson, Beary and Carol (1974) labelled this outcome as the relaxation response. This relaxation response can be elicited through use of (1) a mental stimulus such as a sound or image for focus, in addition to (2) redirection of attention to the technique if external distracting thoughts occur (Barrows & Jacobs, 2002). Comfortable positioning of the body and a quiet environment may be beneficial (Barrows & Jacobs, 2002; Benson et al., 1974), but not essential (Stefano, Fricchione, Slingsby, & Benson, 2001). A focus or awareness of calm, slow breathing is a common element of many of these techniques, and may itself play a role in leading to a relaxed state (Payne, 2000). As relaxation is both a physiological and psychological process (Baer, Hoffmann, & Sheikh, 2003), training can be accomplished using somatic techniques such as progressive muscle relaxation (PMR), involving purposeful relaxation of the muscles, and/or through cognitive approaches such as transcendental meditation, biofeedback, hypnosis, and imagery, or somatic and cognitive approaches combined, such as in yoga (Freeman, 2001; Schultz & Luthe, 1959). Simple suggestions for relaxation and calm (Leuner, 1977) may also be helpful.

Ascertaining the efficacy and effectiveness of mind-body techniques for specific health outcomes, including reduction of high blood pressure, has been difficult because of limited descriptions of actual techniques, and methodological issues such as selection bias, lack of controls, and inadequate power (Barrows & Jacobs, 2002). Therapies such as biofeedback (Yucha et al., 2001), meditation (Infante et al., 1998; Infante et al., 2001), and guided imagery (Crowther, 1983; Young, 1999) have been used successfully, singly and in combination with other psychological therapies, in reducing blood pressure in non-pregnant adults with hypertension. Meta-analyses of effectiveness of psychophysiological approaches such as biofeedback in reducing blood pressure in hypertensive individuals have also been reported. The first concluded that effectiveness of psychological therapies was only evident when compared
with no-treatment controls, but was not more useful than treatment controls such as mild
exercise (Eisenberg et al., 1993). Later, Devine and Reifschneider (1995a) suggested that firm
conclusions could not be drawn regarding effects on anxiety or on blood pressure, while another
reported a significant beneficial blood pressure effect (Linden & Chambers, 1994). Single and
multi-mode relaxation have been reported as equally effective in reducing systolic blood
pressure by 9 to 9.7 mmHg & diastolic blood pressure by 6.1 to 7.2 mmHg (Devine &
Reifschneider, 1995a), but a more recent systematic review conducted for the period 1966-1997
concluded that individualized multi-component combinations of stress-reduction therapies were
more effective in blood pressure reduction than single-component therapies (Spence, Barnett,
Linden, Ramsden, & Taenzer, 1999). Combined methods, however, can be complex,
cumbersome, and costly, and may lead to attrition. Therefore, it is important to identify if a
single-mode strategy would be effective in blood pressure reduction in hypertensive pregnancy.

Psychological Antihypertensive Therapy in Pregnancy

All pharmacologic antihypertensives have side effects (Walker & Gant, 1997), are
known to cross the placenta, and may affect the fetus (Duckett, Kenny, & Baker, 2001). Despite
this concern, potential negative effects of anxiety on maternal blood pressure in hypertensive
pregnancy (Gabbe, 2002), and recommendations that mild to moderate primary hypertension be
managed non-pharmacologically (National High Blood Pressure Education Program Working
Group on High Blood Pressure in Pregnancy (NHBPEP), 2000), only two published research
reports of the effectiveness of psychological therapy on hypertension in pregnancy have been
identified (Little et al., 1984; Somers et al., 1989). In the first of these studies, 60 pregnant
women with blood pressure $\geq 135/85$ mmHg were assigned sequentially to meditation and
progressive muscle relaxation therapy, this relaxation method combined with biofeedback
treatment or routine care groups. Women in the relaxation only group were found to have
significantly lower systolic blood pressure during their last month of pregnancy than controls who received no experimental treatment (study readings $M = 118.0 \text{ mmHg vs. } 125.9 \text{ mmHg, } p < 0.05$; clinical readings $M = 128.7 \text{ mmHg vs. } 134.5 \text{ mmHg, } p < 0.05$). Although there were no significant differences between group means for diastolic blood pressure as measured for the study, the clinic readings were significantly different ($84.0 \text{ mmHg vs. } 88.5 \text{ mmHg, } p < 0.05$).

Each of the experimental groups were also found to have significantly fewer prenatal hospital admissions than controls ($28\% \text{ versus } 28\% \text{ versus } 67\%, \chi^2 = 8.86, p < 0.03$) (Little et al., 1984). However, validity of the findings may be limited by a number of methodological weaknesses, particularly the use of sequential, rather than random allocation to study groups and the combination of small sample size and comparisons across three groups resulting in low statistical power.

Somers, Gevirtz, Jasin, and Chin (1989) later used RCT methods to investigate the effect of another psychophysiologic intervention on blood pressure in 45 women between 30 and 36 weeks of gestation with pregnancy-induced hypertension and prescribed restricted physical activity. The experimental group ($n = 15$) received four hours of training to self-monitor their blood pressure and use relaxation with guided imagery and biofeedback twice daily. An attention placebo group ($n = 15$) received four hours of education designed to increase compliance to bed rest, while a control group ($n = 15$) received routine care including bed rest. The primary outcome measure, mean arterial pressure (MAP) at the last prenatal visit, increased in both the education and control groups, compared with baseline, and significantly decreased in the intervention group ($F(1, 28) = 7.18, p < .025$). The experimental group also had significantly lower absolute blood pressure, when compared to the other groups ($F(2, 42) = 9.30, p < .001$). (See Appendix A)

Most relaxation therapies require an extended period to learn (Jevning, Wallace, &
Beidebach, 1992; Leuner, 1977; NIH Technology Assessment Panel on Integration of Behavioral and Relaxation Approaches into the Treatment of Chronic Pain and Insomnia, 1996), and thus may not be appropriate for use during pregnancy. However, guided imagery has been shown to have beneficial effects on both blood pressure (Salmore & Nelson, 2000; Young, 1999) and anxiety levels (Esplen, 1991; Kwekkeboom, Husby-Moore, & Ward, 1998; Lang, Benotsch, Fick, Lutgendorf, & Berbaum, 2000; Lang & Hamilton, 1994; Lang, Joyce, Spiegel, Hamilton, & Lee, 1996), in a variety of clinical populations, and in reasonably short periods of time.

Guided Imagery as Clinical Intervention

Guided Imagery Defined

Imagery is “the mental invention or recreation of an experience that in at least some respects resembles the experience of actually perceiving an object or event” (Finke, 1989, p. 2), and uses thought processes to stimulate one or all of the senses (Achterberg, 1985; Kreitzer & Snyder, 2002). Physiological and psychological responses similar to those resulting from an actual external stimulus can be generated (Eller, 1999); stimulating mental images - for example, those frightening or sexual in nature - are well known to produce significant physiological responses. Spontaneous use of imagery is well demonstrated empirically (Robb, 2000), although there may be differences in individual abilities to process images (Kunzendorf, 1981).

Guided imagery (GI) has been defined as “the process of purposeful use of mental images by working with another person or by listening to an audiotape, to achieve a desired therapeutic goal” (Bazzo & Moeller, 1999, p. 319). Its therapeutic purposes, ranging from relaxation to psychotherapy, are to (1) promote psychological change and self-development; (2) elicit relaxation; (3) provide distraction or attention-diversion, or; (4) enhance healing. Mental rehearsal, often used to prepare for an event or desired situation such as athletic, musical or other
type of performance, can also be used in clinically therapeutic ways for anticipation of impending health care events such as post surgical recovery or smoking cessation (Payne, 2000). Images may be specific to a healing process in the body, such as increasing blood flow to the heart, an end state of health or well-being, soothing and calming in nature to induce relaxation, or may be goal-directed (Freeman, 2001; Klein-Hebling & Lohaus, 2002; Lee & Olness, 1996).

Although the imagination is used to create images while simply day-dreaming, guided imagery is much more than that. Guided imagery can be conceptualized in a number of ways or frameworks, for example, in terms of the Triple Code or ISM Model, in which Images as centrally aroused sensations have both a Somatic response, and a Meaning (Ahsen, 1984). As such, imagery can also be used in complex ways as symbol or metaphor, and guided imagery techniques have been used extensively in cognitive-behavioural therapy, to counteract negative thinking, to explore and alter thought (cognitive) distortions, and/or change maladaptive behaviours (Payne, 2000). Imagery use in these and other forms of counselling can be used to imagine success in certain aspects of a person’s life, to lessen stress arousal through changing emotional and cognitive responses to stimuli, and/or to teach new ways of coping with stressful situations.

Guided imagery has been shown to provide an alternate focus of attention for the user (Fors, Sexton, & Goetestam, 2002; Harvey & Payne, 2002; L. Lee & Olness, 1996; Lyles, Burish, Krozely, & Oldham, 1982; McCaffery, 1990) and facilitate a relaxation response and calmer emotional states (Achterberg, 1985; Baider et al., 2001; Baider et al., 1994; Butcher & Parker, 1988; Esplen et al., 1998; Hammer, 1996; McCaffery, 1990; Sheikh et al., 2002).

Guided imagery can be delivered either by audiotape or face-to-face contact with a therapist, or a combination of both. Audiotape use, a less costly and more flexible and convenient approach for participants than live one-to-one sessions, is recommended when time
is limited (Dossey, 1995). Equivalence of face-to-face guided imagery with audiotapes is yet to be determined (Eller, 1999; Van Fleet, 2000), but daily practice of guided imagery at home, often with audiotapes, is considered standard for guided imagery programs and protocols (Achterberg, 1985).

**Guided Imagery Effects on Blood Pressure**

A number of published clinical studies report guided imagery (GI) interventions as effective in lowering blood pressure (BP) in samples of hypertensive pregnant women (Somers et al., 1989), non-pregnant hypertensive adults (Crowther, 1983; Henry & Sanacore, 1987; Taylor, Farquhar, Nelson, & Agras, 1977; Young, 1999), cancer patients receiving chemotherapy (Burish, Carey, Krozely, & Greco, 1987; Lyles et al., 1982; Vasterling, Jenkins, Tope, & Burish, 1993), burn patients (Achterberg, Kenner, & Lawlis, 1988), post-surgical patients (Holden-Lund, 1988), and patients undergoing endoscopy (Salmore & Nelson, 2000). The GI intervention used in these studies has generally been in combination with other therapies (See Appendix A); only three studies of GI alone with blood pressure as the primary outcome have been reported (Manyande et al., 1995; Salmore & Nelson, 2000; Young, 1999). (Appendix B)

In the three studies in which guided imagery alone was the intervention, one showed beneficial diastolic BP effects (Salmore & Nelson, 2000), one showed beneficial systolic BP effects (Young, 1999), while the third showed no significant effect on blood pressure (Manyande et al., 1995), but none of these studies were with pregnant women.

Blood pressure has been considered as the primary outcome for a limited number of guided imagery studies, for example, Somers, Gevirtz, Jasin, and Chin (1989), Young (1999), Crowther (1983), and Salmore and Nelson (2000), but more often investigators, for example, Achterberg, Kenner and Lawlis, (1988) and Burish, Carey, Krozely, and Greco (1987) have used
BP as a secondary outcome measure in relation to stress and anxiety levels. Only four of the GI studies in which blood pressure outcomes were reported were actually with hypertensive samples (Crowther, 1983; Henry & Sanacore, 1987; Taylor, 1977; Young, 1999), and three of these samples were already receiving some form of anti-hypertensive medication treatment (Crowther, 1983; Henry & Sanacore, 1987; Taylor, 1977), which could have blunted possible effects of the guided imagery. Still Crowther (1983) reported drops in both systolic and diastolic measures and Taylor (1977) reported systolic BP reduction.

Findings from the guided imagery and blood pressure studies to date do little to clarify the optimal or minimal time of guided imagery required to achieve a blood pressure reduction. Although a number of researchers had study participants engage in three to eight weeks of treatment, generally with daily home practice, only Collins & Rice (1997), Crowther (1983), Henry & Sanacore (1987) and Young (1999) reported practice frequency as identified by the participants; the only researcher to report statistical analysis of practice data in relation to outcomes did not find it to be correlated with blood pressure decreases (Crowther, 1983). It is important to note that significant effects of guided imagery alone on diastolic BP during radiologic procedures have been found even when the intervention was introduced a short time prior to the procedure, supporting the notion that weeks of GI use are not required to achieve a relaxation response (Lang et al., 2000).

Validity of findings varies due to measurement issues. Although a number of guided imagery studies reported no significant blood pressure effects, there are a number of factors which may not have allowed differences to be discerned. For example, Manyande’s (1995) choice of maximum blood pressure value as outcome measure may have been an inaccurate reflection of average BP during and after abdominal surgery. A wide range of clinical circumstances may have caused transient BP peaks during a surgery and immediate
postoperative period, and for which a relaxation response may have had limited effect. Some studies, e.g., Henry and Sancore, (1987), and Somers and colleagues (1989), ensured those measuring BP were masked to group allocation, while other investigators, e.g., Young, (1999) did not undertake this approach to limit observer bias, or failed to report whether or not it occurred (Burish et al., 1987). Validity issues related to blood pressure measurements taken over bandages were raised by another study (Achterberg et al., 1988). Choice of timing of outcome blood pressures may have limited the information available about actual effectiveness of guided imagery interventions; Somers and colleagues (1989), for example, focused on mean arterial pressure at the last prenatal visit only. Blood pressure outcomes in various studies have been based on single measurements, for example, Burish and colleagues (1987), Manyande, (1995), and Salmore & Nelson (2000).

All published studies of guided imagery effectiveness on blood pressure reduction have used traditional mercury measurements. Some studies of psychological therapy for hypertension have used ambulatory blood pressure measures which more closely reflect the dynamic and highly variable nature of blood pressure throughout the day (Jacob et al., 1992; Linden, Lenz, & Con, 2001; van Montfrans, Karemaker, Wieling, & Dunning, 1990). To date, no studies of guided imagery effects on blood pressure have used ambulatory blood pressure measurement, which has so far limited practical determination of the level of effectiveness of this psychophysiological therapy on blood pressure (Hunyor & Henderson, 1996; Staessen et al., 1999). For research use in pregnancy, ambulatory blood pressure monitoring (ABPM) may be particularly ideal, due to the volume and stability of data generated allowing for previously unrecognized associations to be reported (Redon & Lurbe, 2001; Walker, Higgins, & Brennecke, 1998).

Findings regarding guided imagery effectiveness for blood pressure reduction, with or
without progressive muscle relaxation or other psychological therapy, vary. Overall, there is some evidence of beneficial BP effect. However, normal BP at baseline may have contributed to a floor effect for at least two studies (Collins & Rice, 1997; Vasterling et al., 1993), the treatment period may not have been long enough in others, and/or sample size may have been inadequate to distinguish any actual differences present. The mixed findings support the need for further study in this area.

**Guided Imagery and Anxiety**

As blood pressure elevation is a physiological element of both the stress response and anxiety, measures that reduce anxiety may also reduce blood pressure levels; thus studies of guided imagery effectiveness for anxiety reduction are also reviewed here. With few exceptions (Cohen, 2002; Collins & Rice, 1997; Sloman, 2002), guided imagery interventions, with or without the addition of progressive muscle relaxation therapy, are reported to significantly reduce psychological distress and anxiety in a wide range of subject and patient groups, and with a number of standard measures (See Appendices C and D).

As guided imagery has often been used in combination with other psychological therapies (e.g., Baider et al., 2001; Baider et al., 1994; Cohen, 2002; Tsai & Crockett, 1993), it is difficult to ascertain the extent to which guided imagery influenced outcomes in many of the studies. On the other hand, the studies of guided imagery as a single mode of therapy also show statistically significant effects on anxiety (Esplen, 1991; Rees, 1995; Sapp, 1994; Stephens, 1992). Most studies of guided imagery on anxiety outcomes have been randomized controlled trials, other than Esplen (1991), Achterberg (1988), Baider and colleagues (1994), and King (1988). Additionally, in other studies, attention placebo conditions such as inservice education (Tsai & Crockett, 1993) may not have been perceived by participants as benign, and may have evoked stress responses.
As relaxation response is believed to be the opposite of a stress response (Benson, 2000; Benson et al., 1974), it is possible that individuals with higher baseline anxiety levels may be more likely to benefit from guided imagery. On this basis, some authors suggest that psychological treatment of hypertension might be best for individuals who have high levels of perceived stress or those who are particularly interested in using psychological interventions (Linden, 2000; Linden et al., 2001). There is some evidence to suggest that relaxation therapies can produce psychological benefit regardless of baseline anxiety levels (Baider et al., 1994; Vasterling et al., 1993), but it is insufficient to determine whether such therapy is more effective for one group or another. Most studies reported using guided imagery interventions that were four to six weeks or more in length, but shorter exposures to GI starting either the day before or immediately before medical procedures were also shown to be effective (Lang et al., 2000; Thompson & Coppens, 1994).

In pregnancy, relaxation training is a common element of childbirth preparation to decrease anxiety and tension, but only one published report of a study investigating effects of GI on anxiety in pregnancy was found, with no effect found (Cohen, 2002). Additionally, only a single study of GI use for postpartum anxiety was identified (Rees, 1995), reporting positive effect (See Appendices C and D).

The predominant instrument used to measure anxiety across reported studies was the STAI (Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983), but effects were evident when other measures were used. Sample sizes in many of the guided imagery studies reported have been small, limiting generalizability. However, collectively, nearly all (14 of 17) guided imagery investigations in which anxiety was reported as an outcome demonstrated a beneficial anxiety-lowering effect.

Subjects in previous studies rated guided imagery as helpful; Collins and Rice (1997)
reported that 75% of a relaxation group rated the intervention as at least moderately helpful, while 100% of postoperative participants who received a GI intervention in another study reported reduced anxiety, 81% (50/62) reported improved sleep, 91% (56/60) felt it helped their recovery, and 94% (58/62) indicated that they thought all patients having similar surgery should be offered GI tapes (Tusek, Church, Strong, Grass, & Fazio, 1997). Qualitative data also indicated a psychological benefit from GI; for example, individuals using it have described reductions in tension, feeling soothed, at ease and comforted, with some reporting falling asleep during practice (Esplen, 1991; Esplen et al., 1998).

**Guided Imagery for Symptom Management**

Guided imagery has been used as an effective intervention to improve a wide range of other health outcomes such as preterm birth (Janke, 1999), breast milk production (Feher, Berger, Johnson, & Wilde, 1989), depression and self-esteem in postpartum women (Rees, 1995), and reduction of hospital length of stay (Halpin, Speir, CapoBianco, & Barnett, 2002), and procedure times (Lang et al., 2000). However, the most common outcome of interest in the guided imagery literature has been in the management of patient symptoms.

The impact of guided imagery on symptom management, including pain, is inconclusive. Although some investigators have reported no significant effects of guided imagery on migraine pain (Ilacqua, 1994), postoperative pain after rectal surgery (Renzi et al., 2000), and children's pain during cardiac catheterization (Pederson, 1995), others report effectiveness for pain associated with burns (Achterberg et al., 1988) and fibromyalgia (Fors et al., 2002). In one nonrandomized study, more guided imagery subjects (21.7%) than controls (7.6%) reported reduced headaches ($p = .004$), and significantly more improvement in some aspects of quality of life (Mannix, Chandurkar, Rybicki, Tusek, & Solomon, 1999). Qualitative data suggest that people with migraine headache felt better able to cope with the pain with guided imagery.
(Ilacqua, 1994), while women undergoing radiation therapy in a RCT found it enhanced their comfort (Kolcaba & Fox, 1999). In another RCT, pain levels remained stable during the procedure in the hypnosis with a guided imagery group, but increased linearly with procedure time for routine care and attention placebo groups. Patient-controlled intravenous analgesia use in the standard group (1.9 units) was significantly higher than in the attention and hypnosis groups (0.8 and 0.9 units, respectively) (Lang et al., 2000). Tusek and colleagues (1997) reported that guided imagery for three days preceding colorectal surgery and for six days postoperatively plus use of music audiotapes during and immediately following the surgery significantly lowered total analgesia requirements, compared to a control group (Median 185 mg vs. 326 mg, p < 0.001). A systematic review of seven studies, with 362 participants, of relaxation techniques for acute pain management (Seers & Carroll, 1998) concluded that only three studies found reduced sensation or distress due to pain, while the remaining four found no significant differences for these outcomes. Evidence is inadequate to determine effect on acute pain. A systematic review of nine studies, with 414 participants, of relaxation techniques for chronic pain concluded that likewise, there is insufficient evidence regarding whether relaxation techniques do reduce chronic pain (Carroll & Seers, 1998). Overall, it appears that guided imagery has beneficial effect on at least some types of pain, but this relationship requires further study.

The effectiveness of imagery has also been investigated in relation to a number of other psychological and symptom outcomes. Its use has been reported to significantly reduce depression in individuals with HIV (Eller, 1995) and cancer (Bakke, Purtzer, & Newton, 2002; Sloman, 2002), enhance quality of life (Sloman, 2002), reduce insomnia (Rosen, Lewin, Goldberg, & Woolfolk, 2000), and reduce frequency of binging and vomiting in women with bulimia (Esplen et al., 1998).
Summary

The extent of effectiveness of psychophysiologic interventions on clinical outcomes in hypertensive patients requires further study, due to methodological problems demonstrated in previous work, such as limited use of randomization, possible lack of allocation concealment, lack of controls, inconsistencies in conceptualizations of imagery, varying protocols, and insufficient statistical power. Current knowledge suggests that one type of relaxation training does not appear to be more efficacious than others in reducing BP (Devine & Reifschneider, 1995b; Eisenberg et al., 1993; Linden et al., 2001; Somers et al., 1989; Spence et al., 1999).

The empirical evidence suggests that guided imagery has a range of potential health benefits. To date, limited studies of the effects of forms of guided imagery therapy indicate that it may reduce blood pressure levels, in both pregnant and non-pregnant states, and that psychological and physiologic health benefits may be achieved in relatively short timeframes, and be feasible for use in medically complicated pregnancies. However, blood pressure effects of guided imagery specifically have not been well addressed. Few studies have been reported, and most of the research has combined guided imagery with other psychological therapies.

Despite initial indications that relaxation strategies could improve blood pressure levels in hypertensive pregnancy, no subsequent published reports were found. However, recent survey findings indicate that many pregnant women are interested in integrating complementary therapies such as guided imagery as part of their self-care (Gibson, Powrie, & Star, 2001; Ranzini, Allen, & Lai, 2001).

Evidence from one study suggests that individualized relaxation strategies may provide greater blood pressure benefit than generic approaches (Linden et al., 2001). Guided imagery therapies tend to be tailored to the patient (van de Weterling, Bernstein, & Ley, 2003). Therefore, images that are chosen by a participant do constitute a therapy that is individualized,
and may optimize benefit while maintaining a standardized technique (Young, 1999). Guided imagery is reported to be practical and easy to use, and the response to use is generally favourable (Esplen, 1991; Esplen et al., 1998; Freeman, 2001). Therefore guided imagery may be considered an appropriate intervention to test for effectiveness in reducing blood pressure in hypertensive pregnancy.

Conceptual Framework

The conceptual framework guiding this clinical trial is based on key concepts from the preceding literature review, and provides a foundation and organizational structure to explain how maternal blood pressure can be influenced by use of the guided imagery intervention in this study.

Definition of Terms

Guided imagery is a purposeful activity in which the participant is guided by specific words or suggestions regarding the formation of mental images for the purpose of inducing a relaxation response.

A sense of calm or cognitive rest is present when the participant feels a sense of peace, quietude and lack of restlessness (Benson, 2000; Benson et al., 1974).

Focused attention is the direction of a person’s cognitive attention towards images elicited through the guided imagery exercise, and is related to distraction and diversion. If the person’s attention begins to wander, she will be encouraged to passively return to the imagery focus.

Relaxation is both a mental and physical state (Benson et al., 1974; Ryman, 1995). The relaxation response results in decreased sympathetic nervous system and increased parasympathetic activity, and is associated with relaxed musculature, lower respiration rate,
pupil constriction and decreased blood pressure, release of anxiety, and increased calm (Benson et al., 1974)

*Imaging ability* refers to the “ability to generate images and become involved in them as if they were real” (Kwekkeboom et al., 1998, p. 195), and may moderate the effect of guided imagery on some outcomes. An underlying assumption in this study is that despite suggestions that a participant’s imaging ability may mediate responses to this psychological strategy (Kwekkeboom, 1999), all individuals have some capacity to use guided imagery.

*Systolic blood pressure (SBP)* is the peak pressure or force of blood against arterial walls at the point of ventricular contraction (Luckman, 1997) and is reflective of cardiac output (Helewa, Burrows, & Smith, 1997). When an oscillatory blood pressure monitor is used, SBP is based on a rapid increase in arterial oscillation amplitude (Waugh, Halligan, & Shennan, 2000).

*Diastolic blood pressure (DBP)* is the force of blood against arterial walls when cardiac muscles are relaxed immediately prior to the next heart beat (Luckman, 1997), and is reflective of vascular resistance (Helewa et al., 1997). When an oscillatory blood pressure monitor is used, DBP is calculated from systolic and mean arterial pressures (Waugh et al., 2000).

*Mean arterial pressure (MAP)* is \((\text{SBP} – \text{DBP}) + \frac{3}{3} \text{DBP}\), and is based on maximum oscillation amplitude when using an oscillatory monitor (Waugh et al., 2000).

*Anxiety*, or state anxiety, is an emotional state characterized by “feelings of tension, apprehension, nervousness and worry” (Spielberger, Sydeman, Owen, & Marsh, 1999, p. 32) associated with sympathetic nervous system arousal. It is a psychological response to stressful circumstances, or evoked by thoughts (Shapiro, Jamner, Goldstein, & Delfino, 2001). Fluctuations over time can be measured (Spielberger et al., 1983). Trait anxiety or anxiety-proneness, which is relatively stable, can also be measured (Spielberger, et al, 1985).
**Description**

Hunyor and colleagues (1997) argued that use of psychophysiologic techniques for blood pressure management outside pregnancy has a compelling theoretical basis. This basis also holds true for use of such strategies during pregnancy. The sympathetic nervous system is activated in both pre-existing and gestational forms of hypertension in pregnancy (Grassi, 1998; Greenwood et al., 2001; Julius, 1991) and is inhibited by effective antihypertensive medication (de Champlain, 2001). In addition, BP during pregnancy tends to be lower during sleep and at lower physical activity levels (Brown et al., 1998; Halligan & O'Brien, 1996; Halligan et al., 1993) and higher in response to stressful stimuli (Matthews & Rodin, 1992; McCubbin et al., 1996; Nisell et al., 1985; Shulte et al., 1990).

Figure 1 is a diagrammatic representation of the psychophysiological pathways by which maternal blood pressure may be reduced in a pregnant woman with hypertension in the Relaxation and Blood Pressure in Pregnancy (REBIP) study.

*Figure 1. Conceptual Framework for the REBIP Study*

The description to follow provides an interpretation of the conceptual framework in Figure 1. Through participation in the guided imagery intervention in this study, the pregnant woman with hypertension will engage in regular practice of the guided imagery technique.
Guided imagery provides an alternate focus of attention, and when that focus is relaxation, increases a sense of emotional and cognitive calm (Fors et al., 2002; Harvey & Payne, 2002; Lee & Olness, 1996; Lyles et al., 1982; McCaffery, 1990), thereby eliciting a psychophysiological relaxation response (Achterberg, 1985; Baider et al., 2001; Baider et al., 1994; Butcher & Parker, 1988; Esplen et al., 1998; Hammer, 1996; McCaffery, 1990; Sheikh et al., 2002).

Additionally, the alternate focused attention, calm and relaxation response that guided imagery provides may serve as a coping strategy for the mother. Potentially this intervention could influence both sympatho-adreno medullary system (SAM) and hypothalamic-pituitary-adrenal (HPA) systems and provide counterbalance thus benefiting peripheral vascular resistance and blood pressure (Steptoe, 1988; Titlebaum, 1988).

Parts of the cerebral cortex that process sensory-perceptual stimuli can modulate blood flow by the autonomic nervous system, usually via the limbic-hypothalamic system. Likewise, neural processes initiated by the mind through imagining pleasant and calming mental images can influence the nervous and vascular systems (Stefano et al., 2001). The hypothalamus, amygdala, hippocampus and prefrontal cortex regulate emotional functions (Langhinrichsen & Tucker, 1990); the limbic system links these emotional mechanisms and other parts of the brain responsible for cognition and cardiovascular function (Boyle, 1999; Freeman, 2001; Guyton, 1991; Rossi, 1993). Structures in the limbic system can relay mind-influenced stimuli, such as those derived from calming pleasant images, to the hypothalamus, which can inhibit sympathetic and/or activate parasympathetic nervous systems via the vasocontrol centre in the brain stem, (Guyton, 1991). The hypothalamus integrates physiologic regulatory systems such as BP regulation and behavioural control (Guyton, 1991). Studies of regional cerebral blood flow via positron emission tomography (PET) provide evidence of widespread neuronal activation when individuals are guided to construct visual images, similar to that observed during actual visual
perception (Gulyas, 2000; Mellet et al., 2000). Additionally, neuroimaging studies indicate regions of the limbic system are activated during differing relaxation training conditions (Critchley, Melmed, Featherstone, Mathias, & Dolan, 2001), and EEG measures show reduced cortical activity compared with controls (Jacobs, Benson, & Friedman, 1996).

The posited primary mechanisms by which the relaxation response may reduce blood pressure in hypertensive pregnant women are: (1) direct inhibition/dampening of sympathetic nervous system (SNS) activation via neural responses, and/or; (2) increase in parasympathetic nervous system (PNS) stimulation (NIH Technology Assessment Panel on Integration of Behavioral and Relaxation Approaches into the Treatment of Chronic Pain and Insomnia, 1996; Sakakibara & Hayano, 1996; Stefano et al., 2001). These changes subsequently can result in lowered heart rate and contractility (cardiac output) and/or improved relaxation of blood vessels (peripheral/systemic vascular resistance), either process by which maternal blood pressure values may be lowered. Furthermore, guided imagery therapy can also reduce anxiety (Baider et al., 1994; Vasterling et al., 1993); therefore, (3) a diminishment of maternal anxiety may function as a primary or secondary mechanism by which SNS activity is lowered and PNS function is enhanced. The occurrence of a relaxation response may also moderate anxiety-related activation of the sympatho-adreno-medullary system, resulting in heart rate decreases, and diminishment of epinephrine and norepinephrine release, resulting in BP decreases. This in turn can lead to deactivation of hypothalamic-pituitary-adrenal system activity that may have been previously activated, thereby decreasing both total peripheral resistance and blood pressure (White & Porth, 2000).

Finally, in hypertensive pregnancy, depending on the etiology of the hypertension, and the length of time it has been present, either cardiac output or peripheral vascular resistance, or both may be elevated (Beevers et al., 2001). Peripheral vascular resistance may be additionally
increased as a result of damage to blood vessel endothelium (Beevers et al., 2001). (4). The fourth and final pathway by which blood pressure levels may be reduced is a secondary one; endothelial function may be less compromised and blood vessel relaxation enhanced, via peripheral neuro-vascular processes (Stefano et al., 2001) if fewer or less significant acute rises in BP occur (Millgard & Lind, 1998).

Individual responses to both internal and external stimuli can be emotional-cognitive, physiological, behavioural, or any combination of these (White & Porth, 2000). Promotion of an alternate focus of attention, and a sense of calm may limit maternal behaviours such as restlessness, in turn inhibiting sympathetic stimulation, and moderating maternal high blood pressure.

In summary, health care providers such as nurses who work with women who are hypertensive during pregnancy can assist them through promotion of relaxation, and enhancement of or addition to coping skills (McEwen, 2000). As blood pressure is largely modulated via the autonomic nervous system, enhancement or elicitation of a relaxation response can lower BP via autonomic neural pathways, and possibly inhibit endocrine stress hormone secretion. Thus attenuation of elevated blood pressure is expected.

Although there are a number of methods by which a relaxation response may be achieved, the mental processes used in guided imagery are easy to use, and, unlike physical techniques such as yoga and progressive muscle relaxation, are consistent with the current limited physical activity approach to clinical management of women with hypertension during pregnancy. Although the psychological intervention of guided imagery will not cure or likely prevent hypertension during gestation, its use may promote a sense of calm for the mother, and may potentially mediate sympathetic neural activity and/or enhance parasympathetic activity through a series of pathways, thus reducing blood pressure and benefiting women with varying
types of hypertension during pregnancy. The elements of this psychophysiologic model lend themselves to potential inter-relationships between psychological and physiologic elements and pathways between existing hypertension, maternal anxiety, and beneficial blood pressure changes subsequent to elicitation of a maternal relaxation response, in hypertensive women during pregnancy.

If guided imagery can reduce maternal blood pressure via any of the posited pathways, it may also reduce or limit the occurrence of severe hypertension, reduce poor perinatal outcomes, and/or reduce anti-hypertension medication use, related negative sequelae, and use of health care resources. However, before an adequately powered trial on maternal and perinatal outcomes is undertaken, a number of key questions must be answered regarding whether guided imagery can reduce blood pressure levels in hypertensive pregnant women. Research on the effectiveness of guided imagery on maternal blood pressure in hypertensive pregnancy has not been previously reported. Therefore, a preliminary clinical trial was designed to investigate effects on blood pressure and to address the following objectives.

Research Objectives

The objectives of this pilot RCT were to:

1. provide preliminary indicators of the effects of guided imagery compared to a quiet rest condition on a) blood pressure and b) anxiety.

2. determine the appropriateness of measuring the primary outcome at four weeks by examining patterns of weekly daytime MAP across the intervention period for both intervention and control groups;

3. provide an estimate of recruitment rates;

4. assess compliance with allocated treatment;
5. determine participants’ satisfaction with allocated treatment; and;
6. determine the degree of relationship between standard prenatal measurements and average daytime ambulatory measurement of blood pressure during the study period.

Research Questions

Primary Question

What is the effect of a period of daily guided imagery use by pregnant hypertensive women on maternal mean arterial blood pressure (MAP), when compared with women receiving advice for having daily periods of quiet rest?

Secondary Questions

1. When compared with quiet rest, does guided imagery use by pregnant hypertensive women affect:
   (a) Mean daytime ambulatory systolic blood pressure?
   (b) Mean daytime ambulatory diastolic blood pressure?
   (c) Mean daytime ambulatory heart rate?

2. When compared with quiet rest, does guided imagery use by pregnant women with hypertension:
   (a) Reduce the proportion of women who receive antihypertensive medication after randomization?
   (b) Reduce maternal anxiety?
   (c) Increase the length of time from randomization to delivery?

3. Are blood pressure changes related to the reported frequency of guided imagery practice undertaken?
4. Is there a relationship between classification of hypertension and effectiveness of guided imagery?

5. What are the means and standard deviations for daytime MAP after one, two, three and four weeks of exposure to the allocated study condition in the two study groups?

6. Is there a relationship between participants’ evaluation of their imagery experiences and effectiveness of guided imagery?
CHAPTER 3: RESEARCH DESIGN AND METHODS

Design

This pilot study was a randomized controlled trial to determine the effects of guided imagery on mean arterial blood pressure in hypertensive women during pregnancy, in order to answer feasibility questions in anticipation of a larger study and provide data for calculation of a sample size for the main trial. Randomization was centrally controlled and was blocked, using random block sizes of six and eight. Blinding of study participants was not possible due to the nature of the intervention. Clinicians were not informed of study group allocation nor of ambulatory blood pressure readings collected for the study.

Outcomes of guided imagery, the active intervention in this study, were compared with those of quiet rest, a formalization of standard recommendations for rest with elements of an attention placebo, as it is important to make comparisons of intervention effectiveness with “real world” care, rather than with artificial or contrived study conditions (Vickers & de Craen, 2000), as well as to manage potential bias that might occur due to differing amounts or extents of attention.

Setting and Site Eligibility

Initially, the sole study site was one large Atlantic Canadian tertiary care centre, with approximately 4300 births per year. Three additional sites in other Atlantic Canadian cities were added 13 months later to enhance recruitment. One of the three, a second tertiary care centre with approximately 2200 births per year, added participants to the study.

In order for a hospital to be eligible to participate in the study, the site was required to have: (1) prenatal maternity services, comprised of prenatal clinics, a fetal assessment unit, a prenatal inpatient unit and/or other services through which pregnant women with hypertension could be identified and referred to the study; (2) an individual with a hospital appointment or
employment at that health centre to assume the role of study site coordinator; (3) communicated commitment to follow the trial protocol and (4) departmental and ethics approvals for the study.

Operational Definitions

Hypertension classifications for this study were consistent with those endorsed by the International Society for the Study of Hypertension in Pregnancy (ISSHP) (Brown, Lindheimer et al., 2001; Davey & MacGillivray, 1988) and the Canadian Hypertension Society and the Society of Obstetricians and Gynaecologists of Canada (Helewa et al., 1997). Operational definitions for hypertension in this trial were as follows:

*Pre-eclampsia:* The presence of diastolic blood pressure greater or equal to (≥) 90 mmHg, based on clinical readings and documented at least twice ≥ 4 hours apart, or a single diastolic reading of ≥110 mmHg, plus proteinuria, after the twentieth week of gestation, in a previously normotensive woman.

*Proteinuria:* A study participant was considered to have proteinuria at the time of randomization on the basis of an excess of (a) 300 mg/L in any 24 hour collection, (b) a total of 500 mg per 24 hours, or (c) a dipstick measurement of 2+ or more recorded in a random clean catch midstream urine sample, as documented at any point during pregnancy in her medical record.

*Gestational hypertension:* The presence of two or more diastolic blood pressure readings ≥ 90 mmHg or a single diastolic reading of ≥110 mmHg, with no proteinuria, in a previously normotensive woman after the twentieth week of gestation.

*Eclampsia:* A pregnant or postpartum woman was considered to have eclampsia if she had convulsions, unrelated to other pathology (Mattar & Sibai, 2000).

*Chronic hypertension* was defined as the presence of two diastolic blood pressure readings ≥ 90 mmHg or a single reading of ≥ 110 mmHg in pregnancy, with or without proteinuria, if the
condition was diagnosed pre-pregnancy or in the first twenty weeks of gestation.

*Guided imagery* in this study was operationally defined as a purposeful activity in which the participant is guided by specific words or suggestions regarding the formation of mental images for the purpose of eliciting a relaxation response, in contrast to use of guided imagery as a cognitive-behavioural strategy or psychotherapeutic intervention.

*Quiet rest* was considered to be periods of physical rest during which times participants would limit extraneous stimuli such as use of computers, televisions, audio devices and telephones and reading or talking to others.

*Mean daytime blood pressures* (SBP, DBP, and MAP) for this study were based on an average of serial automatic ambulatory blood pressure measurements done every 30 minutes during the woman’s waking hours for a one-day period of time, from early morning until she went to bed that night. The instrumentation was a Spacelabs model 90207 ambulatory blood pressure (ABP) monitor (Seattle, WA, USA) and Spacelabs ABP analysis system software (90209 Data Interface Unit).

*White-coat hypertension* was considered to be present when routinely measured prenatal systolic BP was greater than or equal to \( \geq 140 \), and/or diastolic BP \( \geq 90 \) mmHg, and mean daytime ambulatory BP was within the normal range of \( \leq 133 \) mmHg systolic and \( \leq 81 \) mmHg diastolic at 26-30 gestational weeks or \( \leq 135 \) mmHg systolic and \( \leq 86 \) mmHg diastolic at 31 to 40 gestational weeks (Brown et al., 1998).

*Anxiety*, for the purpose of this study, was considered to be anxiety felt over the past week by a woman, as scored with the state anxiety scale of the Spielberger State-Trait Anxiety Inventory (STAI) (Spielberger et al., 1983).
Sample

*Eligibility Criteria*

Study participants were women who met inclusion criteria and gave consent.

**Inclusion Criteria**

- Pregnant with two or more prenatal diastolic blood pressure readings $\geq 90$ mm Hg and had some form of clinical investigation for hypertension.
- Less than or equal to (≤) 36 weeks and 6 days gestation. Inclusion of women beyond this gestation increases the likelihood of attrition from the study (i.e. not completing at least one full week of the intervention) because routine clinical practice would be to deliver their babies close to term.
- Planning to give birth at one of the designated study sites
- Competent to give informed consent
- Hearing acuity (natural or compensated through use of hearing aids) that was adequate to hear verbal and audiotaped instructions

**Exclusion Criteria**

- Likely to deliver within 10 days, in the judgment of her obstetrical care provider (including women with diastolic BP >110 mmHg, or systolic BP >170 mmHg; unstable diabetes, concurrent antepartum hemorrhage, preterm labour, and/or other significant medical conditions)
- Prescribed antihypertensive medication at baseline. Women who had anti-hypertensive medication initiated once they were in the study were not excluded.
- Documented psychotic illness, with or without current use of anti-psychotic medication; use of guided imagery could exacerbate such symptoms (Harding, 1996; Payne, 2000).
Unable to understand and read English to the extent necessary to understand instructions and sign consent

Procedures for the RCT

Eligibility Screening

Successful recruitment to the Relaxation and Blood Pressure in Pregnancy (REBIP) study was dependent on initial clinician screening of pregnant women with diagnosed or suspected hypertension. Despite little evidence from randomized trials to suggest which methods are most valuable in increasing RCT recruitment (Mapstone, Elbourne, & Roberts, 2007), a range of strategies commonly reported by other researchers were implemented in the REBIP Study (Francis et al., 2007; McDonald et al., 2006). The study was introduced to clinicians through a series of mail-outs and faxes, and through presentations at grand rounds, in which the purpose, research questions and posited conceptual pathways were presented, and clinician support and active recruitment assistance requested. In addition, the researcher or research assistant visited physician offices and units at or near the start of recruitment, to speak directly to physicians, nurses and key office/clinic staff about the study and the importance of their active participation. Support from key perinatologists added legitimacy to the study (Francis et al., 2007).

To maximize clinician recollection of the study and the need to screen all pregnant women with hypertension, colour posters with the study logo and eligibility criteria, with information in large font, in an easy-to-read format and in a clear plastic cover, were provided to each physician office and each relevant clinic and hospital unit (Eligibility Screening Form, Appendix E), and at least on hospital units and in clinics were in easy view and easy reach of clinicians when they were seeing patients and writing in clinic or hospital records. It was hoped that if the physician and key office personnel were introduced to the study and engaged in the
process, that the likelihood of screening of women and referral to the study would be maximized. Unfortunately, very few referrals were received from physician offices. Chart flags were used to identify possible participants scheduled for prenatal clinic or fetal assessment unit visits, and served as a reminder to clinicians to undertake eligibility screening of these women.

Screening was enhanced with ongoing attention and encouragement from study personnel, best seen with contacts with clinical units (either in person or by phone) on at least a daily basis, including weekends and holidays. Due to the nature of clinical management, it was not uncommon for women with elevated blood pressure to be admitted to an inpatient unit late on Fridays for observation and monitoring during a weekend. Contact with inpatient unit staff throughout the weekend regarding new or other patients who might be potential participants was essential, particularly as many of these women were close to gestational eligibility cut-offs, and waiting until Mondays meant many women otherwise eligible could not participate because the window of gestational eligibility had closed by Monday. In addition, staffing and routines on inpatient units tended to vary between weekdays and weekends, meaning that weekend staff might be less familiar with the study and/or have less time to screen. Although contact with inpatient unit staff was primarily during day shifts, calls or visits to inpatient units on evening or night shifts enhanced the likelihood that new admissions could and would be screened in a timely fashion. The extent to which eligible pregnant hypertensive women were “missed” by front-line clinicians and not screened or referred to the study is not known. Early in the study, two to three eligible women were missed on one inpatient unit during weekends, and when identified were no longer eligible. These events were discussed soon after each instance with unit staff, in an effort to sensitize them to the need for timely contact with the study and to identify ways to prevent such events in the future. I, as principal investigator, carried a cell phone 24 hours a day, seven days a week, and research nurses used cell phones or pagers for
easy contact to and from clinicians and study participants.

Although limited funding did not allow payments, staff were provided with tokens of appreciation to acknowledge their time spent in screening women for eligibility. Those who referred women to the study were sent a coffee coupon and had their name entered in a draw for a prize at the end of study recruitment. Snacks were provided on referring units around the holidays as another way to thank staff for their assistance.

Efforts were made to have clinicians and unit/clinic support staff feel vested in the study. Staff nurses and clinical support staff were regularly encouraged to provide their ideas about how best to identify potential study participants, and to inform the principal investigator, site coordinator or research nurse about problems or alternate strategies they identified. Suggestions were generally related to placement of screening materials for improved visibility and access, and timing of study-initiated contacts in relation to unit shift reports and rounds.

In addition to the activities described above, after approximately 15 months after the study began, modifications were made to eligibility criteria to optimize recruitment. The first eligibility criterion to be modified was the cutpoint for clinical blood pressure levels required for study entry. Initially, both systolic and diastolic BP values had to be elevated (> 140 mmHg systolic and > 90 mmHg diastolic) consistent with criteria used by a large pre-eclampsia study at that time. However, this was far more stringent than the standard definition for hypertension in pregnancy accepted by the International Society for the Study of Hypertension in Pregnancy (ISSHP), and by the Canadian Hypertension Society and Society of Obstetricians and Gynaecologists of Canada, a diastolic elevation of ≥ 90 mmHg only. The more restrictive criteria had led to two problems: (1) statistics and anecdotal evidence from recruiting units suggested that potential participants with diastolic but not systolic blood pressure elevations were being lost and; (2) that several participants were advanced in their hypertensive disease
process by the time they met both systolic and diastolic criteria. A decision was made to change the blood pressure eligibility criteria to the less restrictive ≥ 90 mmHg diastolic. This was expected to dramatically reduce the timeline for recruitment and enhance the clinical applicability of the study results.

At about the same point in the study, the eligibility criterion related to gestation at time of study entry was changed from ≤ 33 weeks and six days, to ≤ 36 week, six days. The initial criterion was intended to allow for the large majority of participants to be in the study for a full four weeks prior to delivery. However, the four week timeframe for participant exposure to their randomized study condition had been somewhat arbitrary, and evaluation data 13 months after recruitment began indicated that only 65% of the women in the study had completed four weeks of their assigned study condition; in other words, the early gestational cut-off of 33 weeks and six days had not had the desired effect of allowing for completion of four weeks in the randomized study condition. Therefore, the gestational inclusion criteria was raised to ≤ 36 weeks and six days, to allow higher rates of eligibility for the study and eliminate most concerns about attrition. Concurrently, the timing of the primary outcome daytime ambulatory mean arterial blood pressure was changed to “four weeks, or if delivery is sooner, the most recent set of ambulatory blood pressure measurements available”, rather than “four weeks after randomization” previously designated. At the same time, the exclusion criterion “likely to deliver within one week, in the judgment of her obstetrical care provider” was changed to 10 days, with the intent of not excluding potential participants who could otherwise actually be randomized and remain in the study long enough to provide at least one weekly set of outcome data. All of these modifications were approved by the REBIP Study steering and thesis committees and by the relevant research ethics boards.
Recruitment and Consent

Potential study participants were informed about the trial through posters and brochures during their regularly scheduled visits to physicians’ offices, prenatal clinics and classes, ultrasound departments, inpatient prenatal care units and fetal assessment units, as well as advertisement on community access television and in a parenting newspaper, and could contact the researcher or research nurse directly. In addition, potential participants who met study criteria were approached during a regularly scheduled prenatal office, clinic or fetal assessment visit or during a prenatal inpatient admission by clinic or hospital staff who asked if the woman was willing to hear about the study from a member of the research team. Potential participants who met eligibility criteria gave permission through their nurse or physician care provider for research personnel to contact them, or they contacted study personnel directly. The principal investigator or research nurse (depending on the site) then spoke with these women, confirmed their eligibility, described the study to them and asked them to participate, after which written consent was sought (See schema, figure 2). All women enrolled in the study were informed about the uncertainties regarding benefit of guided imagery for blood pressure reduction and that they had a fifty-fifty chance of being assigned to one study group or the other.
Efforts were made to initiate baseline ambulatory blood pressure monitoring (ABPM) on the same day of patient identification and/or consent, if it was likely that a minimum of eight to 10 of hours of monitoring would be possible that day and the woman was willing to start that soon. This determination was made on the basis of the time of day as well as questioning of the woman about her typical bedtime, rather than limiting a monitoring start time to a set time of day. Otherwise, the baseline BP monitoring was undertaken the following day, with few exceptions. Prior to starting the blood pressure monitoring session, the investigator or research nurse verbally reviewed key points regarding monitor use and technique with the participant, using a brochure titled *The REBIP Study Guide to Ambulatory Blood Pressure Monitoring*, adapted from one used in a hypertension clinic at a large local general hospital (Appendix G).
Women were encouraged to call study personnel immediately if they experienced difficulties with their monitor or had questions.

At the time ABPM was started, an appointment time was set with the woman to pick up the blood pressure monitor, undertake randomization, and introduce her allocated group condition. Randomization usually occurred the morning immediately following the day of baseline blood pressure monitoring, but on rare occasions occurred on the second or third day, due to participant or monitor availability.

On the day of randomization, the researcher or research nurse retrieved the ambulatory blood pressure monitor, completed the study Entry Form (Appendix J) with data retrieved from the participant and her prenatal and/or hospital records, and had the participant complete the state portion of the State Trait Anxiety Inventory (Spielberger et al., 1983) titled the Baseline Self-Evaluation Form (Appendix J). The investigator or nurse then used a telephone (usually a cell phone) to call the centralized computer randomization service based at the Randomized Clinical Trials Unit at the Faculty of Nursing, University of Toronto, and entered the participant identification code and secondary identifier in response to computer verbal prompts. A verbal message from the computer then provided the group allocation, which could then not be altered or reassigned. The researcher or research nurse then documented the group assignment on the Entry Form, prior to introducing the study condition to the participant. Following this, each participant was asked to complete an Expectancy Scale to assess for possible participant expectancy bias due to lack of blinding (Appendix J). After completion of the visit, ABPM data were downloaded using related software, and an assistant at arms length from the participant printed the output and sealed it in an envelope until later data entry.

To ensure a mechanism to access contact information for participants during their time in the study, participant codes, names, telephone numbers, addresses, and enrollment dates were
entered in a password protected database.

**Trial Manoeuvre**

**Introduction to Allocated Group Condition**

Introductions to the study, initiation of baseline ambulatory blood pressure monitoring, randomization, and weekly ambulatory blood pressure monitoring and data form completion occurred in a variety of settings of the participant’s choosing. Most of the sessions occurred in the woman’s home, her hospital room, her prenatal care provider’s office or clinic, or an antepartum fetal testing unit. More rarely, study contacts occurred in a more public place such as a woman’s workplace. Introduction to allocated group conditions occurred in environments in which an initial practice of quiet rest or guided imagery could be achieved. For example, if this visit were taking place in a woman’s home, the nurse identified the need to have a place for the woman to stretch out to practice her allocated group intervention. Usually the practice session then took place with the woman on a couch or reclining chair or on her bed. If the visit occurred in a clinic, the nurse found a quiet examination or other room in which the woman could recline and rest for a few minutes undisturbed.

**Guided Imagery (Experimental Group)**

The guided imagery intervention in this trial was comprised of: (1) a standardized 10-15 minute introduction to guided imagery, provided by either the principal investigator or research assistant and an introductory guided imagery session with an audio CD scripted for the study (*Guided Imagery Script*, Appendix I); (2) written instructions for the guided imagery intervention (Appendix H) and; (3) asking women to use the technique for 15 minutes at least twice daily for their time in the study (for four weeks, or until she had her baby, whichever came first). Participants were asked to undertake their guided imagery in a quiet environment, with the
study CD and headphones, while resting with their legs elevated, either lying on their side, or
reclining in a chair. They could use guided imagery without the CD if they chose.

The guided imagery script included images associated with rest and calm, focused
breathing, and use of multiple senses to optimize imagery effectiveness. As perception of
pleasant images may vary from individual to individual, a range of potentially soothing images
were described. Participants were encouraged to choose one or more that was particularly
soothing or relaxing for them, or to choose their own images. A standardized script for the audio
CD maximized consistency and minimized introduction of experimenter bias. A draft CD was
pilot-tested prior to the study, with pregnant women and with nurses with expertise in high-risk
pregnancy care and/or in psychology and mental health, who were asked to consider the content,
clarity, flow, and their own response in relation to relaxation level. Some minor changes were
suggested and made, primarily regarding pacing of the verbal portion. Since music may further
enhance the effectiveness of guided imagery techniques in evoking imagery (Moffitt Cook,
2003), and engaging more of the senses (Naparstek, 1994), background music was also included
on the CD.

*Quiet Rest (Control Group)*

For this study, women in the Quiet Rest control group were asked to engage in rest
periods at least 15 minutes long, over and above night-time sleep, a minimum of twice daily for
their time in the study, for four weeks or until the baby was born, which came first. Following
randomization, each woman in the control group received a standardized 10 minute verbal
introduction to the Quiet Rest group condition by the principal investigator or research nurse and
were asked to participate in a demonstration or “practice” 15-minute rest period. The women
were asked to rest quietly with legs elevated, either lying on their side, or reclining in a chair, in
a quiet place, with minimal external stimuli, for example, without reading, watching television,
listening to music or engaging in conversation. Participants in this group also received written instructions for quiet rest. (Appendix H)

Both Groups

All usual care, including all clinical and laboratory assessments for maternal and fetal well being, was provided for both study groups. Routine care in hypertensive pregnancies can vary widely, but tends to have at least one consistent element: recommendations for decreased physical activity. Sixty-one percent of recently surveyed Canadian obstetricians reported they advised their patients with non-severe hypertension to stop work, while 26% recommended strict bed rest for these women (Caetano et al., 2004).

Both groups of women were asked to maintain their allocated study condition, whether at home or in hospital, for the next four weeks or until the baby was born (whichever came first). They were informed that they could continue to use their allocated type of rest after that point if they wished. They were also seen weekly for serial data collection for a maximum of four weeks, or until labour and delivery, whichever came first. This data collection usually was done early in the morning, by either the study investigator or research nurse. The length of time spent with each woman at each weekly visit was similar, and content of the visit was focused as much as possible on the goal of the visit. Participants in the Quiet Rest group were asked to complete a Weekly Assessment Form for Women in the Quiet Rest Group (Appendix J), which included state anxiety items, compliance items and items regarding use of antihypertensive medication that week. Participants in the Guided Imagery group also completed these items, as well as others about their experiences with and ability to use guided imagery that week (Weekly Assessment Form for Women in the Guided Imagery Group, Appendix J).

If participant responses to Weekly Assessment Form (Appendix J) items suggested that use of the allocated study condition in the previous week was less than requested and/or that
guided imagery ratings were low, the nurse asked whether there was any particular reason for this, and provided encouragement and recommendations to help enhance use and success with the technique. Participants were provided with a study contact number and encouraged to call if they had any questions, concerns or difficulties with their allocated study condition or other elements of the study. In addition, weekly ambulatory blood pressure monitoring set-ups and completion of weekly assessment forms and retrieval of blood pressure monitors provided opportunities for the nurse to assess participant use of and difficulties with the allocated condition, and to provide positive reinforcement or encouragement.

At each weekly visit, daytime ambulatory blood pressure monitoring was begun for that day. Two initial monitor readings, approximately five minutes apart, were triggered by the study nurse, to confirm that blood pressure values were not extreme before she left the visit. If one of the two initial blood pressure readings exceeded 160/100 mmHg, the woman was advised to lie down and rest for a few minutes. Second, third and perhaps fourth and fifth readings to assess blood pressure response were then triggered by the research nurse in 15 minute intervals, rather than the usual five minutes, to allow time for blood pressure to adjust to position change. After five readings, the monitor could not display the blood pressure readings, but stored in them in memory only. If either of the blood pressure readings was $\geq 170/110$ mmHg, the woman’s prenatal health care provider was also immediately notified of her blood pressure status, and a plan for timely further physician assessment was in place before the researcher ended the visit. There were two occasions when an early blood pressure value in a given week was $\geq 170/110$ mmHg. In one case, the woman saw her physician, and her baby was delivered by that night. The second woman had been seen by the study nurse during a clinic visit at the time of the blood pressure elevation, and was transferred to the labour and delivery suite for further assessment. No other symptoms of advancing hypertensive disease were noted during any visit to warrant
referral to a physician. If after the initial BP elevation, it fell to $\leq 140/90$ mmHg, the nurse counselled the woman to notify her physician about the reading when she was next in contact. If she had an automatic blood pressure machine at home due to her being cared for as part of a prenatal home care program, she was also asked to check her blood pressure with it later, and if elevated to levels determined by her care provider, to notify that care provider.

Women in the study were blinded to all ambulatory blood pressure readings other than the first five which could be viewed on the monitor display. This is consistent with standard ambulatory blood pressure monitoring practices. During protocol development, the potential for having all blood pressure readings display on the monitor for each measurement was considered. However, in testing the monitors with several individuals prior to initiation of data collection, it was evident that most became very focused on checking every reading. When they were questioned about this observed response, they indicated that they would probably relax more if the blood pressure display were not available to them to check repeatedly. Therefore, the decision was made to follow the standard protocol regarding ABPM and not display the readings beyond the first five.

Arrangements were made with each woman regarding retrieval of the ambulatory blood pressure monitor the next day and a date and time and location for the next weekly data collection visit. All appointments were confirmed with participants the day before the scheduled visit, and women were encouraged to call the investigator or research nurse if they needed to reschedule.

Study participants were asked to have a family member or hospital staff member call the REBIP Study telephone number to inform study personnel when the participant’s baby was born. Receipt of this information enabled the research assistant to access most of the perinatal outcomes data from the woman’s and infant’s health records while they were still in the hospital.
post delivery. Otherwise these data were retrieved at a later date from health records. Study personnel abstracted these data, specific to pregnancy and birth related events including initiation of antihypertensive medication at any point after randomization, hospitalization days, labour, birth and postpartum events and complications for both mother and baby, and clinical blood pressure values for the weeks of study participation on an Outcomes Data Form (Appendix J).

A Postpartum Questionnaire for Women in the Guided Imagery Group and a Postpartum Questionnaire for Women in the Quiet Rest Group (Appendix J) were developed for this study to assess the mothers’ experiences in the trial. Participants were contacted by telephone on the day this was mailed to them, for completion at six weeks postpartum. Participants could choose to complete the questionnaire over the phone with a research assistant or complete the questionnaire on their own and mail it back. If a completed questionnaire had not been received, the research assistant called one week later to confirm their receipt of the questionnaire, and up to twice to follow up if the questionnaire was not subsequently returned (modified Dillman technique).

Outcome Measures

Primary Outcome Measure

Mean Arterial Blood Pressure

The primary outcome, average daytime ambulatory mean arterial pressure, as well as daytime ambulatory mean systolic and diastolic blood pressure and heart rate, were measured using a Spacelabs model 90207 ambulatory blood pressure (ABP) monitor (Seattle, WA, USA) automatically at pre-set intervals, every 30 minutes during maternal daytime waking hours during a 24-hour period, once weekly for a maximum of four weeks after randomization. The timing for the primary outcomes was four weeks after randomization, or if delivery was sooner,
the most recent set of ambulatory blood pressure measurements available.

Maternal blood pressure and heart rate data were stored in the monitor memory, and at the end of each ambulatory blood pressure monitoring (ABPM) session, monitors were retrieved and data downloaded, using Spacelabs ABP analysis system software (90209 Data Interface Unit), into a personal computer designated for this study. Daytime mean values and other trends were automatically calculated by the Spacelabs software and these data were later entered into statistical software for analysis.

MAP has been observed to be a better predictor of negative pregnancy outcomes than SBP or DBP, at least based on clinic measurements (Devarakonda et al., 2002). The difference in mean arterial pressure (MAP) between baseline and the last week ambulatory blood pressure monitoring data were available for the participants provided a change value. Because post-intervention MAP was subtracted from MAP at baseline (prior to intervention), a positive difference indicated an increase in the mean arterial pressure, while a negative difference indicated a decrease in the MAP between baseline and the last week participants were in the study. Analysis was undertaken on the MAP change for all women in each group for whom there was at least one week of outcome data, with outcome data available for 31 of the original 34 women randomized to the Guided Imagery group and for 29 of the original 35 women randomized to the Quiet Rest group.

The Spacelabs model 90207 detects oscillations of arterial pressure (Walker et al., 1998; Waugh et al., 2000) and was validated for use in pregnancy (O'Brien, Mee, Atkins, Halligan, & O'Malley, 1993) and severe pre-eclampsia (Shennan, Halligan, Gupta, Taylor, & de Swiet, 1996), per British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI) criteria, although underestimation in relation to mercury measurements had been reported in pre-eclampsia (Natarajan et al., 1999). Automated oscillimetric blood
pressure measurement devices generally under-estimate blood pressure levels in pre-eclampsia, possibly due to the hemodynamic changes such as increased peripheral vascular resistance, reduced circulating volume and reduced arterial compliance associated with this condition (Reinders et al., 2003).

Isolated measurements of blood pressure can be influenced by a range of stimuli, for example, sleeping, waking, physical activity, and emotional state (Kaplan, 1998a) and may not be representative of blood pressure throughout the day. Moreover, observer error related to memory, sensory acuity, fatigue, biases such as terminal digit preference, and systemic errors such as the detection and recording of Korotkoff sounds is reported with use of conventional mercury sphygmomanometry (Kaplan, 1998b). Because ABPM allows for analysis of multiple measurements and reduces measurement error and examiner expectation bias, it is considered more appropriate than mercury measurements for research evaluation of intervention effects on blood pressure (Hunyor & Henderson, 1996; Lungershausen & Howe, 1994; Pickering, Schwartz, & James, 1995; Staessen et al., 1999), and therefore, ABPM requires fewer subjects for research study (Conway, 1991), and has better reproducibility than office BP: the standard deviation for Spacelabs model 90207 measurement in hypertensive pregnancies is 5 mm Hg, as compared to 7 to 8 mm Hg for intermittent self-measurement with automatic oscillatory monitors and 10 mm Hg for clinic-type mercury methods (A. Shennan, personal communication, January 31, 2003), although higher standard deviations have been reported, for example, 6 mmHg for ABPM daytime DBP, 8 mmHg for SBP (Taylor, Freeman, & North, 2001), and 7 mmHg for mean arterial pressure (Walker et al., 2001). ABPM does not appear to evoke an alerting response during measurement (Verdecchia, Schillaci, Borgioni, Ciucci, & Porcellati, 1997), is convenient, non-invasive, and does not rely on participants’ own abilities, accuracy and memory, or investigator presence to obtain measurements.
Outside of pregnancy, organ damage correlates more highly with ambulatory blood pressure than with conventional clinic blood pressure measures (Verdecchia, 2000). In pregnancies complicated by hypertension, ABPM measurements are more highly predictive of subsequent development of severe hypertension (Penny et al., 1998), proteinuria (Halligan et al., 1997; Peek, Shennan, & Halligan, 1996), and poor perinatal outcomes (Halligan & O'Brien, 1996; Halligan et al., 1997; Peek et al., 1996; Penny et al., 1998; Waugh, 2000) than blood pressure measured in clinics or day assessment units.

Daytime ambulatory blood pressure monitoring was chosen for this study to provide the clearest picture possible of a woman’s “real” blood pressure throughout most of her waking hours during one day per week, rather than clinical blood pressure readings which only would reflect a “moment in time” and which also had the potential of reflecting elevated blood pressure readings associated with white coat hypertension. Twenty-four-hour ambulatory blood pressure measurement in pregnancy has been associated with sleep disturbances (Bellomo et al., 1995; Brown et al., 1998; Halligan et al., 1993; Taylor, Gamble, McCowan, & North, 2001), and hypertensive women have perceived night-time use of ABPM as an additional stressor (Taylor, Freeman et al., 2001). Although previous definitions of daytime versus night-time for ABPM studies in pregnancy had been arbitrary and variable (Ferguson, Neubauer et al. 1994; Halligan, Shennan et al. 1997), recent definitions related to periods of maternal sleep and waking hours (Brown et al., 1998; Kyle et al., 1993; Taylor, Gamble et al., 2001). Despite the fact that ABPM generally tends to be for 24-hour periods, there was evidence that women who have nocturnal hypertension in their third trimester of pregnancy also have higher ABPM BP when awake. This suggested that daytime only measurement would provide a satisfactory reflection of a woman’s serial blood pressure (Brown, Davis, & McHugh, 2001).
All ABP monitors were assessed for accuracy prior to the start of the study and at approximately one year intervals (Spacelabs, 2003); no recalibrations were required. A blood pressure protocol provided guidance for study personnel in measurement technique and instructions on how to teach participants about wearing the monitor.

Secondary Outcome Measures

Daytime Ambulatory Systolic and Diastolic Blood Pressures and Heart Rate

The first of the secondary outcomes were average daytime ambulatory systolic and diastolic blood pressures and heart rate, which were automatically measured, stored in memory and calculated via Spacelabs ABPM model 90207 and managed in the same way described for the primary outcome.

The differences in blood pressures and heart rate between baseline and the last week of available ambulatory blood pressure monitoring data were calculated to provide a change value. Because post-intervention blood pressure and heart rate were each subtracted from the values at baseline (prior to intervention), a positive difference indicates an increase in the mean arterial pressure, while a negative difference indicates a decrease between baseline and last available week. Analysis was undertaken on the blood pressure change for all women in each group for whom there was at least one week of outcome data.

Proportion of Women Receiving Antihypertensive Medication after Randomization

Data recorded in the Outcomes Data Form (Appendix J) enabled calculation of the rates of antihypertensive use after randomization, in pregnancy, during labour and birth, and/or during the postpartum period prior to discharge home. The Weekly Assessment Forms (Appendix J) also contained one item to capture data on antihypertensive medication use during that week. These data then allowed separation and consideration of those women who received such medication
only during the window of time between randomization and the last week for which their ambulatory blood pressure and anxiety data were available, for consideration in relation to possible co-intervention.

*Anxiety*

Maternal anxiety was measured by the State Scale of the State-Trait Anxiety Inventory (STAI Form Y-1) (Spielberger et al., 1983). The STAI was completed at baseline (*Baseline Self-Evaluation Questionnaire, Appendix J*) and then weekly for the intervention period, to a maximum of four weeks. (*Weekly Assessment Forms, Appendix J.* Only samples of STAI items are included in Appendix J due to copyright restrictions. Permission to use the STAI was obtained from Mind Garden, Inc., on October 21, 2004.) Responders were asked to identify the intensity associated with each of 20 items as either “not at all,” “somewhat,” “moderately so,” or “very much so”. Each item received a score of between 1 and 4. Total scores can range between 20 and 80, with higher scores indicating greater anxiety. The instrument has established validity and reliability. Alpha reliability is reported to be high at 0.86 to 0.95 in large nonpregnant samples (Spielberger et al., 1983) and 0.93 in the third trimester of pregnancy (Hodnett & Osborn, 1989). This instrument is used to measure anxiety experienced during a particular period or point in time (Spielberger et al., 1983; Spielberger et al., 1999), for example, within the previous two weeks (Hodnett & Abel, 1986; Hodnett & Osborn, 1989), or since the last clinic visit (Gorsuch & Key, 1974). For this trial, participants were asked to complete the STAI items based on their anxiety “during the past week”.

The difference in anxiety between baseline and the last week of available anxiety data for the participants provided a change value. Because post-intervention anxiety scores were subtracted from baseline scores (prior to intervention), a positive difference indicated an increase in the mean anxiety score, while a negative difference indicated a decrease in the score.
Length of Time from Randomization to Delivery

The date and time of randomization were documented on each Entry Form (Appendix J), while date and time of delivery were documented on each Outcomes Data Form (Appendix J). The difference between these allowed calculation of the time from randomization to delivery.

Blood Pressure Changes in Relation to Frequency of Guided Imagery Practice

The frequency of guided imagery practice was based on participant responses to two questions on the Weekly Assessment Form for Women in the Guided Imagery Group. (Appendix J) The total number of guided imagery uses each day was multiplied by the number of days of GI use reported each week, and weekly totals were then added together to calculate the total “dose” of guided imagery for each Guided Imagery group participant.

Changes in average daytime ambulatory mean arterial pressure, and systolic and diastolic blood pressures were based on the differences as previously described.

Hypertension Classification and Guided Imagery Effectiveness

Although no previous research suggests that women with one type of hypertension would be any more or less likely than another to respond to guided imagery, it was important to consider possible differences in relation to the type of hypertension. Classification of hypertension type was done on the basis of symptoms present at the time of randomization, in relation to the operational definitions of pre-eclampsia, gestational hypertension and chronic hypertension, as described earlier in this chapter, and was documented on the study Entry Form (Appendix J). This classification may or may not have been the same as the final hypertension diagnosis made by the participant’s care provider postpartum, but no data on final clinical hypertension diagnoses were collected for this study.
Means and Standard Deviations for MAP by Week of Exposure to Allocated Condition

Ambulatory blood pressure data collected every 30 minutes during daytime hours once weekly for each week a woman was in the study provided data for descriptive analysis of blood pressure patterns by week in the study. Pregnancy timeframes in which to treat hypertension which may occur are narrow. Previous research of psychological therapies for hypertension outside pregnancy tended to involve several weeks of treatment and such timeframes are not viable during pregnancy. Therefore, it was useful to consider whether mean arterial pressure (MAP) and MAP changes varied by week of exposure to the allocated study condition in each study group.

Relationships between Participant Evaluation of Guided Imagery and Effectiveness

The ability to become absorbed in imagery has been associated with degree of effectiveness of guided imagery for symptom management (Kwekkeboom et al., 1998); thus eight items specific to participant evaluation of their guided imagery experiences were included in the Weekly Assessment Form for Women in the Guided Imagery Group (Appendix J). Five of these items were derived from a previously developed imagery evaluation tool which had been designed for use immediately after a single guided imagery session (Kwekkeboom et al., 1998). Wording and item anchors were adapted for the REBIP Study to better reflect the multiple uses of the guided imagery in this RCT over the previous week and that the imagery was chosen by the participants themselves, rather than images identified by a narrator on the audio-CD. Each imagery evaluation item in the original instrument is on a Likert scale with ratings of 0 for “not at all” to 5 for “very much so.” Negatively-worded items are reverse coded. Higher total scores indicate greater perceived vividness and effectiveness of the imagery, and alpha reliability has been reported as .86 (Kwekkeboom et al., 1998). For the REBIP Study, the anchors were changed to “never” and “all of the time”. Relationships between responses for each item for the
last week data were available and effectiveness of guided imagery on study outcomes were considered. When scores from these items were combined (with reverse scoring for certain items), a total guided imagery evaluation score for the last week was formed, with a maximum combined score of 25. The higher the score, the more positive the rating for the guided imagery.

The remaining three items participants answered about their evaluation of guided imagery included one about the frequency with which they undertook guided imagery using the REBIP Study audio CD, and one about the degree of ease or difficulty participants experienced in doing the guided imagery, each with a forced choice format. The final imagery evaluation item was also derived from the Kwekkeboom (1998) instrument, but was changed to focus specifically on relaxation immediately after participants’ last use of guided imagery (rather than their estimation of an average over the past week), and was based on a 0 to 10 Likert scale anchored by 0 (not at all relaxed) and 10 (completely relaxed).

**Other Outcomes**

*Monitoring Compliance*

The women’s compliance with the allocated study group condition was verified via review of data on frequency of rest periods and guided imagery use per day, and number of days per week, collected weekly from all participants immediately prior to the start of ABP monitoring each week (*Weekly Assessment Form for Women in the Guided Imagery Group* and *Weekly Assessment Form for Women in the Quiet Rest Group*, Appendix J). The process of collecting compliance data was the same for both treatment groups. The researcher, on a weekly basis, elicited participant feedback and provided positive reinforcement of their maintaining allocated study group conditions, to further maximize compliance (Broder, 2000) and reduce loss to follow-up. This frequency also ensured that those in the guided imagery group would receive any reinforcement of technique deemed necessary. Assessment only at the end of the
four-week window would not have provided any opportunity for problems or poor technique to be improved upon. Diary use was not part of the protocol as it is known to be associated with large amounts of missing data (Churchill & Beevers, 1996) and compliance problems, whereby high percentages of diary entries have been shown to have been made retrospectively (Stone, Shiffman, Schwartz, Broderick, & Hufford, 2003). Therefore, having participants document their rest and guided imagery uses once per week was unlikely to add to any possible recall bias, beyond the bias likely if we asked women to document each time they used GI or rested.

Compliance with the active intervention condition was defined as use of guided imagery at least five times per week during the woman’s time in the study, with or without use of the audio CD provided. Although this equates to less than half of the twice daily frequency requested of participants, there was previous evidence to indicate that relaxation responses could be elicited after short periods of time, and there was no clear indication whether a minimal frequency was required to achieve any blood pressure reduction which might be observed. This study provides data to clarify this question.

Although a few women in the Quiet Rest control group utilized relaxation techniques on their own, no guided imagery training was provided to this group by the study staff. As long as women in the Quiet Rest group had at least five quiet rest periods of adequate length (≥ 15 minutes) per week, and did not use guided imagery more than once per week, they were considered compliant with their assigned control condition. If any women changed their minds about participation after random allocation to their study group, reasons for their choice, if known, were documented.

Participant Satisfaction

Participant satisfaction was assessed using the Postpartum Questionnaire for Women in the Guided Imagery Group or Postpartum Questionnaire for Women in the Quiet Rest Group.
(Appendix J), to be completed at six weeks postpartum. Both questionnaires included a series of three forced-choice questions regarding satisfaction with study participation and preferences for future use. Ambulatory blood pressure monitoring methods require women to wear a blood pressure cuff for an extended period of time. Therefore, it was also important to ask women about their experiences with this technology during the study. A total of eight items about ambulatory blood pressure monitoring, similar to those used in other studies (O'Brien, Petrie, Littler, de Swiet, Padfield, Altman, et al., 1993; Taylor, Freeman, & North, 2001), were included in the Postpartum Questionnaires; seven of these were Likert type scales, anchored with a low score of 0 if “not at all” and 5 if “very much so”, and one was an area for participant comments.

Women in the Guided Imagery group were asked to complete an additional eight items about their use of guided imagery during their time in the study. Seven of these items were Likert type scales anchored by “not at all” (0) and “very much so” (5), and focused on ease of use, enjoyment, CD choice and recommending guided imagery to others. The eighth and final item addressed whether and when they might use guided imagery in the future (Postpartum Questionnaire for Women in the Guided Imagery Group, Appendix J).

Relationship between Standard Prenatal and Average Daytime Ambulatory Blood Pressure Measurement

All ambulatory blood pressure measurements were undertaken and recorded as described previously in this chapter. Standard prenatal blood pressure was defined as the reading by a clinician as part of routine care done closest in time that week to the ambulatory session and could be within minutes on the same day ambulatory monitoring was done for the study, or could have been done up to three days earlier or later than the ambulatory session. All standard prenatal blood pressure readings for baseline and each subsequent week a woman participated in the study were abstracted on the study Outcomes Data Form (Appendix J), to a maximum of
four weeks after randomization.

Contamination

Women in the Quiet Rest group were never present for orientation to the guided imagery intervention or did they have access to the guided imagery CD used in this study. Likewise, women in the Guided Imagery group were not introduced to the specifics of the quiet rest condition. Some women may have been allocated to a group other than the one to which they had hoped. An item on the Postpartum Questionnaire (Appendix J), administered at six weeks post-partum, provided data as to the extent to which such disappointments occurred. Participant responses to Weekly Questionnaire (Appendix J) items provided data to assess possible contamination between groups.

Co-interventions

As blood pressure elevation over the intervention period may have resulted in administration of pharmacologic anti-hypertensive agents, these medications could have been a significant co-intervention in this study. At the start of this study, the effect of guided imagery on maternal blood pressure levels was not known, nor was whether BP medication use would be more or less likely in a given study group. If BP levels in the control group were to be higher than in the intervention group, and anti-hypertensive medication were introduced more frequently in that group, the primary outcome of interest, change in blood pressure, could be more dramatic than in the intervention group at the end of the intervention period.

Antihypertensive medication use was documented weekly in the study. Outside of pregnancy, 95% of most types of oral blood pressure medication are excreted within 72 hours after ingestion (Canadian Pharmacists Association, 2006). Because the excretion rates may vary in pregnancy, for the purposes of this study, medication use within one week prior to the last weekly ABP monitoring was deemed to have the potential to influence that set of readings and
thus was considered a potential co-intervention.

To control for influences of attention, the time and frequency of participant-researcher contact (both in person and telephone) were consistent for both groups (Margolin, Avants, & Kleber, 1998; Spence et al., 1999), although content varied in relation to group assignment. To prevent any possible co-intervention resulting from perceived social support during study procedures, the focus of weekly contact with the researcher was directed toward the women’s experience with their allocated study condition and the ABPM, and provision of feedback and positive reinforcement, using a standardized approach. The standardized audio CD also minimized bias. All participants underwent baseline ABPM procedures prior to randomization, had daytime ABPM once weekly for the study period of up to four weeks, and completed outcome measures. Both groups of women were asked about their experience with their study condition and to identify how often per day and how many days per week they rested and used guided imagery.

Treatment outcomes may be influenced by patient or clinician expectancy (Kwekkeboom, 2000; Margolin et al., 1998; Pocock, 1983). As trials of cognitive-behavioural interventions, due to the nature of the intervention, tend to not be masked to group allocation (Stephenson & Imrie, 1998), participant expectancy was measured in this RCT to assess any influence on treatment outcome. At baseline, participants in both groups were asked questions regarding their expectations of response to their study condition and scored their expectancy ratings using a ten-point Likert scale (Borkovec & Nau, 1972) (see Appendix J). Primary outcome data, to which participants were masked, were objectively measured, recorded and downloaded via automated blood pressure monitor, limiting measurement bias on study outcomes.
Losses to Follow-up

A number of approaches were intended to minimize loss to follow-up in this RCT. The guided imagery intervention was standardized, but the imagery script encouraged participants to choose images that they personally found appealing and calming, thus increasing the likelihood that they would continue to engage in daily guided imagery for as long as they were in the study, to a maximum of four weeks. The intervention required only 15 minutes twice daily at times that were convenient to each woman, limiting any potential burden associated with participation. Women in both study groups were provided with a telephone number, and encouraged to call research staff if difficulties arose with the assigned study condition and/or with use of the ambulatory blood pressure monitor. In addition, blood pressure measurements were limited to waking hours only, to minimize attrition due to sleep disturbances associated with night-time monitor use.

Completion of weekly questionnaires occurred at times an ABPM session was being started when a research personnel was present. Questionnaires were pre-tested for readability, clarity, and ease of use (Burns & Grove, 2001; Burns & Grove, 2005). The STAI instrument, used to collect baseline and weekly outcome data, required ten minutes or less to complete; few missing anxiety data were therefore expected.

Despite study entry being initially limited to women less than 34 weeks gestation (and changed fifteen months into the study to less than 37 weeks), and the change in the timing of the primary outcome from four weeks post-randomization, to “four weeks, or if delivery is sooner, the most recent set of ambulatory blood pressure measurements available” to limit attrition due to early delivery, some women giving birth prior to the end of the maximum four-week study period was anticipated.
Sample Size

A sample size of 60 was based on a conservative estimate of the number of hypertensive women likely to meet study criteria, be recruited and agree to participate at the initial study site within a twelve-month period.

It was and is unclear what absolute or relative reduction in blood pressure constitutes a clinically important difference in hypertensive pregnancy. A MAP reduction of 10 mmHg may be important based on non-ambulatory methods of measurement (von Dadelszen & Magee, 2002) but a lesser reduction, such as 5 mmHg, may have clinical benefit (A. Shennan, personal communication, January 31, 2003). A sample size of 60 (in a two-group design) would have greater than 99% power to detect a mean ABPM difference of 10 mmHg in mean arterial pressure with a maximum standard deviation of 5 mmHg, or a 48% power to detect a mean difference of 5 mmHg with a standard deviation of 10 mmHg (See Table 1.).

Table 1.
*Power calculation for RCT*

<table>
<thead>
<tr>
<th>If the standard deviation of differences between repeated measures is:</th>
<th>Power to detect a difference of 10 mm Hg</th>
<th>Power to detect a difference of 5 mm Hg</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 mm Hg</td>
<td>1.0</td>
<td>.968</td>
</tr>
<tr>
<td>6 mm Hg</td>
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<td>7 mm Hg</td>
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</tr>
<tr>
<td>10 mm Hg</td>
<td>.968</td>
<td>.478</td>
</tr>
</tbody>
</table>

However, as this was a feasibility study, the primary objective was not to determine effectiveness, but to determine if an adequately powered RCT of guided imagery on pregnancy outcomes is feasible and warranted. A sample size of 60 was determined to be sufficient to make that determination and it was anticipated that 66 women randomized would allow for
possible attrition due to early delivery.

Data Management and Data Validation

Baseline daytime ambulatory blood pressure monitoring data were gathered the day before randomization. Demographic and other baseline data were collected the day of and immediately prior to randomization. Outcome and descriptive data were collected using paper forms by study personnel, via participants’ completion of forms, and through ABPM recording and downloading. Each page of each form was identified with the participant’s unique study identification code and date of birth as a secondary identifier. Data were double entered into a Microsoft Access™ database by two different research personnel, to minimize entry error, and appropriate logic and range checks were used to verify data accuracy. Any discrepancies or unusual data were checked against the original data forms, and were verified and/or corrected. Data were then imported into statistical analysis software (SPSS™ version 14.0).

Data Analysis

Data were analyzed using SPSS™ version 14.0 statistical analysis software (SPSS Inc., Chicago, IL). All participants who were randomized were included in the statistical analysis in the group to which they were originally assigned, in keeping with an “intention to treat” approach. Baseline variables such as weeks of gestation and demographics were analysed using descriptive statistics, including proportions, means and standard deviations.

The primary outcome of change in daytime mean arterial pressure between baseline and at the last week data were available was compared between groups using unpaired t-tests. A two-sided p value of 0.05 was indicative of statistical significance; two-sided tests of hypotheses were used since there was limited evidence of either benefit or risk of the guided imagery intervention on blood pressure in hypertensive pregnancy. Significance levels for secondary
questions were at a .01 level to reflect the multiple comparisons planned. Secondary analysis was done to adjust for mean arterial pressure and gestation baseline values using multiple linear regression. Continuous secondary outcomes such as mean diastolic and systolic blood pressure changes and anxiety score change were analyzed using unpaired t-tests, and presented with standard deviations and 95% confidence intervals.

Dichotomous variables were analysed using chi-squared 2 x 2 contingency table calculations or Fisher’s exact tests. Relationships between outcomes, total dosage of guided imagery, and participant evaluation of guided imagery were evaluated through use of correlations. ANOVA analyses were planned to assess effects in relation to hypertension category, but only descriptive analyses could be undertaken, due to small group sizes. Likewise, comparisons of average daytime mean arterial pressure change by week in the study were presented using descriptive statistics. The extent of influence of co-interventions, primarily concurrent use of antihypertensive medication, on outcomes, was explored first through undertaking independent t-tests with all participants who received antihypertensive medication during their last week of study participation removed from the analyses, and then with multiple linear regression. Demographic and other baseline variables, as well as key labour, birth and maternal and newborn health outcomes during the intrapartum hospitalization period and maternal satisfaction were analysed and compared using descriptive statistics, including means, medians, standard deviations and proportions.

Statistical analysis occurred at completion of all recruitment and data collection for the study. Neither interim analysis, nor use of a Data Safety and Monitoring Committee were undertaken, due to the small sample size and short period planned for data collection.
Ethical Considerations

The Human Subjects Review Committee at the University of Toronto, and the Research Ethics Board or Human Investigation Committee at each of the study sites approved the study protocol. Women were informed of the study during pregnancy and were invited to participate if eligible. Signed informed consent was sought from all eligible potential participants. Participants received verbal and written explanations of the study, including potential risks and benefits, and a copy of the consent. The women were informed that they could withdraw from the study at any time without penalty to themselves or their babies. All participant data were kept confidential. Codes, but no names, were used on questionnaires and other forms. All data on paper and computer media were housed in secure locked filing cabinets. Signed consent forms were housed separately from the data, in locked cabinets. Study data and signed consent forms were accessible only to study staff. Only group data are reported. There are no known risks to participants associated with the use of guided imagery. As the effectiveness of guided imagery in reducing blood pressure in pregnancy is yet to be demonstrated, standard pharmaceutical antihypertensive treatment was not withheld during the study. For this study, clinical decision-making was based on routinely used blood pressure measurement methods, rather than study readings, and pharmacologic anti-hypertensive agents were instituted by physicians as they deemed to be clinically indicated. Therefore, participants were at no additional health risk as a result of study participation.

The study protocol required that research personnel immediately refer any study participant exhibiting evidence of possible advancing hypertensive illness during any episode of assessment during the study to the woman’s obstetric care provider. Evidence included the following indicators: (1) diastolic blood pressure $\geq 110$ mm Hg (based on the initial two readings at the start of each daytime ABPM session); (2) systolic blood pressure $\geq 170$ mm Hg
(based on two readings at the start of each ABPM session); (3) upper abdominal pain (epigastric and right upper quadrant pain in particular); (4) headache, visual disturbance, or other cerebral symptoms; (5) shortness of breath; and/or (6) decreased fetal movement, as reported by the mother. When study participants requested advice on matters beyond the focus of the researcher-participant contacts or had additional problems, research personnel referred them to their care provider.

The trial protocol was registered at ClinicalTrials.gov, identifier number NCT00303173.
CHAPTER 4: RESULTS

The Sample

Of the 554 women screened by clinicians or who made direct contact with research staff, 125 (22.6%) were assessed to be eligible for the Relaxation and Blood Pressure in Pregnancy Study and were referred to the study (Figure 3). The most common primary reasons for noneligibility were gestation beyond the study inclusion criteria (n = 143; 33.3%) and antihypertensive medication use (n = 124; 28.9%); for 73 of the cases, the reason for ineligibility was not recorded by the clinician and is unknown. Of those women referred to the study, nine additional women were subsequently determined to be ineligible, due to one or more reasons: a high likelihood of giving birth within 10 days (n = 4); antihypertensive medication use (n = 2); not enough time to make a decision before the gestational week cut-off for eligibility (n = 2); less than two documented diastolic blood pressure readings of at least 90 mmHg (n = 2); and no clinical investigation of increased blood pressure undertaken (n = 1); one additional woman could not have blood pressure measurements using cuffs due to a health condition. Ninety women provided consent, and of these, ten women changed their minds, most commonly because the ambulatory blood pressure measurements during their baseline data collection were uncomfortable (n = 3). Thus, of the 115 women determined to be eligible by study personnel, 70% (n = 80) agreed to participate and to be randomized. A further ten women developed exclusion criteria prior to randomization, most commonly due to deteriorated maternal and/or fetal health requiring delivery (n = 6), and there was no BP cuff to fit one woman.

Sixty-nine women were randomized, with 34 randomly allocated to the Guided Imagery experimental group and 35 to the Quiet Rest comparison group. Figure 3 provides a summary of sample recruitment and flow of participants through the study. Three women in the Guided Imagery group and six in the Quiet Rest group had no primary outcome data available due to
giving birth \((n = 5)\) or discontinuing their participation \((n = 4)\) prior to any outcome data collection.

**Figure 3.** Flow diagram.

- **554 women screened by clinicians for eligibility**
  - 429 ineligible
    - Gestation \((n = 143)\)
    - BP \((n = 63)\)
    - Anti-hypertension medication \((n = 124)\)
    - Likely to deliver \((n = 17)\)
    - Other \((n = 9)\)
    - Reason not identified \((n = 73)\)
- **125 women assessed as eligible and referred to study**
  - 35 excluded
    - Did not meet inclusion criteria \((n = 9)\)
    - Declined to participate \((n = 25)\)
    - BP only measurable with Doppler \((n = 1)\)
- **90 met criteria and consented**
  - 21 not randomized
    - Developed exclusion criteria \((n = 10)\)
    - Changed mind \((n = 10)\)
    - No cuff to fit \((n = 1)\)
- **Randomized \((n = 69)\)**
  - **34 allocated to and received Guided Imagery**
    - Lost to follow-up
      - Reasons:
        - Gave birth \((n = 1)\)
        - Withdrew \((n = 2)\)
    - Data collected at end of:
      - Week 1 \((n = 31)\)
      - Week 2 \((n = 24)\)
      - Week 3 \((n = 18)\)
      - Week 4 \((n = 16)\)
      - Last week data available \((n = 31)\)
    - 31 analysed for 1st outcome
  - **35 allocated to and received Quiet Rest**
    - Lost to follow-up
      - Reasons:
        - Gave birth \((n = 4)\)
        - Withdrew \((n = 2)\)
    - Data collected at end of:
      - Week 1 \((n = 29)\)
      - Week 2 \((n = 25)\)
      - Week 3 \((n = 21)\)
      - Week 4 \((n = 16)\)
      - Last week data available \((n = 29)\)
    - 29 analysed for 1st outcome
- **Reasons for declining:**
  - Stressed/anxious \((n = 7)\)
  - Busy \((n = 6)\)
  - Perceived high BP settled/ temporary \((n = 3)\)
  - All BP measurement painful \((n = 1)\)
  - Not interested in wearing BP monitor \((n = 1)\)
  - Already relaxed \((n = 1)\)
  - No reason given \((n = 6)\)
- **Reasons for changing mind:**
  - BP measurement uncomfortable \((n = 3)\)
  - Stressed/anxious \((n = 2)\)
  - Busy \((n = 2)\)
  - Not feeling well \((n = 1)\)
  - Perceived BP settled \((n = 1)\)
  - No reason given \((n = 1)\)

\(^{a}\) Ambulatory blood pressure monitoring (ABPM) data were not available for 1 woman due to a technical problem; thus \(n\) for ABPM data = 30.
Baseline characteristics

Table 2 provides an overview of the study groups’ baseline characteristics. Participants ranged in age from 17 to 38 years, with a mean of 29.0 ± 4.9 years. Gestation at baseline ranged from six weeks and one day to 36 weeks and six days (median = 33.29; IQR = 4.57), with a median gestation of 32.50 weeks (IQR = 6.64) for the Guided Imagery group and 33.29 weeks (IQR = 4.29) for the Quiet Rest group; nearly 70% of the pregnancies were at least 30 weeks gestation. The sample was predominantly Caucasian, reflective of the demographics of the cities in which the study was undertaken. Well over three-quarters of the sample had completed postsecondary education (n = 50; 83.3%), and most (n = 68; 98.5%) were in spousal relationships. The large majority of the women (n = 57; 82.6%) were not working outside the home at the time of randomization. Seventeen (24.6%) were prenatal hospital inpatients at randomization, 18 (26.1%) were being followed in a prenatal home care program, while the remaining 34 (49.3%) were having their clinical prenatal care managed as outpatients. Mean state anxiety score was 37.97 (SD = 9.40), while the mean rating for their expectancy regarding their allocated study treatment was 39.09 (SD = 7.10) out of maximum score of 50.

Mean ambulatory blood pressure values were 95.2 (SD = 8.0) for mean arterial pressure, 127.8 mmHg (SD = 9.82) for systolic BP and 79.2 mmHg (SD = 7.59) for diastolic BP. Of the 69 women who met inclusion criteria (including two or more prenatal diastolic BP readings ≥ 90 mmHg) and were randomized, only 22 (31.9%) actually had average baseline ambulatory daytime diastolic blood pressure ≥ 85 mmHg and/or systolic blood pressure ≥ 135 mmHg consistent with the definition of hypertension based on ambulatory readings (Padwal et al., 2007; Magee, Helewa, Moutquin, von Dadelszen, et al., 2008).

There were almost twice as many nulliparous women in the Quiet Rest Group, and the only twin pregnancies were in the Quiet Rest Group. In other respects the two groups appeared...
to be similar in baseline characteristics.

Table 2.
Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Guided Imagery group</th>
<th>Quiet Rest group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 34)</td>
<td>(n = 35)</td>
</tr>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td>Gestational age (weeks), median (interquartile range)</td>
<td>32.50 (6.64)</td>
<td>33.29 (4.29)</td>
</tr>
<tr>
<td>Type of gestation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singleton</td>
<td>34 (100%)</td>
<td>32 (91.4%)</td>
</tr>
<tr>
<td>Twin</td>
<td>0</td>
<td>3 (8.6%)</td>
</tr>
<tr>
<td>Maternal age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 20</td>
<td>1 (2.9%)</td>
<td>2 (5.7%)</td>
</tr>
<tr>
<td>20-35</td>
<td>30 (88.2%)</td>
<td>30 (85.6%)</td>
</tr>
<tr>
<td>&gt;35</td>
<td>3 (8.7%)</td>
<td>3 (8.7%)</td>
</tr>
<tr>
<td>Para</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>11 (32.4%)</td>
<td>21 (60.0%)</td>
</tr>
<tr>
<td>1</td>
<td>23 (67.6%)</td>
<td>12 (34.3%)</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>1 (2.9%)</td>
</tr>
<tr>
<td>&gt;2</td>
<td>0</td>
<td>1 (2.9%)</td>
</tr>
<tr>
<td>Hypertension type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic</td>
<td>6 (17.6%)</td>
<td>3 (8.6%)</td>
</tr>
<tr>
<td>Gestational</td>
<td>25 (73.5%)</td>
<td>29 (82.9%)</td>
</tr>
<tr>
<td>Pre-eclampsia</td>
<td>3 (8.8%)</td>
<td>3 (8.6%)</td>
</tr>
<tr>
<td>Other complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>3 (8.8%)</td>
<td>4 (11.4%)</td>
</tr>
<tr>
<td>Pre-existing</td>
<td>0</td>
<td>2 (5.8%)</td>
</tr>
<tr>
<td>Gestational</td>
<td>3 (8.8%)</td>
<td>2 (5.7%)</td>
</tr>
<tr>
<td>Preterm labour</td>
<td>1 (2.9%)</td>
<td>2 (5.7%)</td>
</tr>
<tr>
<td>Vaginal bleeding</td>
<td>0</td>
<td>1 (2.9%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (8.8%)</td>
<td>1 (2.9%)</td>
</tr>
<tr>
<td>Current Smoker</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (2.9%)</td>
<td>2 (5.7%)</td>
</tr>
<tr>
<td>No</td>
<td>33 (97.1%)</td>
<td>33 (94.3%)</td>
</tr>
<tr>
<td>Education completed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less than high school</td>
<td>1 (2.9%)</td>
<td>0</td>
</tr>
<tr>
<td>High school</td>
<td>7 (20.6%)</td>
<td>11 (31.4%)</td>
</tr>
<tr>
<td>Community college</td>
<td>9 (26.5%)</td>
<td>5 (14.3%)</td>
</tr>
<tr>
<td>University or higher</td>
<td>17 (50.0%)</td>
<td>19 (54.3%)</td>
</tr>
</tbody>
</table>
Table 2
Baseline Characteristics (continued).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Guided Imagery group</th>
<th>Quiet Rest group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethnic background</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>31 (91.2%)</td>
<td>35 (100%)</td>
</tr>
<tr>
<td>Black</td>
<td>3 (8.8%)</td>
<td>0</td>
</tr>
<tr>
<td>Aboriginal/First Nations</td>
<td>1 (2.9%)</td>
<td>0</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married/stable relationship</td>
<td>33 (97.1%)</td>
<td>35 (100%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (2.9%)</td>
<td>0</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not working</td>
<td>27 (79.4%)</td>
<td>30 (85.7%)</td>
</tr>
<tr>
<td>Full time</td>
<td>5 (14.7%)</td>
<td>4 (11.4%)</td>
</tr>
<tr>
<td>Part time</td>
<td>2 (5.9%)</td>
<td>1 (2.9%)</td>
</tr>
<tr>
<td>Patient status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital inpatient</td>
<td>8 (23.5%)</td>
<td>9 (25.7%)</td>
</tr>
<tr>
<td>Home care program</td>
<td>11 (32.4%)</td>
<td>7 (20.0%)</td>
</tr>
<tr>
<td>Outpatient not on home care</td>
<td>15 (44.1%)</td>
<td>19 (54.3%)</td>
</tr>
<tr>
<td>State anxiety, mean (SD)</td>
<td>37.91 (8.32)</td>
<td>38.03 (10.46)</td>
</tr>
<tr>
<td>Expectancy score mean (SD)</td>
<td>39.76 (6.87)</td>
<td>38.43 (7.36)</td>
</tr>
<tr>
<td>MAP, mean (SD)</td>
<td>96.76 (8.34)</td>
<td>93.69 (7.47)</td>
</tr>
<tr>
<td>Systolic, mean (SD)</td>
<td>129.82 (11.04)</td>
<td>125.83 (8.16)</td>
</tr>
<tr>
<td>Diastolic, mean (SD)</td>
<td>80.38 (7.35)</td>
<td>78.00 (7.74)</td>
</tr>
<tr>
<td>Heart rate, mean (SD)</td>
<td>91.38 (11.25)</td>
<td>94.49 (11.62)</td>
</tr>
</tbody>
</table>

Note. Percentages may not total 100 due to rounding.

Compliance

Compliance with study group allocation was excellent during this study. Compliance for women in the Guided Imagery (GI) group was defined as the use of guided imagery, with or without use of the compact disc (CD) provided, at least five times per week. For women in the Quiet Rest group, compliance was considered to be at least five rest periods equal to or greater than (≥) 15 minutes per week, and guided imagery use of no more than once per week.

The mean frequency of guided imagery use in the GI Group ranged from 9.7 (SD = 3.8) in week one, to 10.1 (SD = 4.1) in week two, 9.3 (SD = 3.8) in week three and 8.9 (SD = 4.5) in
week four. There were five instances when reported frequency of guided imagery use was less than five times in a given week and thus were considered to be non-compliant. In any one week, the maximum frequency of noncompliance was two occurrences, as represented in table 3. Three women were noncompliant with their guided imagery for one week; a fourth woman was noncompliant for two weeks. These four women were noted to also have low frequencies of guided imagery use, at five to six times per week during the other weeks they were in the study.

Table 3.
Reasons for Women in Guided Imagery (GI) Group Undertaking GI Less than 5 Times per Week

<table>
<thead>
<tr>
<th>Week</th>
<th>GI &lt; 5 times/ week no. (%)</th>
<th>Reason(s) given$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2 (6.7%)</td>
<td>Too busy at home</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Family illness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Personal illness</td>
</tr>
<tr>
<td>2</td>
<td>1 (4.2%)</td>
<td>Outside noise disruptive</td>
</tr>
<tr>
<td>3</td>
<td>1 (5.0%)</td>
<td>Family and personal illness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Too busy at work and with small child</td>
</tr>
<tr>
<td>4</td>
<td>1 (6.2%)</td>
<td>Family illness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>On blood pressure medication</td>
</tr>
</tbody>
</table>

Note. At week 1, n = 30; at week 2, n = 24; at week 3, n = 20; at week 4, n = 16

$^a$ may have identified > 1 reason

On a weekly basis, women in the Quiet Rest group reported that they rested without any special techniques at least 15 or more minutes (other than nighttime sleep) from four to more than 14 times per week. There were three times when women in the Quiet Rest group reported frequency of rest less than five times in a given week and thus were considered non-compliant. No participants in this group reported use of guided imagery; however, two women in the Quiet Rest group reported using progressive muscle relaxation during their rest periods during the study, which had the potential to elicit a relaxation response. In any one week, the maximum
occurrence of noncompliance in the Quiet Rest group was once. Three women in the Quiet Rest group reported being noncompliant with their allocated group condition, each for one week of their time in the study; for the remainder of their time in the study, their rest periods were consistently above the compliance level of five times per week, with frequencies of use per week ranging between seven and greater than 14. Two women did not identify a reason why they rested so infrequently, while a third woman indicated she was too busy with house guests.

Research Questions

Primary Research Question

There was a statistically significant difference between groups in changes in mean arterial pressure (MAP) \( t = 2.36, p = .02 \); mean arterial pressure increased significantly more between baseline and the last week of available data in the Quiet Rest group (M = 5.93 mmHg, SD = 6.55) than in the Guided Imagery intervention group (M = 1.58, SD = 7.63). See Table 4.

<table>
<thead>
<tr>
<th>Guided imagery group</th>
<th>Quiet Rest group</th>
<th>Between-Treatment Group Difference [95% CI]</th>
<th>t-statistic</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n = 31) Mean (SD)</td>
<td>(n = 29) Mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAP change (in mmHg)</td>
<td>1.58 (7.63)</td>
<td>5.93 (6.55)</td>
<td>4.35</td>
<td>2.36</td>
</tr>
</tbody>
</table>

There were 25 women (86.2\%) in the Quiet Rest group who had an increase in their MAP between baseline and the last week they were in the study, compared with 17 women (54.8\%) in the Guided Imagery intervention group. Two participants in the Guided Imagery group and one in the Quiet Rest group had no change in their MAP during their time in the study; however, 12 women (38.7\%) from the Guided Imagery group had a reduction in their
MAP compared to three (10.3%) in the Quiet Rest group (Fisher’s exact test = 7.24, p = .02).

As change scores alone can overcorrect for initial blood pressure values and introduce more error variance (Norman & Streiner, 2000), post-hoc analysis was then undertaken to adjust for baseline values of mean arterial pressure, using a multiple linear regression approach. Baseline mean arterial pressure and group allocation (as a dummy variable) were entered in the model as independent variables, and mean arterial pressure at the last week ambulatory blood pressure data were available was entered as the dependent variable. A least squares “enter” or “simultaneous” method was used to enter the variables, as the sample was relatively small (n = 60). The regression revealed that the model was significant, with F (2, 59) = 5.41, p = .007, and accounted for a modest 16% of the variance in MAP change ($R^2 = .16$), much less than the desired $R^2$ of .7 or more (Norman & Streiner, 2000). As expected, due to the regression to the mean phenomenon, baseline mean arterial pressure (MAP) was strongly predictive of MAP change between baseline and the last week of study participation in this model at a statistically significant level. However, in this model, the contribution of group allocation to the MAP outcome variability was close to but did not reach a statistically significant level ($\beta = -.24$, $p = .06$). (Table 5)

As there are changes in cardiovascular parameters as pregnancy proceeds, gestation at study entry could possibly influence cardiovascular responses to the intervention. Therefore, a second multiple logistic regression model was run, with gestation added along with group and baseline mean arterial pressure as predictor variables for the dependent variable of mean arterial pressure change. This new model indicated that the three variables now accounted for slightly more of the variability in MAP change than the previous regression (21% versus 16%). The contribution of group allocation to the variability remained at a non-significant level ($\beta = -.19$, $p = .14$). The standardized coefficients ($\beta$) for the other independent variables were all greater
than 0.1. Tolerances were not close to zero, indicating that multicollinearity was not a problem in this model, and plots of regression residuals supported the assumptions of normality and linearity.

Table 5.
*Group, baseline mean arterial pressure (MAP) and baseline gestational age in predicting MAP change at the last week of study participation*

<table>
<thead>
<tr>
<th>Variable</th>
<th>$\beta$</th>
<th>t</th>
<th>Confidence Interval</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>(95% CI)</td>
<td></td>
</tr>
<tr>
<td><strong>Model 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group allocation</td>
<td>-.24</td>
<td>1.91</td>
<td>-7.15, .16</td>
<td>.06</td>
</tr>
<tr>
<td>MAP at baseline $^a$</td>
<td>-.27</td>
<td>2.20</td>
<td>.52, .98</td>
<td>.03</td>
</tr>
<tr>
<td><strong>Model 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group allocation</td>
<td>-.19</td>
<td>1.51</td>
<td>-0.90, 6.38</td>
<td>.14</td>
</tr>
<tr>
<td>MAP at baseline $^a$</td>
<td>-.29</td>
<td>2.39</td>
<td>-.49, -.04</td>
<td>.02</td>
</tr>
<tr>
<td>Baseline gestation</td>
<td>.24</td>
<td>2.00</td>
<td>-.001, 0.58</td>
<td>.05</td>
</tr>
</tbody>
</table>

N = 60

$^a$ MAP = mean arterial pressure

Model 1: $\hat{R}^2 = .16$, $F(2, 59) = 5.41$, $p = .007$; Model 2: $\hat{R}^2 = .21$, $F(3, 59) = 5.12$, $p = .003$

Although group allocation was not significantly predictive of MAP change in either of these models, interaction analysis was undertaken to explore the extent to which guided imagery effect on mean arterial pressure change was influenced by interactions between group allocation and (1) gestation and (2) baseline MAP. These interactions were then added to form a third model, but did not add appreciably to the ability of the model to predict MAP change, and thus were dropped. Overall, even though group allocation did not reach statistical significance, it is important to note its relative contribution to the second model, based on a beta of -.19.
Mean Arterial Pressure Change without Twin Pregnancies

All three twin pregnancies in the sample were in the Quiet Rest group. Primary outcome data were available for two of these, as one of the women carrying twins delivered prior to the end of the first week in the study. As twin pregnancy results in more significant cardiovascular alterations of pregnancy, and thus potentially different response to blood pressure treatment, t-tests of group effects on change in average daytime ambulatory mean arterial pressure were rerun without the twin pregnancies; the differences in mean arterial pressure change remained statistically significant (Table 6).

Table 6.
Group Comparison of Changes in Mean Arterial Pressure (MAP) from Baseline to End of Intervention Period, with Twin Pregnancies excluded.

<table>
<thead>
<tr>
<th></th>
<th>Guided imagery group (n = 31)</th>
<th>Quiet Rest group (n = 27)</th>
<th>Between-Treatment Group Difference [95% CI]</th>
<th>t-statistic</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAP change</td>
<td>1.58 (7.63)</td>
<td>6.11 (6.72)</td>
<td>4.53</td>
<td>2.38</td>
<td>.02</td>
</tr>
<tr>
<td>(in mmHg)</td>
<td></td>
<td></td>
<td>[-.8.34, -.72]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Secondary Research Questions

Results related to each of the secondary research questions posed in this study will be addressed sequentially in the following pages.

Guided Imagery Effect on Mean Daytime Ambulatory Systolic and Diastolic Blood Pressure and Heart Rate.

Table 7 provides the results of the statistical analysis for the comparison between groups for the secondary outcomes involving ambulatory blood pressure and heart rate readings. The blood pressure differences between groups were not statistically significant (for systolic, \( p = 0.12 \); for diastolic, \( p = .74 \)). For heart rate, the difference between groups was also not statistically significant (\( p = .84 \)).
Table 7. *Comparisons of Mean Changes of Systolic and Diastolic Blood Pressures and Heart Rate from Baseline to End of Intervention*  

<table>
<thead>
<tr>
<th></th>
<th>Guided imagery group (n = 31)</th>
<th>Quiet Rest group (n = 29)</th>
<th>Between-Treatment Group Difference [95% CI]</th>
<th>t-statistic</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SBP</strong></td>
<td>1.35 (7.54)</td>
<td>6.59 (8.09)</td>
<td>5.23 [9.27, 1.19]</td>
<td>2.59</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>DBP</strong></td>
<td>1.84 (7.88)</td>
<td>5.45 (7.43)</td>
<td>3.61 [-.36, .57]</td>
<td>1.82</td>
<td>0.74</td>
</tr>
<tr>
<td><strong>HR</strong></td>
<td>.97 (9.26)</td>
<td>.52 (7.48)</td>
<td>-0.45 [-4.82, 3.92]</td>
<td>.21</td>
<td>0.84</td>
</tr>
</tbody>
</table>

*Note.* SBP = Systolic blood pressure in mmHg; DBP = Diastolic blood pressure in mmHg; HR = Heart rate in beats per minute (bpm)

**Guided Imagery Effect on Proportion of Women who received Antihypertensive Medication**

Data regarding antihypertensive medication use subsequent to randomization were not available for four (5.8%) of the 69 participants, due to not delivering at a study hospital (n = 3) or changing her mind about participating in the study (n = 1). Sixteen women in the Guided Imagery group and 20 women in the Quiet Rest group received no antihypertensive medication. Antihypertensive medication was administered to 13 (37.1%) of 35 women in the Quiet Rest group and 16 (47.0%) of the 34 women in the Guided Imagery intervention group between randomization and post-partum discharge. Differences were not statistically significant ($\chi^2$ = 0.74, p = .46). (Appendix K).

**Guided Imagery Effect on Maternal Anxiety**

For the 60 women with at least one week of outcome data, anxiety scores fell slightly between baseline and the last week women were in the study, with a mean difference over time of -1.02 points (SD = 8.54). The differences for individual women ranged from a drop of 17 points to an increase of 16 points. Mean anxiety scores decreased slightly in both groups; the
difference between groups was not statistically significant (Table 8).

Table 8.

<table>
<thead>
<tr>
<th></th>
<th>Guided imagery group (n = 31)</th>
<th>Quiet Rest group (n = 29)</th>
<th>Between-Treatment Group Difference [95% CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>[95% CI]</td>
</tr>
<tr>
<td>State anxiety change a</td>
<td>-1.87 (9.20)</td>
<td>-.10 (7.83)</td>
<td>-1.77 [-6.57, 2.66]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>-.78 .43</td>
</tr>
</tbody>
</table>

* Based on the state portion of the STAI

**Guided Imagery Effect on Length of Time from Randomization to Delivery**

The mean time to delivery was 40.54 days (SD = 43.12). The mean number of days to delivery in the Guided Imagery group was 47.25 (SD = 54.14), and in the Quiet Rest group was 34.03 (SD = 28.12); t = 1.24, p = .22.

**Blood Pressure Changes in Relation to Frequency of Guided Imagery Practice**

Women in the Guided Imagery group reported using guided imagery for three or more days per week, for each of the weeks of their study participation. All used GI once or twice per day for those days, with one exception: one woman who used GI infrequently in weeks one through three did not use GI at all in week four. (Appendix L). On a weekly basis, 25% to 45.8% of women reported undertaking the full number of guided imagery sessions in which they were asked to engage; however, women did not report using the guided imagery intervention any more frequently than the twice per day that was asked of them. The mean reported total weekly use of guided imagery ranged between 8.9 and 10.1 uses per week (SD = 3.8 to 4.5). Although this was 63.8% to 72.0% of the twice daily guided imagery use that they were requested to undertake, use far exceeded the minimum five times per week required for compliance.
For the 31 women in the Guided Imagery group who had at least one set of ambulatory blood pressure data and had completed at least one weekly assessment form, the mean total guided imagery uses while they were in the study was 27.87 (SD =16.49). Ambulatory mean arterial pressure (MAP) changes between baseline and each week were examined in relation to the frequency of guided imagery use reported by those women each week. Correlations indicate no evidence of relationships between the dosage of guided imagery during the last week and changes in MAP, SBP and DBP at the last available week, with Pearson \( r \) of -0.11, -0.08, and -0.09 respectively. No statistically significant relationships were found between the total number of guided imagery uses during women’s time in the study (total guided imagery dose) and MAP change (\( r = -.33, p = .07 \)), SBP change (\( r = -.35, p = .07 \)) and DBP changes (\( r = -.25, p = .18 \)).

**Guided Imagery Effects and Hypertension Classification**

Of the 31 women from the Guided Imagery group with outcome data, 24 (77.4 %) were classified as having gestational hypertension, five (16.1%) as having chronic hypertension, and two (6.4 %) as having pre-eclampsia at the time of randomization.

Differences in ambulatory mean arterial pressure, systolic and diastolic blood pressures, heart rate and anxiety between baseline and the last available week of data were considered for the three hypertension types. Because group sizes for two of the three hypertension classification groups were small, the ANOVA analyses originally planned were not appropriate (Table 9).
Table 9.

*Hypertension Classification and Change in Blood Pressure, Heart Rate and Anxiety between Baseline and Last Available Week for Guided Imagery Group (N = 31)*

<table>
<thead>
<tr>
<th>Change in Outcome</th>
<th>Chronic Hypertension (n = 5)</th>
<th>Gestational Hypertension (n = 24)</th>
<th>Pre-eclampsia (n = 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>MAP</td>
<td>-3.40 (4.72)</td>
<td>2.42 (7.13)</td>
<td>4.00 (18.38)</td>
</tr>
<tr>
<td>SBP</td>
<td>-1.40 (4.39)</td>
<td>1.71 (7.93)</td>
<td>4.00 (11.31)</td>
</tr>
<tr>
<td>DBP</td>
<td>-5.20 (7.50)</td>
<td>2.87 (6.33)</td>
<td>7.00 (19.80)</td>
</tr>
<tr>
<td>HR</td>
<td>5.40 (15.82)</td>
<td>-0.79 (6.72)</td>
<td>11.00 (12.73)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>2.20 (8.14)</td>
<td>-1.75 (9.13)</td>
<td>-13.50 (0.71)</td>
</tr>
</tbody>
</table>

*Note:* MAP = mean arterial pressure; SBP = systolic blood pressure; DBP = diastolic blood pressure; all derived from daytime ambulatory measurements; HR = heart rate

*Means and Standard Deviations for Daytime MAP by Week in Study*

Average daytime mean arterial pressure (MAP) for the Guided Imagery group remained similar across weeks, within approximately 2 mmHg of mean baseline value, but increased more for the Quiet Rest group. (*Figure 4*).
**Figure 4** Daytime ambulatory mean arterial pressure (MAP) change after 1, 2, 3 and 4 weeks of exposure to allocated study condition

![Graph showing MAP change](image)

Note. Error bars show mean +/- 1 standard deviation

For GI group: At week 1, \( n = 30 \); week 2, \( n = 24 \); week 3, \( n = 18 \); week 4, \( n = 16 \)

For QR group: At week 1, \( n = 29 \); week 2, \( n = 25 \); week 3, \( n = 21 \); week 4, \( n = 16 \)

**Participant Evaluation of Imagery Experiences and Effectiveness of Guided Imagery**

Weekly participant ratings of their guided imagery experiences indicated a high degree of acceptability of the active intervention. When asked each week to rate the ease or difficulty of doing the guided imagery, the large majority of women responding rated it as “very easy” or “somewhat easy”, with percentages increasing with time spent in the study, from 76.5% at week one to 86.7% at week four.

The women using guided imagery reported their minds wandering to a moderate degree (weekly medians 2.0 to 3.0 on a Likert scale of 0 to 5, IQRs = 2.0-3.0) but overall, women had little to moderate difficulty concentrating on the imagery, with a trend toward less difficulty concentrating with each progressive week in the study (medians 2.5 to 1.0, IQRs 1.75-3.75).
Although the range for ratings regarding difficulty picturing the images again ranged from the lowest possible to the highest possible, the weekly median rating was 1 for each of the four weeks when the highest rating possible was 5 (IQRs = 1.0-2.0). Most respondents indicated that their imagery appeared real to a high degree, with a median rating of 4 for each week (IQRs = 1.0 - 1.75). Likewise, most respondents consistently rated their enjoyment of the imagery highly each week; the median rating for each of the four weeks was 4 of a maximum of 5 (IQRs = 1.0 - 2.0); two-thirds of the 30 women responding at week one rated their enjoyment of the imagery as either 4 or 5 out of a maximum rating of 5.

When scores from the five weekly evaluation questionnaire items were combined (with reverse scoring for three of the items), a total guided imagery evaluation score was formed with a maximum possible score of 25. Cronbach’s alpha was found to be .71. After one week in the Guided imagery group (n = 30), scores ranged from 10 to 23 (median = 17.0; IQR = 6.0). At the end of the second week (n = 24), scores ranged from 9 to 25 (median = 17.5; IQR = 4.75). At the third week (n = 20), scores ranged from 11 to 25 (median = 18.5; IQR = 6.75), and for the fourth week (n = 15), scores ranged from 11 to 25 (median = 20.0; IQR = 7.0). For the last week of study participation, scores ranged from 10 to 25 (median = 17.0, IQR = 8.0).

Although most women used the study CD for their guided imagery sessions, their reliance on it fell as their time in study increased, suggesting an increasing ability to and/or desire to undertake the imagery on their own. The mean weekly rating of relaxation levels immediately after their last use of guided imagery (on a Likert scale of 0 to 10, when 10 was the greatest relaxation possible) was 7.9 ± 1.9 in week one, 7.9 ± 2.5 in week two, 8.0 ± 2.3 in week three, increasing to 8.67 ± 1.2 for the fourth week. Collectively, these data suggest that although some individual women had some challenges, most commonly with their concentration and/or their mind wandering during their use of the Guided Imagery, overall most women had very
positive experiences with it. When ratings were collapsed into either positive and negative ratings, 18 of 29 women (62.1%) provided positive ratings for four or more of the five Likert-scaled GI evaluation items in week one, 17 of 24 (70.8%) in week two, 14 of 20 (70.0%) in week three, and 10 of 15 women (66.7%) in week four, Six women provided consistently positive ratings for all guided imagery items throughout their time in the study.

Mean arterial pressure change was not found to be significantly correlated with participant ratings of the degree of difficulty concentrating on the imagery ($r = .32$, $p = .08$), difficulty picturing the images ($r = .27$, $p = .13$), their enjoyment of the imagery ($r = -.23$, $p = .22$), the degree to which the images appeared real ($r = -.07$, $p = .72$), nor the extent to which participants’ minds wandered ($r = .10$, $p = .58$). (See Appendix M).

When scores from these five questionnaire items for the last week were combined, with reverse scoring for three items, to create a total guided imagery evaluation score, the mean total score was 17.10 (SD = 4.22) of a maximum possible score of 25 [median = 17.0; IQR = 8.0]. Correlational analysis of this combined score indicated a modest but non-significant negative relationship between ratings of guided imagery for the last week of study participation and mean arterial pressure (MAP) change between baseline and the last week of available data ($n = 31$, Pearson $r = -.30$, $p = .10$).

**Co-interventions**

Antihypertensive medication usage by study participants subsequent to randomization had the potential to be a potent co-intervention in relation to study outcomes for women in this study. The types of oral blood pressure medication administered in pregnancy have limited half-lives, with 95% or more of the medication excreted from the body within 72 hours of administration based on data from non-pregnant samples (Canadian Pharmacists Association, 2006). However, excretion rates in pregnancy are not known. Therefore, to be conservative,
antihypertensive medication use was a co-intervention only if a woman received it anytime during the week immediately preceding their last ambulatory blood pressure monitoring session. Of the 60 participants with primary outcome data, the sub-sample who received antihypertension medication during this timeframe was comprised of eight women (13.3%), six of whom (75%) were in the Guided Imagery group and two (25%) were in the Quiet Rest group. In order to ascertain the extent to which antihypertensive medication played a role in the observed effect of guided imagery on ambulatory mean arterial pressure (MAP), a series of additional analyses were undertaken.

As an exploratory measure, independent t-tests were redone for the primary outcome (mean arterial pressure change at the last week outcome data were available) and for changes in systolic and diastolic blood pressures, heart rate and anxiety between baseline and the last week, with all participants who had received antihypertensive medication during their last week of study participation removed from the analyses. These analyses for the women receiving no antihypertensive medication are depicted in table 10. Mean arterial pressure (MAP) rose in both the intervention and comparison groups across time. However, even without the influences of antihypertensive medication, there was still a trend toward smaller increases of MAP in the Guided Imagery group than for the Quiet Rest group. This trend of a smaller increase in the Guided Imagery group also was evident for ambulatory systolic (SBP) and diastolic blood pressure (DBP) changes, when data from only those women who had not received medication in the last study week were analysed. Differences for MAP and for SBP were not statistically significant at the .01 level, but were at a .05 level. Anxiety scores changed very little between baseline and the final measurement, with very similar changes between study groups between baseline and final measurement; differences were not statistically significant.
Table 10.
*Changes in blood pressure, heart rate and anxiety from baseline to final measurement for women not receiving antihypertensive medication in their last study week*

<table>
<thead>
<tr>
<th></th>
<th>Guided Imagery (n = 25)</th>
<th>Quiet Rest (n = 27)</th>
<th>t-statistic</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAP(^a)</td>
<td>2.12 (7.05)</td>
<td>5.93 (6.79)</td>
<td>1.98</td>
<td>.05</td>
</tr>
<tr>
<td>SBP(^b)</td>
<td>1.92 (7.51)</td>
<td>6.59 (8.40)</td>
<td>2.11</td>
<td>.04</td>
</tr>
<tr>
<td>DBP(^c)</td>
<td>2.08 (7.26)</td>
<td>5.48 (7.70)</td>
<td>1.64</td>
<td>.11</td>
</tr>
<tr>
<td>HR(^d)</td>
<td>0.76 (9.16)</td>
<td>0.41 (7.50)</td>
<td>-.15</td>
<td>.88</td>
</tr>
<tr>
<td>Anxiety</td>
<td>-0.12 (8.64)</td>
<td>-.11 (7.73)</td>
<td>-.004</td>
<td>1.00</td>
</tr>
</tbody>
</table>

\(^a\) MAP = mean arterial pressure in mmHg; \(^b\) SBP = systolic blood pressure in mmHg; \(^c\) DBP = diastolic blood pressure in mmHg; \(^d\) HR = heart rate in beats per minute

Due to the small numbers of women in both groups receiving anti-hypertensive medication in their last week of study participation, it was not appropriate to undertake statistical analysis other than descriptive in relation to the extent of blood pressure change between baseline and the final ambulatory blood pressure measurement. More women in the Guided Imagery group (n = 6) received blood pressure medication in the last week of their study participation than did women in the Quiet Rest group (n = 2). Group mean arterial pressure outcomes at the last week of measurement varied; a mean drop of .67 mmHg (SD = 10.17) was found for those in the active intervention group, compared with an increase of 6.00 mmHg (SD = 0.00) for those in the Quiet Rest group. Overall there was also a trend towards better responses in the Guided Imagery group than for the Quiet Rest group for blood pressure and anxiety.

In addition, mean arterial pressure (MAP) data were analyzed by multiple linear regression, using the least squares ‘enter’ method, and using group allocation and medication use
at last week of study participation as dummy predictor variables. The regression was not a good fit ($R = .31$, $R^2 = .10$); only 10% of the variation was explained by the model, and the overall relationship was not significant ($F = 3.03$, $p = .06$). Only group allocation was significantly associated with the MAP outcome ($\beta = .28$, $p = .03$), as depicted in Table 1.

Table 1.

*Group allocation and antihypertensive medication use and mean arterial pressure change between baseline and last week of study participation*

<table>
<thead>
<tr>
<th>Variable</th>
<th>$\beta$</th>
<th>$t$</th>
<th>95% Confidence Interval (CI)</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group allocation</td>
<td>.28</td>
<td>2.18</td>
<td>.33, 7.87</td>
<td>.03</td>
</tr>
<tr>
<td>Antihypertensive medication in last week</td>
<td>-.09</td>
<td>.72</td>
<td>-7.53, 3.55</td>
<td>.47</td>
</tr>
</tbody>
</table>

$R^2 = .10, F (2, 59) = 3.03, p = .06$

Other Outcomes related to Study Objectives

Due to this research being a pilot study, a number of objectives beyond the research questions were addressed. Each objective is discussed in sequence below.

*Appropriateness of Measuring the Primary Outcome at Four Weeks*

Thirty-two (46.4%) of the 69 women randomized completed four weeks of study participation, 10 (14.5%) completed three weeks, seven (10.1%) completed two weeks, and 11 (15.9%) finished one full week, while nine (13.0%) were no longer participating at the end of their first week in the study. These data clearly indicate that although it may be important to ascertain whether a certain number of weeks of guided imagery intervention are required to achieve blood pressure effects, measuring the primary outcome at four weeks was not ideal in this study due to attrition, most commonly due to early delivery.
Provide an Estimate of Recruitment Rates

Centre Recruitment

The Relaxation and Blood Pressure in Pregnancy (REBIP) Study was begun at a single tertiary care hospital. Initially, the monthly recruitment rate for the Relaxation and Blood Pressure in Pregnancy (REBIP) Study was expected to be five participants randomized per month. With conservative estimations, recruitment of the full REBIP Study sample size was anticipated within 12 to 15 months, by no later than November 2005. However, after 10 months of recruitment at this one site, less than half the intended sample had been recruited and nine additional centres were invited to become study sites. Key clinical and administrative leaders in obstetric/maternity departments were contacted through personal phone calls, meetings and emails, and were provided with details of what was required in terms of study involvement. Follow-up contacts were maintained to encourage and facilitate participation. One additional tertiary care centre and two regional health centres met study eligibility criteria, as described in the Methods chapter, agreed to participate and proceeded through institutional departmental and ethics approvals.

Estimated and Actual Recruitment Rate

In this study, recruitment of 60 participants with outcome data required 28 months, more than twice the time originally anticipated (see Figure 5). The original site met their recruitment goal for only two months; the second site met their monthly goal of three randomized participants for three months. Clinicians screened 554 women for study eligibility. Of the 429 women screened as ineligible by clinicians, the most common reasons were gestation beyond the study inclusion criteria \((n = 143; 33.3\%)\) and antihypertensive medication use \((n = 124; 28.9\%)\); for 73 of the cases, the reason for ineligibility was not recorded by the screening clinician and is unknown. Twenty-one percent of women screened \((n = 115)\) were eligible for the study. Of these,
25 declined to participate and a further 10 changed their minds between consenting and the point of randomization, for a combined refusal rate of 30.4%. Sixty-nine of the 554 women screened (12.4%) were eligible, agreed to participate and were randomized. The initial site, which began recruitment 13 months before the additional three sites were added, provided 78.3% of the sample; the second tertiary centre provided the remainder of the study participants (see Table 12). A third centre recruited one woman who provided baseline data but became ineligible before randomization.

Figure 5. Cumulative Recruitment.

Table 12.

Recruitment Chart

<table>
<thead>
<tr>
<th>Site</th>
<th>Level</th>
<th>Births/year</th>
<th>Monthly goal</th>
<th>Total participants recruited</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Tertiary</td>
<td>4300</td>
<td>5</td>
<td>54</td>
</tr>
<tr>
<td>02</td>
<td>Tertiary</td>
<td>2200</td>
<td>3</td>
<td>15</td>
</tr>
</tbody>
</table>
Participant Satisfaction

Participant Likes and Dislikes

Fifty-nine of the 69 women (85.5%) provided data at six weeks postpartum about their level of satisfaction about their allocated treatment; 29 (85.3%) of those in the Guided Imagery group and 30 (85.7%) of those in the Quiet Rest group (Table 13). Five of the women in the Guided Imagery group did not return their postpartum questionnaires, despite follow-up mail-outs and phone calls; two of these participants could no longer be located and were lost to follow-up. Two had discontinued their study participation, and the fifth woman was admitted to hospital for delivery within hours after only her introductory guided imagery practice. Of the five women from the Quiet Rest group who did not return their postpartum questionnaires, two had moved and could not be reached, one had left the study before the end of the first week, and two (including one who had experienced death of her newborn) did not respond to follow-up contacts.

The most common factor identified by participants that they liked about their study participation was their helping to answer an important research question (74.6%), followed by contacts with the study nurse (72.9%). Most women in both groups (57.6%) liked that there were few or no extra demands on them due to the study. Only one participant liked nothing about the study. A much greater proportion of the sample (42.4%) indicated that their being in the study helped them feel reassured, compared to the proportion (3.4%) who felt it added to their worry.

The women in the Guided Imagery group who identified additional things they liked about their study participation noted the following: “calmed me down, let me nap”; “gave me more time for myself”; “having study nurse come to my home, no driving on my part”; “helped to learn about relationship between blood pressure and relaxation”; “learned a lot about
hypertension”; “the music was great!!” Two additional women verbally described that their use of guided imagery improved their sleep. The first indicated that she was better able to sleep due to the guided imagery, that she seldom got to hear the end of the CD because she would fall asleep while listening to it, and that she experienced a dramatic decrease in the frequency of her previously common nightmares. A second woman indicated that listening to the GI CD enabled her to nap in the afternoons, something she previously could not do.

Table 13.
Participant Satisfaction with Study Participation

<table>
<thead>
<tr>
<th></th>
<th>Guided Imagery Group (n= 29)</th>
<th>Quiet Rest Group (n= 30)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td>Liked:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contacts with study nurse</td>
<td>20 (69.0%)</td>
<td>23 (80.0%)</td>
</tr>
<tr>
<td>Randomized to group wanted</td>
<td>12 (41.4%)</td>
<td>7 (23.3%)</td>
</tr>
<tr>
<td>Being in study helped feel reassured</td>
<td>12 (41.4%)</td>
<td>13 (43.3%)</td>
</tr>
<tr>
<td>Few or no extra demands on time, finances, energy</td>
<td>18 (62.1%)</td>
<td>16 (53.3%)</td>
</tr>
<tr>
<td>Helped to answer important research question</td>
<td>20 (69.0%)</td>
<td>24 (80.0%)</td>
</tr>
<tr>
<td>Liked nothing</td>
<td>1 (3.4%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Other likes</td>
<td>6 (20.7%)</td>
<td>4 (13.3%)</td>
</tr>
<tr>
<td>Disliked:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contacts with study nurse</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Not randomized to group wanted</td>
<td>1 (3.4%)</td>
<td>6 (20.0%)</td>
</tr>
<tr>
<td>Being in study caused worry</td>
<td>2 (6.9%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Extra demands on time, finances, energy</td>
<td>4 (13.8%)</td>
<td>2 (6.7%)</td>
</tr>
<tr>
<td>Disliked nothing</td>
<td>20 (69.0%)</td>
<td>15 (50.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (10.3%)</td>
<td>6 (20.0%)</td>
</tr>
</tbody>
</table>

*Note.* Percentages may not total 100% due to women choosing more than 1 like or dislike

Women in the Quiet Rest group identified these additional things they liked about their study participation: “knowing first few BP measurements each week (even though I had my own
BP monitor at home); “nice to take a few minutes every day to relax”; “that it improved my health”; and flexibility about day of the week the cuff worn.

Most women responded that there was nothing that they disliked about being in the study \( (n = 35, 59.3\%) \), with 69% of respondents in the Guided Imagery group choosing this response versus 50% of those in the Quiet Rest group. Seven of the 59 study respondents (11.9%) identified that they were disappointed with their study group allocation; two (3.4%) noted that their being in the study caused them some degree of worry; six (10.2%) disliked extra demands on their time or energy; while nine (15.3%) disliked something else about being in the study.

Of the four women in the Guided Imagery group who noted specific “other dislikes”, only two of the dislikes related to their use of guided imagery, with statements including “I am not someone who listens to music to relax”, and “would have liked more music at the end of the CD”. One additional woman who did not provide postpartum questionnaire data indicated verbally that she “did not like guided imagery or being in the study”. One woman who delivered before the end of her first week in the study noted her disappointment that her participation was “too short”, while another noted a blood pressure monitor issue. Six women from the Quiet Rest group identified specific “other dislikes” about their participation in the study, but none of these comments related to their experience with the Quiet Rest condition itself; five of the six dislikes related to the ambulatory blood pressure monitor, and are addressed later in this chapter.

Postpartum Ratings of Guided Imagery

At six weeks postpartum, participants from the Guided Imagery group were asked to rate their guided imagery during their time in the study using a Likert scale of 0 to 5. All of the 29 respondents indicated that the instructions provided for the guided imagery were easy to follow, with Likert scores of 4 or 5. Similarly, nearly all \( (n = 28) \) rated the study CD as very easy to use,
with ratings of 4 or 5. Women’s perspectives about whether they would have liked different choices of CDs to use varied considerably, but the majority preferred having more than one from which to choose. Nearly half (n = 14; 48%) of respondents indicated they would have liked a wider range of CD choices, with scores of 4 or 5, nine (31%) were neutral in their response, with ratings of 2 or 3, while six women (21%) were satisfied with using a single CD, based on their scores of 0 or 1.

Twenty four (83%) women responded that it was very easy for them to imagine a restful, calming place when they used guided imagery. One woman indicated that it was not at all easy (with a rating of 0), while four women (13.8%) provided neutral or moderate responses, with a rating or 2 or 3. Over half the women (n = 16; 55.2%) indicated that they became very able to imagine a restful, calming place on their own, without using their CD. Four women (13.7%) indicated that they were not able to achieve this (with ratings of 0 or 1), and nine others respondents (31.0%) were moderately able, with ratings of either 2 or 3. The extent to which women enjoyed the guided imagery had a much greater range of responses. Three-quarters of the women (n = 22; 75.8%) rated their enjoyment as high (scores of 4 or 5), while one (3.4%) provided a zero rating, two (6.9%) rated enjoyment as “2”, and four (13.8%) provided a moderate rating of “3”.

All respondents from the guided imagery group, regardless of how they rated their personal enjoyment of guided imagery, indicated they would recommend it to other women with high blood pressure in pregnancy; twenty-seven (93%) women said they would highly recommend it and two indicated a moderate recommendation (score of 3).

Although women in the study were not asked if they used guided imagery between the end of their four weeks or less in the study and six weeks postpartum, occasionally they spontaneously indicated verbally that they continued to use the CD beyond the intervention
period; these occurrences were not tallied, but study documentation shows that two women indicated that they had used their study CD during labour, with one stating she “used the CD during labour. Very helpful!”

In addition, one woman who had consented and provided baseline blood pressure data and had then required antihypertensive medication (thus making her ineligible for randomization) was provided with a CD at her request. In the approximately 36 hours between this and an expedited delivery due to deteriorating health status, she listened to the CD repeatedly. Following the birth of her child, who then required surgery and an extended hospitalization, she asked to keep the CD player loaned to her by the study so that she could continue to listen to the CD. She listened to the CD at least daily for several weeks, until the baby’s discharge to home, and described it as an important part of how she coped with her anxiety and stress.

Future Preferences for Guided Imagery Use

When asked at six weeks postpartum if they would use guided imagery again, 26 of the 29 Guided Imagery group respondents (89.6%) said they would. Nineteen (66.5%) responded that would use guided imagery again if their blood pressure was high in a future pregnancy, while 21 (72.4%) indicated they would use it when they felt stressed.

Acceptability of Daytime Ambulatory Blood Pressure Monitoring

Women were asked to respond to seven items, based on a five-point Likert scale, about their use of the ambulatory blood pressure monitor. Although responses ranged widely, mean responses regarding the monitor use were generally favourable.

Despite the monitor causing moderate discomfort (M = 2.34 ± 1.43), women reported that instructions for use were easy to follow (M = 4.93 ± 0.41), with minimal problems with
monitors not working properly ($M = 0.66 \pm 1.21$), noise from the monitor ($M = 0.73 \pm 1.10$), and with worry because of the monitor ($M = 0.32 \pm 0.75$). Women rated monitor interference with activities as moderate ($M = 2.15 \pm 1.39$) and with resting as low ($1.44 \pm 1.53$).

Some women ($n = 6$) commented that they had no difficulty with the blood pressure monitor or that they were able to adapt or address those experienced fairly easily: “It was very easy to use with no problems”; “The only discomfort I had with the monitor was wearing the strap around my neck/shoulder. So I just put the strap around the top of my belly, like a belt, which made it more comfortable to wear”; “machine worked well and was comfortable. The only complication was that I had to limit my bath to less than 25 minutes, which isn’t a big deal at all”; “only one problem which my nurse handled quickly”; “…the blood pressure machine was a little in the way, but nothing too serious”; “The cord was the biggest problem but you just have to ‘thread it’ through shirt sleeves etc to take up the extra slack.”

In addition to blood pressure monitor issues noted as “other dislikes” previously described, some respondents ($n = 10$) provided specific comments about their once weekly use of the study blood pressure monitors: “cuff made my hand swell.”; “….discomfort associated with the blood pressure monitor and swelling in my hands and wrist”; “The last day the machine would not work properly”; “I found toward the end of the day that the monitor would be annoying on my arm. I couldn’t wait to get it off.”; “machine was pumping too tightly and often twice.”; “difficult wearing the monitor on days with outside appointments, running around doing things.”; “I found it difficult to take my 1.5 – 2 hour nap in the afternoon while wearing the cuff.”; “machine only caused discomfort due to the itchiness I was experiencing from my condition during my pregnancy.”; “the monitor really hurt my arm, and it made it go tingly [sic]and itchy (extremely) afterwards.”; “The only thing with the study I didn’t care for was trying to wear the monitor. I am very tall … and I couldn’t get the monitor to fit down to my
belt / pocket so I had to carry it everywhere I went; it kind of got in my way. Also, whenever I had to drive the monitor wouldn’t properly take a reading. It would always error.” Although the study protocol included the ambulatory blood pressure monitor displaying the first five readings in each weekly monitoring session, two women wished they could have seen all of their readings. All of the women being cared for in a prenatal home care program had blood pressure measured by a nurse or physician daily and had a self-monitoring blood pressure monitor that they used themselves two or more times per day.

The use of this ambulatory blood pressure measurement method did deter some women from study participation, either being a reason for certain women choosing to not participate ($n = 1$) or for women consenting and then withdrawing between starting baseline ambulatory blood pressure monitoring and the point at which they were to be randomized ($n = 3$). In addition, one woman with a rare autoimmune condition was unable to have her blood pressure measured in any way other than with a Doppler, and one woman declined because all blood pressure measurements of any kind were painful for her.

The ambulatory blood pressure monitor also created discomforts for some women during the study. Of the women who were randomized, one participant who had a previously undiagnosed circulatory problem experienced dramatic colour changes and discomfort in her hand with each cuff inflation. Although she continued study participation, her ambulatory blood pressure readings after week one (when this problem was identified) were limited to one or two to limit possible harm due to multiple monitor cuff inflations. Women whose arm size required a large rather than a regular sized cuff tended to experience more discomfort and difficulties with the cuff such as pressure or pinching, and in one case bruising.
Willingness to Participate in REBIP Study Again

Of the 60 women who provided data at six weeks postpartum, 50 (83.3%) indicated that they would definitely or probably choose to be in the study if they had to make the decision again. The ten remaining respondents indicated that they were not sure or would probably not choose to be in the study again. Decisions regarding their willingness to participate again may have been related to aspects of the study they disliked, as described previously in this chapter.

Relationship between Standard Prenatal and Average Daytime Ambulatory Blood Pressure Measurement

The standard clinical blood pressure reading recorded for this study was the prenatal blood pressure reading by a health care provider for that patient, measured in closest proximity (in time) to the ambulatory reading done that week, and documented in the prenatal health record. Although mean arterial blood pressure (MAP) can be calculated through an equation which includes values for systolic and diastolic values, it is normally not calculated in clinical practice, and MAP based on standard prenatal measurement was not calculated for this study. Both systolic and diastolic blood pressures were higher when measured each week with standard prenatal methods than with the ambulatory method.

When daytime ambulatory and standard clinical measurements of systolic blood pressure were compared with each another, moderate and statistically significant correlations were found for those done at baseline, week one \( (r = .46, p < .01, \text{ two-tailed}) \), week two \( (r = .57, p < .001) \) and week three \( (r = .56, p < .001) \), but not for week four \( (r = -.18, p = .36) \). For comparisons for diastolic blood pressure, correlations of daytime ambulatory and standard clinical measurements were moderate for baseline \( (r = .46, p < .01) \) and for weeks one \( (r = .40, p < .001) \), two \( (r = .41, p = .005) \) and three \( (r = .36, p = .03) \), but not for week four \( (r = .16, p = .42) \). Overall, standard clinical measurement of blood pressure was not strongly reflective of what women’s daytime
ambulatory systolic or diastolic blood pressures were in any given week of study participation.

When differences between systolic and diastolic blood pressure changes between baseline and the last available reading were compared across ambulatory and standard clinical methods, greater changes in both systolic and diastolic values, and smaller standard deviations were evident with the ambulatory method than with standard clinical methods (Table 14).

Table 14. 
Blood Pressure Changes (in mmHg) Based on Ambulatory versus Standard Measurements

<table>
<thead>
<tr>
<th>Change in Blood pressure</th>
<th>Ambulatory measurement (n = 60) Mean (SD)</th>
<th>Standard measurement (n = 59) Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic</td>
<td>3.88 (8.18)</td>
<td>1.15 (13.37)</td>
</tr>
<tr>
<td>Diastolic</td>
<td>3.58 (7.82)</td>
<td>-1.02 (9.00)</td>
</tr>
</tbody>
</table>

*a Standard measurement = The blood pressure measured by a clinician by manual (or automatic) machine closest in time to the daytime mean ambulatory blood pressure reading for that week.

Note. One participant did not have a standard blood pressure measurement in the week she had her last ambulatory readings.

Additional Analyses

Predictors of Time to Delivery

Mean times between randomization and delivery were different between groups, with wide standard deviations (see Appendix O); therefore, t-test analysis was undertaken to determine if the difference between groups was statistically significant; it was not (t = 1.24, p = .22). A post-hoc multiple regression analysis, using simultaneous entry of variables, was performed to explore whether gestational weeks at baseline was a predictor variable in relation to time to delivery. As was expected, the number of gestational weeks at baseline was strongly predictive of the time between randomization and delivery. (Table 15)
Summary of multiple linear regression for variables predicting time (in days) between randomization and delivery.

<table>
<thead>
<tr>
<th>Variable</th>
<th>$\beta$</th>
<th>t</th>
<th>CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group allocation</td>
<td>-.10</td>
<td>-1.01</td>
<td>-36.18, 11.93</td>
<td>.32</td>
</tr>
<tr>
<td>Gestation at baseline</td>
<td>-.66</td>
<td>-6.83</td>
<td>-9.13, -5.00</td>
<td>&lt; .01</td>
</tr>
</tbody>
</table>

N = 65
$R^2 = .43$, $F(2, 64) = 23.36$, $p < .01$

Predictors of Gestation at Delivery

A multiple regression analysis, using simultaneous entry of variables, was then undertaken to explore whether gestational weeks at baseline was a predictor variable in relation to gestation at delivery. Baseline gestation and group allocation were entered in the model. Notably, there were three sets of twins in the study, all in the Quiet Rest group, the group with the shorter time to delivery, but the small number of twins did not warrant inclusion in the model. This model was not predictive of gestational weeks at delivery ($R = .15$, $R^2 = .02$, $F = .75$, $p = .48$).

Summary of Results

The primary research question in this feasibility study sought to determine the effect of guided imagery use on average daytime ambulatory mean arterial pressure (MAP), when compared to quiet rest. Independent t-tests indicated that there were statistically significant differences in the changes in MAP between the Guided Imagery group and the Quiet Rest group. When participants receiving antihypertensive medication in the week prior to their last set of ambulatory blood pressure measurements were removed from the analysis, the guided imagery effect was still evident at a statistically significant level. However, multiple regression analyses suggested that baseline gestation and baseline average daytime ambulatory mean arterial
pressure (MAP) were associated with change in MAP observed between baseline and the last week.

Secondary research questions sought to determine possible influences on the effect of guided imagery on daytime ambulatory systolic and diastolic blood pressures, heart rate and anxiety, and other outcomes. Although not statistically significant, there was a smaller increase in MAP at each week of study participation for the Guided Imagery group than for those in the Quiet Rest group. There was also a small inverse relationship between better MAP outcomes with more guided imagery uses, again not statistically significant.

Although systolic blood pressure change was 5.23 mmHg higher and diastolic blood pressure change was 3.61 mmHg higher in the Quiet Rest group than in the active intervention group, the BP differences between groups were not statistically significant. Little between-group difference was observed for heart rate change. Only slight and non-statistically significant decreases in mean anxiety scores were found for both groups. The proportion of women in the Guided Imagery group who received antihypertensive medication subsequent to randomization was also not found to be statistically different than the proportion in the Quiet Rest group. There was no evidence of guided imagery effect on the length of time from randomization to delivery, compared with quiet rest, based on t-test analysis. Then, when gestational weeks at baseline was entered with group allocation in a multiple regression model, only gestation was predictive of the time between randomization and delivery. It was not possible to determine guided imagery effects in relation to hypertension classification, due to the small numbers of women in this sample in two of the three hypertension classifications at randomization.

Compliance rates in the study were high. Most women were satisfied with their group allocation, regardless of their group. The large majority of the women in the Guided Imagery
group stated that they would use guided imagery again, particularly for any future hypertension in pregnancy and for stressful situations.
CHAPTER 5: DISCUSSION

In this chapter, compliance issues are discussed, and each individual research question is then addressed and discussed in relation to the current relevant literature. Limitations and strengths of the Relaxation and Blood Pressure in Pregnancy (REBIP) Study are also presented.

Compliance

The success of any clinical intervention depends, at least in part, on a high degree of patient compliance and acceptability. The rate of compliance in the Guided Imagery group was high, at 93.3% to 95.8% each week, but was slightly lower than the rate of 93.8% to 100% for the Quiet Rest group. Most women assigned to the Guided Imagery condition were consistently compliant across the weeks they were in the study. Reasons identified by participants for non-compliance with their guided imagery condition were not related to the GI itself, but were more related to personal and family illness and other demands at home. Only one participant contacted study personnel because of an issue with her guided imagery, an emotional response to references to the baby made on the guided imagery CD, which was addressed with her successfully.

Although two women in the Quiet Rest group used progressive muscle relaxation, it is possible that other women in that group actually undertook some type of spontaneous focused relaxation which may have elicited a relaxation response, but were not aware of or did not identify it.

Although noncompliance with group allocation was infrequent, the findings are important in underlining that some women with hypertension during pregnancy continue to maintain very busy lives, despite health care provider recommendations for increased rest. There were at least eight times in which participants could not fit in five fifteen minute periods of
relaxation, other than night-time sleep, in an entire week due to personal demands. An additional eight women had declined to participate due to their busy schedules.

Primary Research Question

Effect of guided imagery on mean arterial pressure

Statistically significant between treatment-group differences were found for changes in average daytime ambulatory mean arterial pressure (MAP) between baseline and the last week data were available. These findings indicate that guided imagery was effective in comparison with quiet rest, in lessening the extent of blood pressure increases across time. Mean arterial pressure did not fall over time for either the Guided Imagery or Quiet Rest groups, but the average increase in MAP was 4.35 mmHg more for the Quiet Rest group than for the Guided Imagery group, suggesting that the guided imagery had a beneficial effect. However, when the influences of baseline mean arterial pressure and baseline gestation were controlled for, the contribution of group allocation to MAP change was not at a statistically significant level.

Because the primary purpose of this study related to feasibility, the sample was small. As with all small trials, it was prone to both Type 1 and Type 2 errors, influenced by imbalances between groups. It was also insufficiently powered to discern between-group differences to a statistically significant level when baseline values were controlled for.

As 19.3% of women in the GI group and 6.9% of those in the QR group received antihypertensive medication in a timeframe in which the medication could be considered as a co-intervention, it was possible that the medication may have accounted for some of the GI effect observed. However, even when women who received antihypertensive medication in their last week of participation were excluded from analysis, the mean increase in mean arterial pressure was still 3.81 mmHg less for the Guided Imagery group than for the Quiet Rest group, which was statistically significant. For those who received medication in their last study week, mean
arterial pressure fell for women in the Guided Imagery group and increased in the Quiet Rest group. However, these sub-group sizes were quite small, making it impossible to draw conclusions about guided imagery effects with concurrent antihypertensive medication use.

Any between-group differences in MAP did not appear to be due to potentially different cardiovascular responses in multi-fetal pregnancies. Without the twin pregnancies in the analysis, the between-group difference in mean arterial pressure change was 4.53 mmHg and remained statistically significant.

It is interesting that neither the active intervention Guided Imagery group nor the comparison Quiet Rest group demonstrated a fall in mean arterial blood pressure, but in fact had a blood pressure increase between baseline and the last set of ambulatory readings available. The reason for this pattern is unclear, but may reflect the well-documented physiological occurrence of maternal blood pressure falling slightly in the first half of pregnancy and returning to pre-pregnancy values by term (Atkins, Watt, Milan, Davies, & Crawford, 1981; Capeless & Clapp, 1989; Hermida et al., 2001), and/or the development of pre-eclamptic symptoms for some participants as their pregnancies progressed. This finding is also consistent with observations made during another recent study of hypertension treatment in pregnancy, in which mean DBP was higher at 36 weeks than at 28 weeks (Magee et al., 2007). In addition, this pattern may have been influenced by a floor effect; only 31.9% (n = 22) of the women actually had baseline awake ambulatory readings that met ambulatory BP criteria of $\geq 135/85$ mmHg for hypertension (Khan et al., 2007; Magee et al., 2008); eleven had elevations of both DBP and SBP, while four had increased DBP only and seven had increased SBP only. On this basis, one could question whether this sample was truly hypertensive. None the less, these women were clinically labeled as being hypertensive and as such, were undergoing considerable maternal and fetal health surveillance and other elements of clinical management for hypertension.
Guided imagery effects on MAP in this study varied from effects reported from the only other RCT of relaxation therapy in pregnancy on MAP outcomes, in which 60% of the relaxation group had MAPs at their last prenatal visit consistent with hypertension, compared with 93% for each of the comparison groups, and in which MAP significantly decreased for the intervention group and increased in the comparison groups (Somers et al., 1989).

Secondary Research Questions

Effect on Systolic or Diastolic Blood Pressure, Heart Rate

Between-group differences were not statistically significant for either systolic or diastolic blood pressure change, but both measures of blood pressure tended to have smaller increases between baseline and the last week of ambulatory monitor readings for the Guided Imagery group than for the Quiet Rest group (SBP increased 5.23 mmHg more for QR than for GI; DBP increased 3.61 mmHg more for QR than for GI). When women who received antihypertensive medication were removed from the analyses, the between-group difference in SBP change (4.67 mmHg) was statistically significant (p = .04), while the between-group difference for DBP change (3.4 mmHg) was not.

The between-group difference in diastolic blood pressure in this study was similar to the effect of a 3.5 ± 1.5 mmHg difference found in the CHIPS pilot RCT of aggressive versus less aggressive pharmacologic treatment for hypertension in pregnancy, based on DBP target values (Magee et al., 2007). However, REBIP study groups both experienced increases in blood pressure across time, while CHIPS predictably found decreases in DBP. The trend of lesser diastolic and systolic blood pressure increases in the active intervention group than for the Quiet Rest group was consistent with similar trends in one other study of relaxation for hypertension in pregnancy (Somers et al., 1989). However, REBIP study findings were much more modest than those reported for a study of progressive muscle relaxation in a sample of normotensive pregnant
women with asthma, in which the between-group difference in SBP was 14.3 mmHg (Nickel et al., 2006). In samples of hypertensive but non-pregnant participants in which a guided imagery effect was reported, reductions in DBP and/or SBP were observed. Again, any blood pressure elevations or blood pressure change over time in pregnancy is superimposed on the normal physiologic dynamics of pressures which fall from early to mid-pregnancy and naturally increase to pre-pregnancy levels by the end of term. Ultimately, the extent of diastolic and/or other blood pressure changes that constitute clinically meaningful differences in hypertensive pregnancy remains unclear.

Very small non-statistically significant heart rate changes were observed. Interestingly, baseline heart rate for the sample was high, ranging from 64 to 121 beats per minute (bpm), with a mean of $93.0 \pm 11.5$ bpm, somewhat higher than baseline heart rate in another RCT of relaxation effects in pregnant women, in which the baseline rate ranged between 82.5-96, with a mean of 89.5 (Teixeira, Martin, Prendiville, & Glover, 2005). The reason for the higher values is not known. Regardless of the actual heart rates, no significant change in heart rate was detected. This finding differs from findings reported by Teixeira et al. (2005), who found one-time use of multi-modal relaxation therapy with guided imagery at 28 to 32 gestational weeks of pregnancy lowered heart rate significantly more than did quiet rest. However, measurement timelines varied in these two studies, with heart rate outcomes assessed many hours post-relaxation session in the REBIP study, compared to immediately after relaxation in the Teixeira study. Heart rate findings also vary from guided imagery effects in a non-pregnant sample reported by Manyande et al. (1995), who found significantly lower maximum heart rates during surgeries in their imagery group versus controls.

**Antihypertensive Medication after Randomization**

Guided imagery did not significantly reduce the proportion of women who received
antihypertensive medication in this sample. Seven women in the Guided Imagery (GI) group (including one who received it only transiently during the first week and went on to participate in the study for another three weeks) and two women in the Quiet Rest (QR) group were receiving medication at some point during their four weeks or less in the study. Another two women in the GI group and four more from the QR group started medication during pregnancy, but after their maximum four weeks of study participation. Another seven women (10.8%) had medication started during their time in labour and delivery, while seven (10.8%) more started medication during their post-partum hospital stay. Of the women in the Guided Imagery intervention group, 47.0% received antihypertensive medication at some point between randomization and post-partum discharge compared with 37.1% of women in the Quiet Rest group. In addition, more than 23% of women screened for the REBIP study were ineligible for randomization because they were already receiving pharmacological treatment for their high blood pressure. In comparison, between 69.7% and 89.2% of women in the CHIPS pilot trial received antihypertensive medication after randomization, in order to maintain diastolic blood pressure at either 85 or 100 mmHg (Magee et al., 2007). However, use of antihypertensive medication at baseline was an exclusion criterion for the REBIP study, while it was the treatment of focus for the CHIPS pilot study.

Effect on Anxiety

Anxiety scores changed very little between baseline and the final measurement, with very similar changes between study groups between baseline and final measurement; differences were not statistically significant. Although this finding is consistent with findings from one study of GI effects (Danhauer et al., 2007), it is inconsistent with most other RCTs of either guided imagery alone or combined with other relaxation techniques on anxiety outcomes, including one with a sample of pregnant women (Esplén, 1991; Hudetz, Hudetz, & Reddy,
2004; Kwekkeboom et al., 1998; Lang et al., 2006; Lang & Hamilton, 1994; Lang et al., 1996; Rees, 1993; Teixeira et al., 2005). There are at least two possible explanations which may help account for this. The first is that there may have been a floor effect; REBIP Study mean state anxiety (STAI) scores at baseline were similar to scores reported for women with low risk pregnancies (Bergner, Beyer, Klapp, & Rauchfuss, 2007; DiPietro, Novak, Costigan, Atella, & Reusing, 2006; Field et al., 1999), in other samples of pregnant women with hypertension (Ross-McGill et al., 2000), and norms for females aged 19-39 (Spielberger et al., 1983).

Another perhaps more likely explanation is the timing of anxiety measurement in relation to the actual guided imagery use. Most other studies demonstrating GI effects on anxiety have measured anxiety outcomes within minutes of guided imagery relaxation use, e.g., Hudetz et al., (2004) and Teixeira and colleagues (2005). In the REBIP Study, many hours may have passed between the last use of guided imagery and anxiety measurements. It is possible that short-term reductions in anxiety may have occurred in this study and may not have been stable in the longer term. Although literature indicates that the state anxiety scale of the STAI is appropriate to measure any period of time in the recent past (Spielberger et al, 1983), including a weekly interval (C. Spielberger, personal correspondence, June 12, 2003), state anxiety may have better measured immediately after guided imagery use.

Despite trends toward improved blood pressure in the intervention group, there was almost no difference in anxiety between or within study groups from baseline to the last week of study participation, suggesting that any blood pressure benefit might not be as a result of anxiety reduction as postulated in the conceptual model for this study. However, it is possible that shorter-term anxiety reductions may have occurred with guided imagery episodes, which still may have provided a psychophysiologic pathway by which blood pressure differences occurred.

On the other hand, blood pressure changes may have resulted from more direct pathways
described in the conceptual framework.

Satisfaction data from the Relaxation and Blood Pressure in Pregnancy Study indicate that the majority of participants in the guided imagery group would use guided imagery again, with more who would choose it for stressful situations than for other reasons. This suggests they may have experienced perceived psychological benefit that was not necessarily captured in the measure of anxiety used in this study. It may be that these women experienced an improvement in their quality of life, improved coping and/or diminished perceived stress, or other psychological benefit. State anxiety measurement using the STAI has been shown to be reliable in pregnancy. However, some researchers now suggest that more pregnancy-specific instruments may be more sensitive in measuring stress or anxiety during the unique timeframe and experience of pregnancy (Da Costa et al., 1999; DiPietro et al., 2006).

*Time from Randomization to Delivery*

Although the between-group difference for mean time to delivery was not statistically significant, it was potentially clinically significant, at approximately 13 days longer in the guided imagery group than in the quiet rest group. However, women who began their study participation earlier in their pregnancies were naturally more likely to have a longer time frame between randomization and delivery than women entering the study closer to their due dates. Nearly 81% of the Guided Imagery group joined the study in their third trimester of pregnancy, versus 93.1% of the Quiet Rest group. Four women in the Guided Imagery group and only one from the Quiet Rest group were in the study by 20 gestational weeks. As expected, regression analysis results supported that gestation at baseline was a greater predictor of the time between randomization and delivery than was the study group. However, the proportion of preterm births is perhaps more relevant than time to delivery; there were a total of 15 preterm births in the GI group compared with 16 in the Quiet Rest group, despite all three sets of twins in this sample
being from the Quiet Rest group. Regression analysis did not find gestation at baseline to predict gestation at delivery, but the study may have been under-powered to detect such a relationship.

Blood Pressure Changes and Frequency of Guided Imagery Practice

It is important to note that the total dose (frequency) of guided imagery practice in the REBIP study was largely a function of the length of time a woman was in the study prior to delivery. The frequency of guided imagery use was between 8.9 to 10.1 uses each week, considerably more than frequency of home practice reported in other recent guided imagery relaxation studies (Cohen & Fried, 2007; Kingston, Chadwick, Meron, & Skinner, 2007). Modest inverse relationships approaching statistical significance were found between total guided imagery dosage and changes in ambulatory mean arterial pressure and systolic blood pressure. Most previous studies of guided imagery effects on blood pressure have made no mention of findings in terms of dose response or reported frequency of guided imagery use (Achterberg et al., 1988; Burish et al., 1987; Carey & Burish, 1987; Collins & Rice, 1997; Lyles et al., 1982; Salmore & Nelson, 2000), but one study reported finding no significant relationship between frequency of use and BP outcomes (Crowther, 1983). Reports of dose response effects for guided imagery for other outcomes have been mixed, with one found in relation to breast milk production (Feher et al., 1989) and psychological and physiological measures of stress in pregnancy (Cohen, 2002), but not for changes in salivary cortisol or mood in a non-pregnant sample (Watanabe, Fukuda, & Shirakawa, 2005).

Classification of Hypertension and Effectiveness of Guided Imagery

The rates of differing types of hypertension in this study were somewhat similar to those reported from a large epidemiological study on hypertensive disorders in pregnancy in Nova Scotia. In the REBIP Study, 13.0% of the sample had chronic hypertension, 78.3% had
gestational hypertension and 7.8% had a pre-eclampsia diagnosis, as compared with 10% (with approximately 40% progressing to pre-eclampsia), 77%, and 13% respectively (Allen, Joseph, Murphy, Magee, & Ohlsson, 2004). Slight differences in rates may be due to the epidemiology data for a 12 year period having been collected retrospectively, compared to the small REBIP sample with prospective data collection.

It was not possible to discern whether guided imagery was more or less effective for high blood pressure associated with one type of hypertension diagnosis versus another, due to small group sizes for two of the three hypertension classifications. Mean arterial pressure in the chronic hypertension group increased by less than 1 mmHg in the GI group, compared to increases of 3.0 mmHg and 4.1 mmHg for women with hypertension diagnoses of pre-eclampsia or gestational hypertension respectively. When only women in the Guided Imagery group were considered, reductions were noted for MAP, SBP and DBP for the chronic hypertension group, versus increases for MAP, SBP and DBP for both the gestational hypertension and pre-eclampsia group. This suggests that perhaps guided imagery may be more beneficial in women with chronic hypertension in pregnancy than for those who develop hypertension during the pregnancy, but further study is required to make that determination.

The classification of hypertension was on the basis of whether women met the criteria for one versus another at the time of randomization. However, it is possible that some of the women diagnosed as having chronic hypertension or gestational hypertension may have developed pre-eclampsia subsequent to randomization, and hypertension classification at baseline may not be an adequate reflection of actual disease processes or pathophysiology present. Fifteen to 30% of pregnant women who initially have non-proteinuric hypertension will go on to develop pre-eclampsia (Magee et al., 2007; Saudan, Brown, Buddle, & Jones, 1998). However, no data were collected regarding how many women in the REBIP Study had their hypertension progress from
one classification to another. Hypertensive disorders may not be static during pregnancy, and may be challenging to differentiate one from another, so close surveillance of all pregnant women with hypertension is warranted (Meher, Abalos, & Carroli, 2005; National High Blood Pressure Education Program Working Group on High Blood Pressure in Pregnancy (NHBPEP), 2000). It is possible that a large proportion of participants had white-coat hypertension, based on approximately 68% of the sample who had above-normal clinical blood pressures and subsequently normal baseline ambulatory readings, based on Canadian Hypertension Education Program ambulatory criteria for hypertension. However, it may be important to include such women in future study of hypertension management during pregnancy, as the presence of white-coat hypertension may not be benign; in one study, 40% of pregnant women with white-coat hypertension subsequently developed gestational hypertension and eight percent developed pre-eclampsia (Brown, Mangos, Davis, & Homer, 2005).

*Daytime MAP by Week of Exposure to the Allocated Study Condition*

Average daytime mean arterial pressure (MAP) across weeks remained within approximately 2 mmHg of the baseline value for the Guided Imagery group, but increased by 2.8 to 6.2 mmHg for the Quiet Rest group, with a trend toward greater between-group differences with progressive weeks, other than for week three. These changes are based on group sizes that diminished across the four week window of blood pressure data collection, but suggest possible benefit even without extended use over several weeks. This pattern is consistent with findings from a study of relaxation therapy in which systolic and diastolic blood pressure readings collected over four weeks fell with sequential weeks (Vasterling et al., 1993). It also may be reflective of a dose-effect with increased total use of the guided imagery intervention as time in the study increased.
Evaluation of Guided Imagery and its Effectiveness

No statistically significant relationship was found between any single imagery evaluation item score at the last week of study participation and mean arterial pressure change between baseline and the last week of participation. Although there was a modest negative relationship between the total imagery evaluation score and mean arterial pressure change for the last week, this correlation was also not statistically significant. Ease of guided imagery use increased as women spent more time using guided imagery. The trend towards lesser increase of mean arterial pressure over time with more positive ratings of guided imagery suggests that there may be more blood pressure benefit when pregnant women feel more positive and experience less difficulty with their guided imagery experiences. However, more research is necessary to make that determination.

Other Outcomes Related to Study Objectives

Appropriateness of Measuring the Primary Outcome at Four Weeks

As less than 50% of the women randomized completed the four weeks of study participation originally intended for this study, it would not be advisable for future studies to have blood pressure at four weeks as the primary outcome. It is important to note that when mean arterial pressure changes were compared by group and week, there was little change in blood pressure across weeks for the Guided Imagery group, whereas the trend for the Quiet Rest group was towards larger increases in blood pressure with each subsequent week of study participation, with the maximum between-group difference of 5.12 mmHg at week four. This suggests that although there may some limited benefit present after as little as one week of guided imagery intervention, there may be increased benefits with a longer duration of guided imagery use, and such potential differences may be more easily discerned at or after four weeks. Due to the feasibility issues in collecting serial blood pressure data for four weeks as a result of
early deliveries, the approach of measuring the primary outcome at “the last week data were available” provided a practical means to assess whether guided imagery provided benefit during the window of time women actually experienced hypertension during their pregnancy.

*Provide an Estimate of Recruitment Rates*

Subject accrual was the greatest challenge in completing the Relaxation and Blood Pressure in Pregnancy Study and was reflective of recruitment challenges in many randomized controlled trials (Watson & Torgerson, 2006). Recruitment was dependent on timely identification of women meeting study eligibility criteria, but funding did not allow for the employment of full-time personnel to undertake this identification process. The frequency with which clinical personnel missed eligible patients due to lack of screening, lack of time or other reasons is not known.

REBIP Study recruitment patterns indicated that for women screened, the eligibility rate was 20.8%, much less than had been anticipated prior to study initiation. The initially tight blood pressure eligibility criterion of 140 mmHg systolic and 90 mmHg diastolic was thought to have contributed to slow recruitment. However, the subsequent amendment of this criterion to “DBP of ≥ 90 mmHg” and the change in the gestational criterion from ≤ 33 weeks and six days to ≤ 36 weeks and six days did not enhance monthly recruitment rates. The predominant reason for slower than anticipated recruitment experienced in this study was the high rate of antihypertensive medication use in women who may have otherwise been eligible; at least 124 (22.4%) of screened women of appropriate gestation were ineligible because they were already receiving anti-hypertensive medication. This was surprising in light of a lack of evidence to support its use or benefit in women with mild to moderate hypertension, but is consistent with other recent Canadian studies of hypertension management during pregnancy (Caetano et al., 2004; Magee et al., 2007).
The refusal rate was 30.4%, calculated on the basis of the number of eligible women who initially declined plus the number who changed their mind after consent, quite similar to a rate of 32.0% in another recent study of hypertension treatment in pregnancy (Magee et al., 2007). Approximately half of this number indicated that their choice was due to being too stressed or busy to take on additional commitments. A nearly 70% participation rate suggests that a large proportion of eligible women for this study were open to guided imagery relaxation as a possible complementary therapy for their high blood pressure. It was notable that some women who declined acknowledged that they believed an increased focus on relaxation through study participation would likely be helpful to them and regretted that their personal circumstances did not permit it. Efforts were made to minimize physical or emotional demands on women participating in the REBIP study, by arranging randomization, blood pressure monitoring set-ups and data collection at their homes, clinic or physician appointments, hospital rooms, or at other times and places of their choosing. Meetings in clinical environments were arranged so women spent very little extra time there due to the study, and were often achieved while women were waiting to be seen by their health care provider. Over half the sample particularly liked that the demands on them from the study were low, and this response may be explained, as least in part, by the participant-focused nature of scheduling.

The addition of a second site was important in completing this study. The Relaxation and Blood Pressure in Pregnancy (REBIP) Study was feasible, despite the extended period of recruitment required to accrue the sample size. However, future trials such as this would benefit from sufficient funding to facilitate all aspects of the research and extending recruitment to multiple sites.

Although the sample size for this study was arbitrary and based on anticipated participant accrual at one site over one year, the a priori power calculations based on clinically relevant
blood pressure difference suggested the study could be adequately powered, depending on the standard deviations and between group differences found. The standard deviation of differences between repeated measures in this study was 7.40, mid-range in comparison to the standard deviations used in the power analysis. However, the between-group difference in MAP was smaller than the 5 mmHg used in the power calculation. On the basis of proportions of the groups that actually had a reduction in mean arterial pressure (GI, \( n = 12, 38.7\% \); QR, \( n = 3, 10.3\% \)) versus those whose MAP increased or was unchanged, there was an absolute increase of 28.4% in the proportion with a MAP reduction for the Guided Imagery group. Therefore, the number needed to treat (NNT) is 4 (95% Confidence Interval 0.08, 0.49), indicating that guided imagery relaxation could potentially help limit blood pressure elevations for one in four women with hypertension in pregnancy. When the outcome was a MAP reduction of \( \geq 5 \) mmHg (GI, \( n = 6, 19.3\% \); QR, \( n = 1, 3.4\% \)) versus those with either a MAP which was increased, unchanged or decreased but by less than 5 mmHg, there was an absolute increase of 15.9% for the Guided Imagery group. Therefore, for one woman to have a MAP reduction of \( \geq 5 \) mmHg, seven women would need to use daily guided imagery for at least one week.

This low-risk intervention may help maintain blood pressure closer to or within normal limits, and by so-doing, may limit exposure to antihypertensive medication and its potential side effects. Ultimately however, the most important pregnancy outcomes relate to whether maternal and newborn outcomes can be improved. Labour, birth and newborn outcomes, such as mean gestation at delivery, postpartum length of hospital stay, and neonatal intensive care admissions appear to be similar for the Guided Imagery and Quiet Rest groups. (See Appendices N, O & P) Further study with a larger sample size would be required to adequately determine whether guided imagery has any effect on these outcomes.
Participant Satisfaction

A number of findings provide indicators of how acceptable guided imagery was to women with hypertension during pregnancy in this sample. First, although study participants were not asked to identify if or when they used guided imagery between completion of their time in the study and six weeks postpartum, there were occasional reports of continued use between the end of study participation and admission to hospital for delivery, use during labour and/or postpartum.

Secondly, although guided imagery did not actually reduce blood pressure or state anxiety scores for some women in this study, 89.6% of the women who used guided imagery stated they would use it again, suggesting that they perceived it had benefited them in some way. Nearly three-quarters said they would use it for stressful situations, indicating they may have experienced some calming psychological benefit. Improved sleep/rest and time to oneself were perceived benefits specifically mentioned by participants. This observation is consistent with qualitative and quantitative findings from other studies of guided imagery relaxation in which sleep benefits were also reported (Cohen & Fried, 2007; Esplen, 1991; Esplen et al., 1998; Harvey & Payne, 2002; Renzi et al., 2000; Richardson, 2003; Stephens, 1992; Tsai, 2004), and may be particularly relevant for pregnant women with hypertension. Problems with sleep disturbances are common in pregnancy, especially in the last trimester (Barratte-Beebe & Lee, 1999; Hedman, Pohjasvaara, Tolonen, Suhonen-Malm, & Myllylä, 2002; Lee, 1998; Santiago, Nolledo, Kinzler, & Santiago, 2001; Signal et al., 2007), while stress, anxiety, and/or environmental factors may also influence a woman’s ability to sleep (Lee, 2007). It may also be possible that participants experienced other unmeasured benefits such as enhanced quality of life. Guided imagery effect on quality of life has been reported in pregnant women with asthma (Nickel et al., 2006) and other patient groups (Baird & Sands, 2006; Yoo, Ahn, Kim, Kim &
Thirdly, regardless of their ratings of their own enjoyment of guided imagery, 100% of respondents from the Guided Imagery group indicated they would recommend it to other women with high blood pressure in pregnancy. This proportion is slightly higher than proportions of treatment groups in the CHIPS Pilot Study (Magee et al., 2007) willing to recommend the same pharmacologic treatment they received to a friend (93.9% of the “less tight” and 95.1% of the “tight” blood pressure management groups). In addition, the high rate of compliance and the average frequency of guided imagery use in that study group also suggest that the guided imagery intervention appeared to be acceptable to most of those women allocated to it. Finally, the finding that 69% of the Guided imagery group identified that there was nothing at all about the study they disliked indicates that the intervention was quite acceptable to most women using it. Findings also indicate that guided imagery was easy to use and practical for use by most of the pregnant women in this sample, and are consistent with those reported by other researchers who studied guided imagery in nonpregnant samples (Esplen, 1991; Esplen et al., 1998; Freeman, 2001; Lang et al., 2006; Lang et al., 1996).

Of the women who participated in the study, 83.3% said that they would definitely or probably choose to participate if they had to make the decision again. This is impressive when one considers that this was a longitudinal study, with daily use of an allocated group condition and weekly serial data collection, including ambulatory blood pressure monitoring with cuff inflations every half-hour.

Three women who consented withdrew their participation prior to randomization because of discomfort from the blood pressure monitor during their baseline blood pressure monitoring, while the monitor was identified specifically by two women as the reason for their declining to participate in the study. The monitors did interfere somewhat with resting during the day and
with daily activities. General satisfaction with ABPM use as well as documentation of moderate discomfort during cuff inflation and other problems with use of the Spacelabs 90207 ambulatory blood pressure monitor in this study were similar to findings reported by other researchers (Ernst & Bergus, 2003; Taylor, Freeman et al., 2001; van der Steen, Lenders, & Thien, 2005; Walker, Permezel, Brennecke, Tuttle, & Higgins, 2004; Westhoff et al., 2005).

Relationship between Standard and Average Daytime Ambulatory Blood Pressure Measurement

Findings regarding changes in systolic and diastolic blood pressure for mean measurements taken with ambulatory monitoring and based on standard clinical measurements varied. Ambulatory measurement showed increases for both systolic and diastolic readings between baseline and the last week data were available (SBP increase of $3.9 \pm 8.2$ mmHg, DBP increase of $3.6 \pm 7.8$ mmHg), while standard clinical measurement showed a slight increase in systolic pressure and a slight drop in diastolic blood pressure.

Standard clinical blood pressure measurements described in this study were performed by clinicians in the way they normally did them but the extent to which these practices were consistent with current Canadian Hypertension Education Program recommendations for blood pressure monitoring technique (Padwal, Hemmelgarn, McAlister, McKay, Grover, Wilson, et al., 2007) is not clear. In one site, standard measurements were obtained using aneroid machines, while the second site used automatic blood pressure machines. Automatic blood pressure machines tend to low-read in pregnancy, and particularly in pregnancies with hypertension, and it is not known whether monitors used in various clinical settings were validated for use in such pregnancies.
Strengths and Limitations

**Strengths**

This is the first randomized controlled trial to investigate the effects of guided imagery relaxation on blood pressure in pregnant women with hypertension. The major strength of this study was the use of a RCT method to evaluate the effectiveness of the guided imagery intervention. All participants were randomized based on a centralized computerized telephone system, and each had a fifty-fifty chance of being randomized to either the experimental Guided imagery group or to the comparison Quiet Rest group. An audit pathway confirmed that participants were randomized to the intended group, with no violations. Groups appeared similar, other than a larger proportion of women having first babies and all three sets of twin pregnancies being in the Quiet Rest group. Participant compliance with the study protocol was excellent.

Standardized approaches for the intervention and control condition added to the strength of the study, along with individualization or tailoring of the intervention, to potentially maximize any blood pressure benefit (Khan et al., 2007; Linden et al., 2001; Young, 1999). Individualization also involved timing and location of introductory and weekly sessions convenient for each woman, and each woman made their own choices about timing for guided imagery practice, which may have enhanced their sense of control and ability to relax. Data suggested that participants considered this approach beneficial; most women rated the demands on their time and energy from study participation to be limited and that this was a positive part of the study for them. We also ensured that participants in this study had telephone access at any time to a nurse experienced with guided imagery use to address questions or concerns with any aspect of their guided imagery; only two participants made contact with study personnel for this purpose, and average ratings regarding ease of guided imagery use were high. There was no
indication of harm resulting from guided imagery use in this study; one woman reported that the references on the CD to the baby made her feel emotional, but that guided imagery also helped her relax.

As it was important to separate the potential effects of guided imagery relaxation from the effects of rest, the Quiet Rest group condition was designed to be a formalization of usual care with elements of an attention placebo. That decision was shown to be a good one, as it became clear that the Quiet Rest condition was in fact different in character than usual rest/activity conditions for many women in that study group. After being introduced to their Quiet Rest study condition, many women in this group noted that resting quietly without external stimuli such as computers, televisions, stereos and phones, which they were asked to undertake twice daily, was not part of their daily resting repertoire. However, some women identified that they appreciated that such rest had the potential to benefit them; this subjective data is supported by the findings from the expectancy scores women completed after being introduced to their study condition.

Data were collected systematically; where available, reliable and valid tools were chosen with which to measure the outcomes and other variables in the trial. One example was the use of ambulatory blood pressure monitoring, an objective method of measuring blood pressure, uninfluenced by white-coat syndrome or other issues related to manual measurements in clinical settings. This approach was more likely to provide an accurate and reliable reflection of women’s “real” blood pressure over longer periods of time than standard clinical measurement methods and has been better studied in pregnancy than has self-measurement of blood pressure.

In addition, the memory capacity of the ambulatory blood pressure monitors used in this study ensured an objective and reliable method of recall, not influenced by participant bias or choice of timing and/or what blood pressures they would or would not document. Observations
from the REBIP Study underlined the value of this choice. In both groups, some women
intermittently monitoring their own blood pressures in addition to the study monitoring tended to
choose times of day when they thought their blood pressure would be low. At other times, they
did not document high readings, but undertook a period of rest and continued to repeat BP
readings until the monitor readout display indicated a more acceptable reading. This observation
is inconsistent with findings that patient-measured and documented readings were accurate in a
sample of pregnant women with hypertension (Waugh, Habiba, Bosio, Shennan, & Halligan,
2003), but is consistent with previous studies in non-pregnant samples, in which participants
who were unaware that their blood pressure monitors had memories reported blood pressure
values to be lower than those retained in memory by the monitors (Mengden et al., 1998; Myers,

Clinicians were blinded to ambulatory blood pressure data and made clinical decisions
based on standard blood pressure readings normally available to them. Although it was not
possible for participants or study personnel interacting with these women to be blinded to group
allocation, personnel interacting with participants were not privy to ambulatory blood pressure
data during a woman’s time in the study. Data extraction and data entry were undertaken by
study personnel at arm’s length from participants. Although some eligible women chose to not
participate in the REBIP Study because of time or stress issues or not wanting to wear the
ambulatory blood pressure monitor cuff for extended periods of time, none of the women who
were invited to participate indicated that their reason for refusal related to their preference for
one treatment or the other. The potential for expectation bias resulting from participants
knowing their group allocation was managed by having the women complete an expectancy of
outcome scale after they were introduced to their allocated study condition. Some women
expressed pleasure when they learned of their allocation, but expectancy scores were
surprisingly similar for both study groups.

The inclusion of women with varying types of hypertension in this study was intended to allow for preliminary examination of differential responses across the types of hypertension most common in pregnancy, maximizing generalizability of findings. Although statistical analysis of responses across hypertension was not possible because of small group sizes, broader rather than narrow inclusion criteria was still the most appropriate choice for a feasibility study such as this. The use of two study sites may have added to heterogeneity in the sample, while minimizing the variability that may be introduced with a multisite study, especially with the small sample size of this study.

It was important in this study to determine how feasible guided imagery use was for pregnant women with hypertension. Therefore, the intention to treat approach to data analysis used in this study, in which women’s data were analyzed in the group to which they were originally allocated, was particularly important. It provides information about practical, realistic, clinically relevant effects of treatment, rather than about efficacy and preserves the nonbiased approach provided by randomization.

The investigation of clinical strategies for blood pressure management that are potentially less toxic to fetuses and more acceptable to pregnant women than pharmacologic treatment continues to be important; nearly 11% of eligible women approached for a RCT of “tight” versus “less tight” management of hypertension in pregnancy declined because they wished to avoid antihypertensive medication (Magee et al., 2007).

Overall, this study addressed a number of considerations recommended by other authors for rigorous guided imagery research, including measurement of dose response, differentiation of imagery effects from those of rest alone, participant evaluation of guided imagery and levels of relaxation achieved, as well as a longitudinal approach, sound methodology, rigor and reliable
and valid outcome measures (Menzies & Taylor, 2004).

**Limitations**

This randomized controlled trial has limitations. As with any small RCT, the major limitation is the great risk of both Type 1 and Type 2 error. Despite random allocation, the imbalances in baseline characteristics in the two study groups, particularly in relation to twin pregnancies and parity, may be at least partial explanations for the differences in MAP change and the lack of evidence of effect for other study outcomes.

Due to the nature of the intervention in this RCT, it was not possible to blind participants to group allocation, potentially introducing the risk of performance bias. However, group means of participant ratings of outcome expectancies from their allocated study condition provided at baseline were very similar (39.8 ± 6.9 points for Guided Imagery group, versus 38.4 ± 7.4 points for Quiet Rest group), suggesting that women in the comparison group had nearly as high expectations for benefit as did those in the active intervention group. Although clinicians were not notified about the group to which women were randomized, it is possible that they may have on occasion become aware of allocation if they noticed a study CD player or instruction sheet that may have been left in their view. However, as outcome measures were primarily based on automated machines and self-reports, it is unlikely that any clinician bias would have influenced study outcomes.

Although ambulatory blood pressure monitoring (ABPM) provided a more consistent method to measure blood pressure in this study than other methods, its use may have also been a limitation. Because 24-hour ABPM was deemed to be too disruptive to sleep to use for weekly serial measurements with this sample of pregnant women, an a priori decision was made to restrict its use to daytime hours. Ambulatory BP monitoring was begun as early in the day as possible, with the aim to collect eight or more hours of blood pressure data during each weekly
monitoring session. However, the length of time women wore the monitor, and thus the number of ambulatory blood pressure measurements available, varied and may have provided less insight than 24-hour monitoring data. Although it is not clear how many or how few readings are required to provide an adequate reflection of daytime ambulatory blood pressure in pregnancy, a minimum of >14 daytime readings has been suggested for useful ambulatory blood pressure monitoring generally (O'Brien, Beever, & Lip, 2001; O'Brien et al., 2000). Women in the REBIP Study wore the BP monitor an average of 9.4 ± 3.3 to 10.1 ± 1.7 hours for each week monitoring session. Very few blood pressure means were based on a total of 14 or fewer recorded readings, with frequencies ranging from 4.3% to 15.6%, depending on the week. A lower limit was not set in the REBIP Study for the number of readings for any woman in any given week, because it was assumed that even one reading could be more reflective of “real” blood pressure than a clinic reading and this was a feasibility study. All of the recorded readings were considered to be physiologic, or not out of the realm of possibility; therefore all readings remained in the analysis.

Although the Spacelabs ambulatory blood pressure monitor model 90207 was validated for use in hypertensive pregnancy, it is no longer recommended for use in this population group as there is a newer ambulatory blood pressure measurement device with higher validation testing ratings. This may raise concerns regarding the validity of the study’s blood pressure data. However, it is the monitor most tested and most used in research with pregnant women with hypertension. Also, as the blood pressure outcomes in this study were based on changes in blood pressure, and not absolute blood pressure values, the potential concern regarding the type of blood pressure monitor used is likely not a major one.

The measure of guided imagery dosage in this study was a crude one, which did not necessarily capture the daily variability in dose. More precise measurement should be
incorporated in future studies.

Recommendations for bed rest and/or restriction of physical activity, either at home or in hospital, are common in the management of high blood pressure during pregnancy, despite lack of evidence to demonstrate whether or not it is beneficial (Caetano et al., 2004; Meher & Duley, 2005). Quantifying rest and activity in pregnancy research is challenging, and interpretation of rest and reduced activity recommendations can vary widely among pregnant women with hypertension (Meher & Duley, 2005), and this was indeed evident in this study. It is possible that the amount of physical rest undertaken by study participants may have influenced blood pressure findings. Participant diaries or logs of activity and rest were not part of the study protocol, due to the unreliability of this approach to data collection (Stone, Shiffman, Schwartz, Broderick, & Hufford, 2003). Although we asked women to identify how frequently they undertook rest without using a particular relaxation method and how frequently they used guided imagery, to determine compliance, this was not insightful in determining the extent (total time) women rested. Although the total frequency of rest periods, with and without guided imagery, was greater in the Guided Imagery group than for the Quiet Rest group, the total time resting each week (with or without GI) for both groups was not known. Data are also not available regarding the level of maternal activity and rest on the particular days blood pressure data were being collected. Attempts were made to have women who provided baseline data on a day they had a hospital or clinic appointment have their other weekly data collections on another appointment day, or alternately, to maintain a pattern of data collection on a home day, if their initial data collection was started at home. However, participant and research personnel scheduling did not always allow for this level of consistency. However, it is important to note that although this reality may have influenced variability of outcomes to some extent, this was a clinical trial conducted in real life conditions, rather than a laboratory experiment.
There is no way to know the extent to which women in the Quiet Rest group may have actually evoked a relaxation response on their own, without recognizing it or reporting it. Two women, both health care providers, indicated that they had used progressive muscle relaxation techniques during quiet rest. Data regarding use of other relaxing activities such as massage or spa treatments were not collected for either study group. Therefore, it is not possible to ascertain whether such activities may have influenced study results.

Although the choice of mean arterial pressure as the primary outcome allows a reflection of guided imagery effect on both systolic and diastolic blood pressures, it may also be a limitation of this study. It is not generally used as a clinical measure of blood pressure, other than when invasive cardiovascular monitoring is used in critical care environments, and in fact, MAP readings are not available on manual and many automatic blood pressure machines and its derivation requires calculation based on an equation. Diastolic blood pressure is the one blood pressure measurement used in definitions of hypertension in pregnancy (Padwal et al., 2007) and may be a more clinically relevant and practical choice (L. Magee, personal communication, May 2003). However, both systolic and diastolic values are considered in clinical management decisions, and mean arterial pressure is a composite of both these values. In addition, systolic and diastolic blood pressure changes were secondary outcomes of this study.

Generalizability of findings to the population of pregnant women with hypertension is not possible, primarily due to the small study sample, group imbalance in participant baseline characteristics, and lack of clarity regarding what actually constitutes a clinically significant difference in blood pressure.
CHAPTER 6: SUMMARY, IMPLICATIONS AND CONCLUSIONS

Summary of the Project

Considerable clinical guidance given to pregnant women with hypertension has related to “taking it easy” and “relaxing”, yet there has been no empirical evidence to support that relaxation could provide blood pressure or other health benefit to these women. Guided imagery relaxation is an intervention easily implemented by nurses and pregnant women with hypertension and familiar to many clinicians who work with childbearing women. It warranted testing regarding its effectiveness in relation to maternal blood pressure outcomes. Psychophysiology suggested pathways by which blood pressure benefit could be possible with guided imagery use.

The primary purpose of this study was to evaluate the effectiveness of guided imagery relaxation on maternal blood pressure and anxiety, in relation to the comparison condition of quiet rest. Although it is more clinically important to determine whether interventions such as guided imagery relaxation can enhance maternal and newborn health outcomes in pregnancies with hypertension, ascertaining whether it could improve blood pressure outcomes was a first step in this process. Secondary objectives related to timing of measurement for the primary outcome, estimation of recruitment rates, assessment of compliance and participant satisfaction, and comparison of ambulatory daytime blood pressure measurement with standard prenatal measurements.

In this two-site study, 69 women considered to have hypertension based on clinical blood pressure readings were randomly allocated to an experimental group \( n = 34 \) and a comparison group \( n = 35 \). The experimental Guided Imagery (GI) group were asked to use guided imagery relaxation for at least 15 minutes twice per day for the time they were in the study, up to a maximum of four weeks, and a comparison Quiet Rest (QR) group \( n = 35 \) were asked to rest
quietly with a minimum of external stimuli for the same periods of time. Ambulatory blood pressure data were collected for daytime hours, one day each week for four weeks, or up until delivery, whichever occurred first. Statistical analyses were based on intention-to-treat principles.

Although the average daytime ambulatory mean arterial blood pressure (MAP) between baseline and the last week data were available was not reduced following use of the guided imagery intervention, the mean increase in MAP was 4.35 mmHg less for the guided imagery group than for the comparison group of quiet rest, a statistically significant difference. It is not clear whether such a difference between groups constitutes a definitive clinical difference, although 4.35 is close to the 5 mmHg difference suggested a priori by hypertension experts as being potentially clinically meaningful. When the potential co-intervention of anti-hypertensive use was addressed by removing those who received such medication within a week of their last ambulatory blood pressure monitoring session from the analysis, the difference in MAP change remained statistically significant. As guided imagery use (total dosage) increased in the experimental group, a small non-statistically significant relationship toward greater blood pressure benefit was observed ($r = -0.33, p = 0.07$). There may be possible benefits to exposure to longer term guided imagery practice, but further study in this area is required. When means and standard deviations for daytime MAP were considered by week spent in the study, mean values were relatively stable with weekly increases of 2.04 mmHg or less beyond baseline values for the Guided Imagery group, compared with increases of 2.76, 4.40, 3.62 and 6.19 mmHg by week beyond baseline for the Quiet Rest group. Although the relationship between women’s ratings of their guided imagery experiences and mean arterial pressure change was not statistically significant ($n = 31$, Pearson $r = -0.30$, $p = 0.10$), smaller mean arterial pressure increases with more positive ratings of guided imagery was observed.
Although not statistically significant, smaller increases in both systolic and diastolic blood pressure were also evident for the Guided Imagery group (1.35 ± 7.54 mmHg for GI versus 6.59 ± 8.09 mmHg systolic for QR; 1.84 ± 7.88 mmHg diastolic for GI versus 5.45 ± 7.43 mmHg diastolic for QR). No statistically or clinically significant differences in heart rate were found.

The proportions of participants who were administered antihypertensive medication after entering the study were not statistically different (47.0%, n = 16 for Guided Imagery; 37.1%, n = 13 for Quiet Rest). A range of factors influencing prenatal care decision-making may have played a role in if or when antihypertensive medication was introduced in this study sample. Further study with a larger sample would be warranted.

Mean state anxiety scores changed little in this study, with a reduction of 1.87 ± 9.20 points for the Guided Imagery group, versus a reduction of 0.10 ± 7.83 for the Quiet Rest group; the difference was not statistically significant. Although this may suggest that blood pressure effects from the Guided Imagery intervention may not be due to reduction in anxiety, at least at the points in time anxiety was measured for this study, it is too early to discount the role of this psychophysiologic pathway for blood pressure changes observed. The findings from this study did not shed light on the mechanism(s) by which blood pressure was reduced. It would be useful to determine whether anxiety measured at different points in time would glean different results in future study.

There was no evidence of a statistically significant effect on the length of time from randomization to delivery from guided imagery in this sample. Although women in the Guided Imagery group had a clinically significant 13 days longer between randomization and delivery than did the Quiet Rest group, this difference may have been influenced by more women in the experimental group entering the study in early pregnancy.
Due to the small sample size, there were small numbers of women with chronic hypertension and with pre-eclampsia in comparison to gestational hypertension at baseline. This lead to an inability to determine whether there was preferential benefit from guided imagery for women with one type of hypertension versus another in this study, and so will be an important focus for further investigation.

The results of this pilot study are encouraging, and suggest guided imagery could be of benefit in controlling maternal blood pressure. Guided imagery is a simple and low cost intervention to implement, and one which is likely acceptable to a high proportion of women experiencing hypertension during pregnancy, based on this study’s findings. It can be easily used within research protocols and in clinical practice. Although the Relaxation and Blood Pressure in Pregnancy (REBIP) Study was feasible, similar trials would benefit from sufficient funding to maximize recruitment and data collection efforts.

Implications for Research

Hypertensive disorders in pregnancy can have serious consequences for mother and/or baby and current treatments have potential side effects. Research answers regarding target levels for blood pressure in hypertensive pregnancy are several years away. In the meantime, this study provides the first preliminary evidence that the non-pharmacologic approach of guided imagery may be effective in limiting blood pressure increases in pregnancies already complicated by hypertension. Therefore, further rigorous study of guided imagery effects on blood pressure and other health outcomes for pregnant women with hypertension and their infants is warranted. In addition to the response rate in this study, there is evidence from elsewhere to suggest that pregnant women with high blood pressure may be particularly open to nonpharmacologic methods to help manage their hypertension. A desire to avoid drugs in pregnancy was identified as one of the most common reasons why women declined to
participate in a recently reported Canadian study comparing two approaches to pharmacological treatment of hypertension in pregnancy (Magee e al, 2007). Recent survey findings also indicate that on a yearly basis, 58% of Canadian adults of childbearing age use alternative or complementary health therapies (Esmail, 2007).

Study of guided imagery effects on subsequent development of hypertension may also be valuable. Other researchers have found emotional stress during pregnancy to be associated with increased risk for development of a hypertensive disorder of pregnancy, and suggest that psychosocial interventions in pregnancy to address this stress may potentially reduce hypertension risk (Leeners et al, 2007).

If there is a maternal physiologic response to guided imagery, there may very well also be a fetal response to guided imagery that is important to investigate. Therefore, potential exists for study of immediate and longer-term guided imagery effects on such fetal response and physiologic health indicators as fetal movements and fetal heart rate patterns, or on Doppler blood flow patterns.

Research which helps us understand the basic mind-body pathways and processes by which responses to techniques such as guided imagery occur is important, as is investigation of individual differences in response (NCCAM, National Institutes of Health, 2007). This provides support for investigations to explore factors that affect guided imagery effectiveness on maternal blood pressure. For example, measurement of imaging ability has been suggested as useful in determining whether guided imagery is an appropriate intervention for individual patients (Kwekkeboom, Kneip, & Pearson, 2003). Although this may be useful in better understanding the phenomenon, it may not be practical if guided imagery were to be used in day-to-day clinical practice. Based on feedback from participants in this study, future research protocols for guided imagery over extended periods of time should provide more than one choice of guided imagery
audio-CD, so that participants can have variety when and if they desire. It may also be useful to extend the music at the end of the guided imagery exercises for those who wish to continue to listen. However, it would also be important to study differential effects of various scripts and other components of guided imagery.

Research on any type of relaxation technique effects in pregnancy has been rare. As mind-body interventions have been demonstrated to improve sleep, mood, quality of life and coping in samples from non-pregnant patients with health problems, study of guided imagery effects on quality and quantity of sleep, coping, perceived stress, measures of pregnancy-specific stress, and on quality of life in pregnancy may be warranted. There is also much potential for further scientific investigation of guided imagery effects on a series of maternal and fetal health outcome measures for women with complications of pregnancy other than hypertension. It is also important to undertake studies about the influence of relaxation techniques other than guided imagery on blood pressure in pregnancy, as well as effects on perinatal outcomes.

Implications for a Larger Randomized Controlled Trial

Findings from this study provide guidance for future research. First, sufficient funding for a multi-site study would be essential for future randomized clinical trials of guided imagery.

Use of antihypertensive medication was a major problem in recruiting for this study. Although inclusion of women already receiving anti-hypertensive medication in any larger clinical trial would bring with it the potential for co-intervention, the influences of medication on outcomes could be controlled through prognostic stratification based on whether or participants are receiving antihypertensive medication at randomization. It may also be beneficial for future research to limit study sites to those which are conservative in their approach to antihypertensive medication use. Multiple regression analyses findings suggested that it may be useful to consider stratification on the basis of baseline blood pressure values and for gestational age at study entry.
in a full randomized controlled trial. There was insufficient information from this study to provide a basis upon which to recommend prognostic stratification by study centre, by hypertension classification at randomization, or by singleton versus multiple gestations for a large RCT of guided imagery effects on perinatal outcomes.

Although it would be interesting to consider the influence of hospitalization versus home care versus outpatient care on blood pressure and other associated health outcomes, it would be challenging within the current Canadian clinical perinatal context, as pregnant women with hypertension often move back and forth between these levels of care across the course of their pregnancies. Although there is insufficient evidence currently as to whether bed rest does actually result in lowered BP in pregnant women with hypertension, controlling for frequency and duration of rest periods would be useful in future RCTs of interventions on BP in pregnancy to help clarify the relationships between extent of physical rest and blood pressure outcomes.; however, strategies by which to achieve reliable physical activity data in a large clinical trial, especially in one involving serial data collection, would have to be carefully considered.

In order to limit the influence of floor effects on blood pressure outcomes in future studies, it may be worth considering limiting study eligibility to only those women who actually have hypertension based on baseline values rather than clinic measurements. However, this change would diminish the study focus from effectiveness to efficacy; in reality, women whose clinic blood pressures are elevated tend to be clinically assessed and managed as if they indeed do have hypertension.

Study findings clearly indicated that measurement of primary blood pressure outcomes after four weeks of intervention was not feasible due to early deliveries. Between-group differences were observable for each week of study participation. However, it is difficult to determine what timeframe for outcome measurements would be ideal to choose for future
research because of the wide diversity in trajectories of hypertensive disorders in pregnancy. Serial data collection for a period of weeks may provide far more insight regarding patterns of blood pressure change than a single point in time at “x” number of weeks for blood pressure outcomes measurement. However, regardless of gestation at study entry, some women with hypertension in pregnancy will deliver with each successive week of participation. For this reason, measurement of blood pressure outcomes at “four weeks or last week data were available before delivery, whichever comes first”, as per this pilot study, may be a reasonable and practical approach for other future research.

Blood pressure measurement with a device which stores readings in a computer memory and which is validated for use in pregnancies with hypertension, is advisable for use in future research on guided imagery relaxation on blood pressure and other pregnancy outcomes. It is possible that such monitoring could be initiated by the patient for each of several readings or via the traditional ambulatory approach of leaving the blood pressure cuff on for several hours at a time, as long as multiple readings are produced during daytime hours. Home blood pressure measurement provides several of the same advantages as ambulatory BP monitoring, including avoidance of the white-coat syndrome and multiple readings (Celis, Hond, & Staessen, 2005) and may be less uncomfortable than the monitor used in this study. Authors now suggest that that patient-initiated self-monitoring of their blood pressure with automated devices is appropriate for blood pressure determination in clinical trials (Baguet & Mallion, 2002). Even though research of home blood pressure monitoring outcomes with samples of pregnant women has been limited, it is likely multiple readings at home would provide a more accurate picture of a woman’s real blood pressure than many fewer readings in an office or clinical environment.

In future longitudinal research studies of guided imagery in pregnancy, more precise measurement of guided imagery dose should be undertaken, by having participants document
their GI uses for each of the days since the previous point of data collection, rather than having them identify use on the basis of questionnaire items regarding the number of days per week and times per day. It would also be useful to include postpartum questionnaire items about the extent of guided imagery use during the window of time between the end of the intervention or last measurement and the time of the postpartum questionnaire. This would provide more insight regarding actual continued usage of guided imagery beyond the window in which blood pressure data were collected. This would be especially important in any study in which labour and birth outcomes are a predominant focus.

Hypertension rates in Canada continue to creep higher, with the 2005 prevalence for females reported as 15.7%, with some provincial rates even higher, for example, at 19.9% for Nova Scotia and 20.5% for Newfoundland and Labrador (Statistics Canada, 2006). Although there is evidence that low-dose aspirin or calcium supplementation, but not antioxidants, can provide small to moderate reductions in the risk of developing pre-eclampsia for women at risk (Duley, Henderson-Smart, Meher, & King, 2007; Hofmeyr, Atallah, & Duley, 2006; Rumbold, Duley, Crowther & Haslam, 2008), little meaningful progress has been made in finding treatments to manage hypertension in pregnancy or to reduce negative outcomes associated with it. As the financial strain on health care systems increases, interest is growing regarding the potential economic benefits of complementary therapies (Baer, 2007), and many women with hypertension prefer to not use drugs for blood pressure management during pregnancy (Magee et al., 2007). In a large clinical trial, it would be important to evaluate the economic impact of guided imagery as an intervention for pregnant women with hypertension. Few studies of guided imagery, or any relaxation therapy, have included economic outcomes. One exception is one RCT of self-hypnosis (similar to guided imagery) during interventional radiologic procedures which showed a reduction of health care costs (Lang & Rosen, 2002).
For future RCTs of guided imagery effects in pregnant women, a three-group design may be worth consideration. A “usual care” control group in addition to quiet rest comparison and guided imagery intervention groups would shed additional light on differential effects of quiet rest versus guided imagery versus usual care.

Implications for Practice

The Relaxation and Blood Pressure in Pregnancy Study provides preliminary evidence that blood pressure is moderated with the use of guided imagery relaxation, that there is no evidence of harm, and that guided imagery is acceptable to pregnant women with hypertension. This evidence suggests that guided imagery could be offered to all pregnant women who are deemed to be hypertensive. However, without further study, it would be impossible to determine whether benefit observed in this study was related to specific content or other elements of the guided imagery used for this study, or if similar results could be achieved with other guided imagery approaches and/or scripts.

Clinical techniques for blood pressure management in pregnancy are limited in variety and scope. The findings from this study add to existing evidence that guided imagery is a simple relaxation technique that is easy to implement in home/community and hospital settings. The time required by clinicians to introduce and support patient use of guided imagery appears to be reasonable; introduction to the guided imagery required a very short verbal explanation of 10 to 15 minutes, and a 15-minute “practice” using the study audio CD. Collectively, this suggests that guided imagery can be easily introduced in clinical practice with minimum demands on staff and/or patients. In addition, guided imagery is an approach known and implemented by many nurses and other clinicians who work with childbearing women, to help women visualize changes in their bodies and to relax during labour and birthing.

The observation that women prescribed increased rest by care providers had widely
ranging interpretations and applications of this recommendation is important. Despite the fact that women may have been encouraged to stop paid employment and limit their physical activity at home, many women continued to maintain busy active lives with or without “their feet up”, and had little time to truly rest. This indicates that perhaps clinicians may need to undertake additional assessments of women about their interpretations of rest recommendations and the factors in their lives that could prevent or limit their ability to rest, and help women identify ways they can enhance the quantity and/or quality of their rest.

Spontaneous comments from study participants and occasional clinical observations by study personnel suggest that there is considerable variation in blood pressure measurement technique in clinical practice, and sometimes inconsistencies with national recommendations. This has the potential to artificially increase blood pressure, add to white-coat effect and/or otherwise provide inaccurate blood pressure information. Issues with measurement technique may have often been due to, or exacerbated by, the physical layout of many examination rooms, in which the blood pressure machines are often attached to walls next to examination tables, for example. Therefore, it may be advantageous to take women’s blood pressure as per national recommendations (Khan et al., 2007), and/or consider changes to the physical environment of office and clinic exam rooms to better facilitate clinician’s ability to undertake measurements in an optimal way.

Clinicians caring for women in this study relied heavily on antihypertensive medication use to reduce blood pressure in situations when women had mild to moderate hypertension during pregnancy, although the benefits and harms of antihypertensive medication for mild to moderate hypertension in pregnancy remain unclear (Abalos et al., 2007). The uterus has no capacity to auto-regulate blood flow in the event of significant maternal blood pressure drops, which may result in less than optimal blood flow to the fetus. Interestingly, there is little
discussion of this in the perinatal literature despite anecdotal evidence that it does occur. Therefore, it is important to ensure pregnant women taking antihypertensive medication and/or other treatments are familiar with and respond to signs and symptoms of hypotension which may occur as a side-effect of treatment.

Conclusions

Guided imagery is one of a range of techniques that may be used by women who experience hypertension during pregnancy to help them relax. The evidence from this study suggests that guided imagery may have benefit in moderating or limiting blood pressure increases in pregnancies in which blood pressure has been elevated. Women allocated to the guided imagery condition had mean arterial blood pressure elevations significantly lower than for women allocated to quiet rest, and lower non-statistically significant elevations in systolic and diastolic blood pressures. These benefits were evident whether or not women receiving antihypertensive medication were considered in the analyses, and despite the finding that there were no between-group differences in participant anxiety outcomes. Guided imagery relaxation was acceptable to pregnant women with hypertension, based on their use of it during and after the study and their intent to use it for future stress and high blood pressure. Further research is required to determine whether guided imagery can improve physical and psychological health outcomes during pregnancy, labour, birth and postpartum. In addition, further research is needed to explore whether guided imagery may have differential effects depending on the underlying physiologic type of hypertension, to understand factors which may influence the effectiveness of guided imagery in pregnant women with hypertension and to explore whether the technique may have benefits for women with high-risk pregnancy conditions other than hypertension. It will be useful to undertake research on how psychophysiological techniques other than guided imagery may effect blood pressure and other perinatal health outcomes. Guided imagery is easy to use, of
limited cost, and can be implemented by nurses working with hypertensive pregnant women in a variety of clinical environments. Evidence from this feasibility study suggests that guided imagery was beneficial and that further study with a larger sample is warranted.
References


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Teixeira, J., Martin, D., Prendiville, O., & Glover, V. (2005). The effects of acute relaxation on


## Appendix A

Summary of Research on Blood Pressure Effects of Guided Imagery combined with other Relaxation Therapy

<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Findings</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>Achterberg et al (1988)</td>
<td>Allocation to groups not randomised.</td>
<td>149 hospitalized severely burned patients</td>
<td>Relaxation group (n = 34): audiotape of breathing techniques, muscle relaxation &amp; ocean sounds; Guided imagery (GI) &amp; relaxation group (n = 39): audiotape of breathing techniques, muscle relaxation &amp; GI (mental rehearsal of wound care); GI, relaxation &amp; biofeedback group (n = 26): asked to listen to audiotape of breathing techniques, muscle relaxation &amp; undertake biofeedback. Controls (n = 50) received usual care.</td>
<td>Pain on scale of 1-10; anxiety (SAI; Spielberger 1970) mood (Profile of Mood States/ POMS), systolic blood pressure (SBP), diastolic blood pressure (DBP) &amp; heart rate (HR), muscle response &amp; thermal response.</td>
<td>No significant effects on SBP or DBP, but mean SBP fell in treatment groups &amp; rose in control group.</td>
<td>3 training &amp; 3 treatment sessions; total time not identified. DBP values not reported. BP (mercury) measured over bandages, or based on a clinical reading done near time of study procedures. More analgesia &amp; sedation in biofeedback group. No practice of technique reported. No random allocation.</td>
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<tr>
<td>Burish et al (1987)</td>
<td>RCT to evaluate effectiveness of PMR and GI on adverse chemotherapy symptoms</td>
<td>24 patients receiving cancer chemotherapy</td>
<td>Experimental group: GI plus progressive muscle relaxation (PMR) (1-3 30-45 minute training sessions, prior to start of initial chemotherapy + therapy sessions immediately prior to first 5 chemotherapy appointments &amp; encouragement to practice daily, using audiotapes). Control group participants asked to rest quietly prior to chemotherapy.</td>
<td>SBP &amp; DBP; anxiety (MAACL; (Zuckerman, 1964) &amp; 7-point self-rating &amp; nurse-rated scales; Nausea, vomiting (7-point self-rated &amp; nurse-rated scales)</td>
<td>Effect in reducing DBP, SBP &amp; HR at end of chemotherapy treatments.</td>
<td>BP based on single mercury measurements. Absolute BP values depicted graphically only. Whether data collectors were masked to group allocation was not reported. Family members invited to also learn technique.</td>
</tr>
<tr>
<td>Carey &amp; Burish (1987)</td>
<td>RCT to evaluate effectiveness of 3 different ways of PMR and GI training on adverse chemotherapy symptoms</td>
<td>45 cancer chemotherapy patients randomized to 1 of 4 groups (matched for cancer site &amp; chemotherapy)</td>
<td>PMR + GI over 3 sessions; frequent practice recommended. Patients in all groups received standard anti-emetics. PMR + GI provided by a therapist; or PMR + GI provided by trained volunteer; or PMR + GI provided by audiotapes; or Control group: usual care</td>
<td>SBP, DBP, HR, (single measures pre- &amp; post-chemotherapy infusions); Anxiety (7-point scale &amp; MAACL -short); nausea (7-point scale)</td>
<td>No effect on SBP or DBP. Those who received professional therapy less anxious than if therapy from volunteer or if in control group.</td>
<td>No actual BP values reported. No report of whether nurses measuring BP were masked to group allocation. Completed expectancy questionnaire</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Sample</td>
<td>Intervention</td>
<td>Outcomes</td>
<td>Baseline Differences Control</td>
<td>Dropout Similarity</td>
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<td>Collins &amp; Rice (1997)</td>
<td>RCT</td>
<td>50 adults with myocardial infarction in last 12 weeks &amp; attending cardiac rehabilitation, stratified by 1 of 4 sites.</td>
<td>Experimental group members provided with instruction on PMR &amp; imagery use at first study visit, with daily home practice (x 6 weeks) with audiotape &amp; written instructions. Imagery involved a place that was pleasant and restful for that person, and visualization of a healthy heart. Control group received routine care.</td>
<td>Stress responses: BP &amp; HR, after 6 weeks treatment: (mercury, standard procedures); Anxiety (STAI); stress (symptom checklist -90 revised; Derogatis, 1992,1974). No effect. SBP lower after routine care, but control group had more cardiac medication increases during study. HR lower after treatment than for controls (p &lt; .05). Baseline differences in BP controlled via ANCOVA.</td>
<td>No intention to treat analysis; analysis based on 43 subjects. Dropout similar across groups. Normal baseline BP may have contributed to floor effect.</td>
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<tr>
<td>Crowther (1983)</td>
<td>Randomization not indicated, but stratification by age, gender &amp; BP to 3 groups. Demographics of groups similar.</td>
<td>34 adults (Age 18-65) with primary hypertension (BP &gt;140/90) on stable anti-hypertensive medication.</td>
<td>Group 1: 8 weekly training sessions (each 45 minutes) of GI (warmth, heaviness &amp; individualized relaxing image), deep breathing &amp; PMR with 20-minute tapes, discussed problems relaxing, &amp; home practice after week 3 with written instructions only. Group 2: same GI training as group 1, plus stress management training, including review of person’s responses to stress, coping skills &amp; weekly homework. Control group: asked to note weekly BP assessments in physician’s office.</td>
<td>SBP, DBP, &amp; hypertension rate, based on standard procedures &amp; average of 3 -5 measurements (mercury) at 8 weeks; also at 1, 3 &amp; 6 months post-treatment. Effect for both GI + PMR, &amp; GI + stress management in reducing SBP &amp; DBP, &amp; HR. Both treatments also effective in lowering rate of hypertension. Combination of findings from pilot study &amp; replication study. Data at 3-months imputed for 4 people. No significant relationship found between frequency of use and BP outcomes. Similar expectancies of effect across groups. Short-term effect: No BP group differences at 3 or 6 months.</td>
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<td>Henry &amp; Sancore (1987)</td>
<td>RCT, to compare effects of PMR with GI and PMR alone on DBP &amp; SBP.</td>
<td>47 adults with primary hypertension (stratified by type of anti-hypertensive medication) to 3 groups. (Excluded if previous use of PMR or GI, diabetic, or psychiatric hx)</td>
<td>GI plus PMR group (n=14): Asked to listen to PMR &amp; imagery tape x 2 per day for 4 weeks; PMR group (n= 14): Asked to listen to PMR tape x 2 per day for 4 weeks. Both treatment groups &amp; Control group (n = 12): received hypertension education &amp; a 10-minute general information audiotape.</td>
<td>SBP &amp; DBP, using standard protocol &amp; median of 3 BP (mercury) measurements per session. No effect on SBP or DBP. Significant within-group SBP &amp; DBP reductions for both PMR group &amp; the GI with PMR group; no significant drop in BP for control group. Analysis of 40 of 47 subjects; reason for withdrawals not reported. Content of imagery not reported. Participants &amp; those measuring BP masked to allocation. Controls received less teaching &amp; tape time than treatment groups. Reported audiotape use &lt; 60% of that requested; reasons not reported.</td>
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<table>
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<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Outcome Measures</th>
<th>Findings</th>
<th>Notes</th>
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<tbody>
<tr>
<td>Lyles et al (1982)</td>
<td>RCT</td>
<td>50 cancer patients randomized to 1 of 3 groups, stratified by type &amp; day of chemotherapy.</td>
<td>Experimental group: participants received relaxing GI combined with PMR, &amp; participated in 1 pre-training, 3 training &amp; 1 follow-up session, all immediately prior to 5 sequential chemotherapy treatments, averaging 15 days apart. GI, based on patient input continued during chemotherapy. 1. Attention placebo group: therapist support condition 2. Control group: rested quietly prior to chemotherapy sessions.</td>
<td>Adverse symptoms due to chemotherapy at follow-up: SBP &amp; DBP at end of 5 sessions; Anxiety (MAACL score, 7-point self- &amp; nurse-rated scales); nausea &amp; vomiting (7-point self-rated &amp; nurse-rated scales; depression.</td>
<td>GI &amp; PMR post-training effect on both SBP &amp; HR. DBP outcomes not reported. No effect at follow-up.</td>
<td>BP based on single mercury measurements. Sample not hypertensive.</td>
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<tr>
<td>Somers et al (1989)</td>
<td>RCT</td>
<td>50 women, 30-36 weeks gestation, with pregnancy-induced hypertension &amp; prescribed reduced activity, randomized to 1 of 3 groups.</td>
<td>Experimental group (n=15): 4 hours of training to self-monitor BP &amp; use biofeedback + relaxation (including GI) with audiotape twice a day. Attention placebo group (n=15): received 4 hours of education to increase compliance to bed rest; Control group (n=15): received routine care, including bed rest.</td>
<td>Mean arterial pressure (MAP) based on single measurements (mercury), using standard technique, at last prenatal visit prior to hospitalization for delivery.</td>
<td>Effect of intervention on MAP (F, 2, 42) = 9.30, p&lt;.001). MAP decreased in relaxation group; increased in other groups (F, 1, 28 = 7.18, p&lt; .025).</td>
<td>Excluded if primary hypertension. Hypertension = MAP&gt;95 or DBP &gt; 90 or 15mmHg increase, or 30mmHg SBP pregnancy increase. Attrition: 5 of 50. Those measuring BP blinded to group allocation. No association between bed rest compliance &amp; MAP.</td>
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<td>Taylor (1977)</td>
<td>RCT to compare BP effects of relaxation therapy with attention placebo &amp; routine care</td>
<td>31 medically treated essential hypertensive adults (not defined) randomized to 1 of 3 groups.</td>
<td>Experimental group: (n =10) instructed on tension &amp; BP, muscle relaxation, breathing, &amp; imagining individualized pleasant scene, for 5 30-minute sessions. Asked to practice using audiotape at least once a day for 8 weeks &amp; use when feeling stressed. Attention placebo group (n =10) BP management information from therapist. Control group (n =11) usual care only</td>
<td>SBP and DBP 8 weeks after baseline</td>
<td>Intervention effect in SBP, when compared with usual care group &amp; nonspecific therapy group. No significant effect on DBP.</td>
<td>Frequency &amp; length of time for the non-specific therapy similar to that of active intervention. Participants were asked to document when technique used.</td>
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<td>Vasterling et al (1993)</td>
<td>RCT</td>
<td>72 cancer chemotherapy patients randomized, stratified by anxiety score, cancer site, medication type, to 1 of 3 groups.</td>
<td>Experimental group: asked to engage in patient-chosen GI and PMR; Attention placebo group: (cognitive distraction): asked to play video games with therapist present for support. 45-minute training sessions prior to 3 chemotherapy treatments. Encouraged to use during chemotherapy. Control group: asked to rest before chemotherapy sessions.</td>
<td>Chemotherapy side effects at follow-up: SBP &amp; DBP, (single readings); Anxiety (MAACL &amp; nurse &amp; patient ratings on 7-point scales).</td>
<td>Effect on SBP &amp; DBP after each training session (p &lt; .03) for intervention compared with control. Attention group had lower SBP post 1st &amp; 2nd training sessions &amp; significant DBP effect only at 2nd training session. No BP effect at follow-up.</td>
<td>No home practice reported. Only absolute BP reported. Analysis based on 60 subjects; dropout similar across groups. No interaction for either distraction or relaxation with anxiety level found. A normotensive sample; possible floor effect.</td>
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</table>
## Appendix B

### Summary of Research of Guided Imagery Effects on Blood Pressure

<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Findings</th>
<th>Comments</th>
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<tbody>
<tr>
<td>Manyande et al (1995)</td>
<td>RCT of imagery</td>
<td>51 patients undergoing minor abdominal surgery</td>
<td>Experimental group: Guided mental rehearsal &amp; relaxation imagery tapes</td>
<td>Pain, coping, analgesia, maximum systolic blood pressure (SBP), diastolic blood pressure (DBP),</td>
<td>No effect on either SBP or DBP during or post-surgery. HR significantly lower for imagery</td>
<td>BP outcomes based on a maximum value, A single mercury reading.</td>
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<td>as way to enhance coping</td>
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<td>starting on preoperative day to relax, imagine surgery-related discomforts, &amp;</td>
<td>heart rate (HR), &amp; cortisol, adrenaline, &amp; noradrenaline levels during &amp; post-surgery.</td>
<td>than controls during surgery, recovery, but not post-operatively.</td>
<td>Statistics not reported. GI tape used significantly more than control tape.</td>
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<td>think positive thoughts about coping with them; Control group participants</td>
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<td>(n = 25) were asked to listen to audiotape about the hospital.</td>
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<td>Salmore &amp; Nelson (2000)</td>
<td>RCT</td>
<td>63 patients undergoing gastrointestinal endoscopic</td>
<td>Experimental group: Brief introduction to guided imagery (GI) technique,</td>
<td>SBP, DBP &amp; HR, measured every 15 minutes “using vital sign monitors” &amp; amount of analgesia used</td>
<td>Effect on DBP. No effect on SBP or HR. No significant difference found in amount of analgesia</td>
<td>Baseline BP based on single reading, done after introduction to study, to minimize white-coat effect. Short-term effectiveness of GI in reducing BP in this non-hypertensive sample may not be clinically meaningful. Frequency of GI use not reported.</td>
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<td>examinations allocated to experimental or control</td>
<td>plus pamphlet to reinforce technique &amp; audiotape of music. Imagery related to</td>
<td>throughout endoscopic procedure.</td>
<td>used.</td>
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<td>conditions, stratified by procedure type</td>
<td>floating on a cloud. Participants were asked to practice every evening, &amp; use</td>
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<td>GI during endoscopy. Comparison group: participants received usual care,</td>
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<td>including a pre-operative home visit.</td>
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<tr>
<td>Young (1999)</td>
<td>RCT, Pre-test</td>
<td>47 adults with mild to moderate essential hypertension</td>
<td>Experimental group participants were given an audiotape (introduction,</td>
<td>SBP &amp; DBP using standard procedures, &amp; based on average of 2 aneroid-manometer measurements 15</td>
<td>Effect on SBP post-treatment; significant effect at 1-week post-treatment. No effect on</td>
<td>Analysis on 46 of 47; 1 did not complete due to medication change. Standardized images used. Individual measuring BP was not masked to group allocation. Reported audiotape use varied significantly by group. No ongoing support in GI use reported.</td>
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<td></td>
<td>post-test design</td>
<td>(sustained SBP of 140-179 mmHg, or DBP between 90-109)</td>
<td>instructions &amp; 15-minute GI exercise) for home use twice a day for 2 weeks.</td>
<td>minutes apart at the end of 2 weeks, &amp; at follow-up 1 week later.</td>
<td>reducing DBP post-treatment or at 1-week post-treatment.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Images standard &amp; specific to BP, arteries &amp; heart restoration, with</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>relaxation elements. Comparison group received attention placebo audiotape</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>of similar length of poem (The Raven) to listen to twice a day.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*SBP, diastolic blood pressure; DBP, diastolic blood pressure; HR, heart rate; GI, guided imagery*
### Appendix C

**Summary of Research on Effects of Guided Imagery Alone on Anxiety**

<table>
<thead>
<tr>
<th>Author</th>
<th>Method</th>
<th>Sample</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esplen (1991)</td>
<td>Pre-test post-test design.</td>
<td>21 student musicians</td>
<td>Single group: Introduction to guided imagery (GI) technique, plus asked to practice daily with audiotape for 7 days prior to musical performance.</td>
<td>Performance anxiety (STAI scores)</td>
<td>GI effective in reducing anxiety. STAI scores fell: M = 51.39 (10.53) to M = 41.23 (9.35) t = -5.6, p &lt; .0001</td>
<td>Not an RCT. Effect may relate to extremely high baseline anxiety &amp; ceiling effect.</td>
</tr>
<tr>
<td>Lang et al (2000)</td>
<td>RCT</td>
<td>241 adults undergoing invasive medical procedures</td>
<td>Experimental group: (n=82) Self-hypnotic relaxation (included imagery). Attention placebo group: (n=80) structured attention Control group (n=79): usual care.</td>
<td>Patient-rated pain &amp; anxiety using 1–10 scales before, every 15 min during &amp; after procedures.</td>
<td>Effective compared with standard care (p = 0.0022); difference between relaxation &amp; placebo NS (p = 0.0804). Anxiety decreased during procedure for all 3 groups; slopes -0.04 (standard), -0.07 (attention), &amp; -0.11 (hypnosis).</td>
<td>Medication use lower in attention and hypnosis groups than in standard group; Hypnosis patients more haemodynamically stable &amp; shorter procedure times than for other patients.</td>
</tr>
<tr>
<td>Rees (1995)</td>
<td>RCT pretest-posttest design</td>
<td>60 first-time post-partum women with health full-term babies</td>
<td>Experimental group (n = 30): Relaxation with GI, starting near the time of post-partum discharge from hospital. Asked to listen to a 15-minute GI audiotape each morning for 4 weeks Control group (n = 30): Asked to listen to tape-recorded music for 15 minutes each morning</td>
<td>Anxiety (STAI), depression (CES-D; Radloff, 1977), &amp; self-esteem (Rosenberg, 1979) after 4 weeks</td>
<td>Effective in reducing anxiety &amp; depression, &amp; enhancing self-esteem State anxiety (t = -2.64, p = .006)</td>
<td>Participants asked to maintain a daily log. Author reports no missing data. Details regarding type or amount or training not reported.</td>
</tr>
<tr>
<td>Stephens (1992)</td>
<td>RCT</td>
<td>159 first-year nursing students</td>
<td>GI: audiotape for 5 days, then 3 times per week for 3 weeks; GI &amp; PMR: Same GI audiotape with extra 5 minutes of PMR. Control: No treatment.</td>
<td>Anxiety (STAI scores &amp; examination scores)</td>
<td>GI effective with, or without PMR, in reducing anxiety, compared with controls (p &lt; .001); difference between treatment groups NS. Test performance did not differ significantly (p=.067).</td>
<td>Participants also reported increased well-being, improved sleep, more energy, &amp; more self-confidence.</td>
</tr>
<tr>
<td>Sapp (1994)</td>
<td>RCT</td>
<td>100 students</td>
<td>Experimental group: 4 GI sessions over 4 weeks (included relaxation, thought-stopping, &amp; reinforcement). Asked to practice between sessions. Placebo control group: asked to monitor behavior &amp; study time for 4 weeks.</td>
<td>Worry about test performance, emotionality, &amp; grades</td>
<td>Effective in reducing test anxiety-related worry (F (1, 85) = 15.24, p &lt; .001) &amp; emotionality (F (1, 85) = 17.79, p &lt; .001). Grades higher in GI group (F (1, 18) = 17.98, p &lt; .001). Improvements still present at 6 week follow-up.</td>
<td>GI was offered to control group after the study.</td>
</tr>
</tbody>
</table>
### Appendix D

Summary of Research on Effects of Multi-component Guided Imagery and other Relaxation on Anxiety Outcomes

<table>
<thead>
<tr>
<th>Author</th>
<th>Method</th>
<th>Participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achterberg et al (1988)</td>
<td>Allocated to 1 of 5 groups. Not RCT</td>
<td>149 hospitalized severely burned patients</td>
<td>Relaxation group (n = 34): audiotape of breathing techniques, muscle relaxation &amp; ocean sounds; Guided imagery (GI) &amp; relaxation group (n= 39): audiotape of breathing techniques, muscle relaxation &amp; GI (mental rehearsal of wound care); GI, relaxation &amp; biofeedback (n = 26): audiotape of breathing techniques, muscle relaxation &amp; undertake biofeedback. Controls (n = 50) usual care.</td>
<td>Pain on scale of 1-10; anxiety, using State Anxiety Index (Spielberger et al, 1970); mood based on Profile of Mood States (POMS), systolic blood pressure (SBP), diastolic blood pressure (DBP) &amp; heart rate (HR), muscle response &amp; thermal response.</td>
<td>All interventions effective in significantly reducing anxiety, compared with control group. For relaxation alone group, this only for post-training score, and not the post-treatment score</td>
<td>3 training &amp; 3 treatment sessions for experimental groups. Biofeedback group received significantly more analgesia &amp; sedation. No practice of technique reported. No random allocation.</td>
</tr>
<tr>
<td>Baider et al (1994)</td>
<td>Pre-test/ post-test design</td>
<td>123 cancer patients</td>
<td>Single group: Guided imagery (GI) of positive images + progressive muscle relaxation (PMR) + breathing (90-minute weekly training x 6 weeks). No report of home practice.</td>
<td>Psychological distress (Brief Symptom Inventory; Impact of Event Scale; Multiple Locus of Control) at end of 6 weeks.</td>
<td>GI plus PMR effective in reducing distress scores (t = 10.07, p &lt; 0.001)</td>
<td>Group training sessions. Not an RCT 30% drop-out rate (baseline measures similar to those who continued); analysis based on 86.</td>
</tr>
<tr>
<td>Baider et al (2001)</td>
<td>RCT</td>
<td>116 cancer patients</td>
<td>Experimental group (n =63) PMR +GI. Weekly group sessions (x 60 minutes) x 6 weeks Control group (n = 27): standard care</td>
<td>Psychological distress via Brief Symptom Inventory (BSI) &amp; Impact of Events Scale (IES), Global Severity Index (GSI) 6 months post-intervention</td>
<td>Effective in decreasing distress; reduction of 2.3 points in treatment group vs. 1.2 point increase in control group (P=.005)</td>
<td>Authors suggest initial screening of cancer patients for psychological distress.</td>
</tr>
<tr>
<td>Burish et al (1987)</td>
<td>RCT</td>
<td>24 cancer chemotherapy patients</td>
<td>Experimental group: GI + PMR (1-3 training sessions + therapy sessions prior to first 5 chemotherapies + asked to practice daily, using audiotape. Control group: Asked to rest quietly prior to chemotherapy.</td>
<td>Anxiety (Multiple Affect Adjective Check List; MAACL) Zuckerman,1964) &amp; 7-point self-rating &amp; nurse-rated scales; SBP &amp; DBP; Nausea , vomiting (7-point self-rating &amp; nurse-rated scales)</td>
<td>Effective in reducing anxiety (p &lt; .05)</td>
<td>Masking of data collectors to group allocation not reported. Family members invited to also learn technique.</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Sample</td>
<td>Interventions</td>
<td>Outcomes</td>
<td></td>
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</tbody>
</table>
| Carey & Burish (1987)         | RCT     | 45 cancer chemotherapy patients (matched on cancer site & type of chemotherapy) | **Experimental groups:** PMR + GI over 3 sessions; frequent practice recommended.  
PMR + GI provided by a therapist; or PMR + GI provided by trained volunteer; or  
PMR + GI provided by audiotapes;  
**Control:** routine care & rest.  
Patients in all groups received standard antiemetics. | Anxiety (7-point self-rated & nurse-rated scales & MAACL-short); SBP, DBP, HR; nausea (7-point scale).  
GI & PMR when provided by therapist effective in reducing anxiety; lower self-rated anxiety during chemo (M = 1.88) than controls (M = 2.73), lower nurse-rated anxiety (M = 2.76) than controls (M = 3.58), & lower HR (72.77 bpm) than controls (M = 83.58 bpm), p < .05. |
**Attention placebo control** (n = 21) perinatal education & social support  
Stress: STAI (state); Perceived Stress Scale (Cohen, 1983); Pregnancy Anxiety (Dunkel-Schetter, 1999); Life Event Distress Scale, modified (Lobel, 1999);  
Plasma & salivary cortisol | No significant effects.  
Trend towards greater decreases in stress measures in late 2nd and 3rd trimester (p > .05), NS. |
| Collins & Rice (1997)         | RCT     | 50 adults with myocardial infarction in last 12 weeks & attending cardiac rehabilitation, stratified by 1 of 4 sites. | **Experimental group:** provided instruction on PMR & imagery use at first study visit, with daily home practice (x 6 weeks) with audiotape & written instructions.  
Imagery involved a place pleasant and restful for that person, & visualization of a healthy heart.  
**Control group:** routine care.  
Psychological & physiologic stress outcomes: Anxiety (STAI); stress (symptom checklist -90 revised)  
Derogatis (1992; 1974); BP & HR, after 6 weeks treatment. | No effect in STAI scores (t [42] = 0.21, p > 0.05), but tension levels reduced in intervention group (t [18] = 7.13, p < 0.001) post-practice & at 6 weeks.  
HR lower for relaxation than controls (8.6 bpm, p < .05);  
Relaxation group within-group HR reduction(t [19] =2.09, p< 0.05). |
| Holden-Lund (1988)            | RCT     | 24 adults having gall-bladder surgery                                  | **Experimental group:** GI of the wound healing well, with PMR, using audiotapes on day prior to surgery & over first 3 post-operative days.  
**Control group:** quiet rest  
Psychological stress (state anxiety via STAI), physiological stress (urinary cortisol), & wound healing. | Effective in reducing state anxiety (F=6.24, df = 1, 44, p< .01) & cortisol levels (4.7 times preop) less in intervention group than control (12.5 times preop), p< .05. |
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Additional Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>King (1988)</strong></td>
<td>One group pretest/post-test design.</td>
<td>33 graduate nursing students (with no history of depression, psychosis, or cardiac irregularities)</td>
<td><strong>Single group:</strong> GI + muscle relaxation (not PMR); script administered 3 times in small groups before or after classes at 3-week intervals. Asked to imagine a calm &amp; peaceful place.</td>
<td>State anxiety (STAI) effective; significantly reduced anxiety after each of 3 sessions: #1: M = 43.03 (14.97) to M = 29.45 (8.58), t = 6.98, p &lt; .001; #2: M = 45.12 (12.91) to M = 32.39 (9.41), t = 8.82, p &lt; .001; #3: M = 45.09 (12.09) to 31.45 (9.13), t = 10.88, p &lt; .001</td>
<td>Sessions 30 minutes in length. Effect short-lived; participants returned to pre-imaging anxiety levels within 2-weeks post-intervention.</td>
</tr>
<tr>
<td><strong>Sloman (2002)</strong></td>
<td>RCT</td>
<td>56 patients with advanced cancer &amp; anxiety &amp; depression.</td>
<td><strong>Experimental groups:</strong> 1. GI training; 2. PMR training; 3. Both GI &amp; PMR. All 3 interventions included use of audiotape played twice weekly (30 minutes), &amp; practice twice daily with tape. <strong>Control group:</strong> equal contact time but no training.</td>
<td>No significant effect on anxiety; difference between groups: (F = 2.678, p = .057). Significant improvements in depression &amp; quality of life.</td>
<td>Sample size small &amp; large number of study groups.</td>
</tr>
<tr>
<td><strong>Thompson &amp; Coppens (1994)</strong></td>
<td>RCT</td>
<td>41 patients receiving magnetic resonance imaging (MRI)</td>
<td><strong>Experimental group:</strong> (n = 20) Explanation of MRI + GI relaxation + 10 minute audiotape to listen to prior to &amp; during MRI. <strong>Control group</strong> (n = 21): explanation of MRI</td>
<td>Anxiety (STAI) &amp; physical body movement of clients during MRI procedure based on observer determination</td>
<td>Effective in reducing STAI scores, compared to controls (p &lt; .001) &amp; in reducing body movements (p &lt; .001)</td>
</tr>
<tr>
<td><strong>Tsai &amp; Crockett (1993)</strong></td>
<td>RCT Pre-test/post-test design.</td>
<td>137 Taiwanese nurses from 3 hospitals, stratified by hospital.</td>
<td><strong>Experimental group:</strong> 2 90-minute relaxation training sessions (GI, breathing exercises, &amp; meditation) 1 week apart. <strong>Attention placebo control:</strong> Equal contact hours of in-service education on nursing theory analysis.</td>
<td>Work stress: (Nurse Stress Checklist, Chinese version; Benoliel, 1990); &amp; health (Chinese General Health Questionnaire) at end of 2nd session, &amp; at follow-up in week 5.</td>
<td>Intervention effective in lowering work stress. Main effect (F [1,132] = 5.69, p &lt; .05). Interaction effect of time and treatment on stress (F [1,132] = 12.5, p &lt; .05)</td>
</tr>
</tbody>
</table>
Appendix E
Eligibility Screening Form

If A Pregnant Woman you are caring for has **High Blood Pressure**, PLEASE SCREEN HER for eligibility for the Relaxation in Pregnancy (REBIP) Study

### Study Criteria

<table>
<thead>
<tr>
<th>Study Criteria</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is this woman’s pregnancy currently less than or equal to (≤) 33 weeks, 6 days gestation?</td>
<td>YES ⇒ continue</td>
<td>NO ⇒ STOP - Not eligible</td>
</tr>
<tr>
<td>Is she currently prescribed antihypertensive medication?</td>
<td>YES ⇒ continue</td>
<td>NO ⇒ STOP - Not eligible</td>
</tr>
<tr>
<td>Has she has 2 or more prenatal diastolic blood pressure readings equal to or greater than (≥) 90 mm Hg? (at one or more clinic, physician office, FATC, hospital &amp;/or prenatal homecare visits)</td>
<td>YES ⇒ continue</td>
<td>NO ⇒ STOP - Not eligible</td>
</tr>
<tr>
<td>Has this woman had any clinical investigation of her hypertension? (Includes referral to obstetrician or to FATC, hospital admission, laboratory testing, etc.)</td>
<td>YES ⇒ continue</td>
<td>NO ⇒ STOP - Not eligible</td>
</tr>
<tr>
<td>Is this woman planning to give birth at the IWK Health Centre?</td>
<td>YES ⇒ continue</td>
<td>NO ⇒ STOP - Not eligible</td>
</tr>
<tr>
<td>Is this woman appear to competent to give informed consent?</td>
<td>YES ⇒ continue</td>
<td>NO ⇒ STOP - Not eligible</td>
</tr>
<tr>
<td>Can this woman hear well enough (naturally or through hearing aids) to hear verbal &amp; audiotaped instructions?</td>
<td>YES ⇒ continue</td>
<td>NO ⇒ STOP - Not eligible</td>
</tr>
<tr>
<td>Is this woman able to understand &amp; read English?</td>
<td>YES ⇒ continue</td>
<td>NO ⇒ STOP - Not eligible</td>
</tr>
<tr>
<td>Is this woman likely to deliver within 1 week, in the judgment of her obstetrical care provider?</td>
<td>YES ⇒ STOP - Not eligible</td>
<td>NO ⇒ continue</td>
</tr>
<tr>
<td>Does this woman have a documented psychotic illness, with or without current use of anti-psychotic medication? (Depression not included)</td>
<td>YES ⇒ STOP - Not eligible</td>
<td>NO ⇒ continue</td>
</tr>
</tbody>
</table>

On the basis of the above criteria, is this woman eligible for the REBIP study, as determined by nurse or physician?

- [ ] NO
- [ ] YES ...

If yes, please now assess her willingness to have someone from the study tell her about it, using the Introduction to Prospective Participants Form.  

*Thanks, Faith*
Appendix F

Sample of Consent Form
Information and Consent Form

Title of Research Project: The Relaxation and Blood Pressure in Pregnancy (REBIP) Pilot Study

Researcher: Faith Wight Moffatt, BN, MN, RN, and PhD Candidate, Graduate Department of Nursing Science, University of Toronto & Assistant Professor, School of Nursing, Dalhousie University

Funded by: The Nursing Research Fund, Dalhousie University, AWHONN Canada, with Canadian Nurses Foundation (CNF) Nursing Care Partnership (NCP), & the IWK Health Centre with CNF NCP.

Introduction: Over 10% of women have high blood pressure (hypertension) during their pregnancy. Right now, we do not know how to prevent most high blood pressure in pregnancy, and the only treatments involve rest and medication. Studies have found that simple mental relaxation methods can lower blood pressure for some people, but we do not know if they can lower blood pressure during pregnancy. We do not know if a form of relaxation based on using the imagination, called “guided imagery”, can lower blood pressure in pregnancy, and we do not know how women will feel about using it. We also do not know if regular, short periods of quiet rest will lower blood pressure.

You are invited to participate in the Relaxation and Blood Pressure in Pregnancy (REBIP) Pilot Study; it is your choice whether you want to participate or not. This study will include 66 pregnant women. Faith Wight Moffatt is conducting the study while she is a PhD student in the University of Toronto under the supervision of Professor Ellen Hodnett, in partial fulfillment of the requirements for the PhD degree.

Purpose of Study:
This research study is designed to find out if the type of relaxation pregnant women with high blood pressure use will affect their blood pressure, and to find out how women feel about the type of relaxation they are asked to use. The study will compare two types of relaxation: guided imagery and quiet rest.

Study Design:
If you agree to take part in this study, you will have ambulatory blood pressuring monitoring for 1 day this week and then 1 day per week for 4 weeks or until you give birth, whichever comes first. Ambulatory blood pressure monitoring involves wearing a blood pressure cuff for a day, during waking hours, while you go about your normal activities. Every half hour the cuff will automatically inflate, and the machine will record your blood pressure. At the beginning of the study, we will also ask you to answer a few questions about you and your pregnancy and about your feelings. This will take about 20 minutes to complete. After your first day of blood pressure monitoring, you will be “randomly assigned” to one of two groups, either the quiet rest group or the guided imagery group.

If you are in the quiet rest group, we will ask you to rest (sitting up or lying down) for at least 15 minutes, twice a day, for 4 weeks or until you give birth, whichever comes first. If you are in the guided imagery group, the nurse will teach you how to use your imagination to help you to relax, will give you a CD to listen to, and will ask you to use guided imagery for 15 minutes, twice a day for 4 weeks or until you give birth, whichever comes first.

“Random assignment” or “Randomization” means that the process of determining the group to which you will be assigned is random, or by chance, rather than being chosen by you, your doctor or the researcher. This means that if you agree to be in this study, you will have a fifty-fifty chance of being in one group or the other. This type of assignment to group is very important to be able to find out how helpful the two types of relaxation are in lowering blood pressure in pregnancy.

You will have your blood pressure checked on a regular basis during 1 day per week for 4 weeks or until you give birth, whichever comes first. You will be able to see the blood pressure reading on the machine display only for the first two or three times the cuff pumps up. After that, the display is blank, but the machine records all the blood pressure readings. If your nurse or doctor has asked you to measure your own blood pressure at home, you will still be able to do this in the morning and at bedtime using the blood pressure cuff s/he has advised or has given to you. Otherwise, the nursing and medical care you and your baby receive will not change because you are participating in the study.

Each week, a research nurse will ask you about how often you relax, and will ask you to answer a few written questions. This will take about 15 minutes. After your baby is born, a study staff member will collect information about your labour and the birth of your baby from your and your baby’s hospital charts. Later,
we will send you another questionnaire about what it was like to be in this study, for you to fill out 6 weeks after your baby’s birth. This takes about 20 minutes to complete.

**Potential Harms:**
Using the imagination to relax is considered safe. Because it is distracting, you should not use guided imagery while driving. It is rare, but some women could be emotionally upset from the guided imagery. If that happens to you, we will, with your permission, let your doctor know so that you can be referred for appropriate counseling or therapy. It is also possible that you may experience slight discomfort when the blood pressure cuff pumps up, but any discomfort tends to be limited to the first couple of times the cuff inflates. If at the start of any blood pressure measuring session, your blood pressure is extremely high or if you have symptoms that your doctor would want to know about, you will be asked to call your doctor, because s/he may want to see you that day. You do not give up any legal rights by participating in this study.

**Potential Benefits:**
Your being in the REBIP study may provide useful information to nurses and doctors about whether guided imagery can help manage high blood pressure in pregnant women. Many participants in previous studies of relaxation have said that they felt more relaxed and less anxious afterwards, but there is no promise that your being part of this study will benefit you directly.

**Withdrawal from Participation / Alternatives to Participation:**
You have the right to refuse to be in the study. You also have a right to withdraw from the study at any time. If you refuse to enter the study, or choose to withdraw, the care you or your baby receive from your doctors, nurses and other caregivers will not be affected in any way.

**Confidentiality:**
All information about you and your baby will be kept confidential. A code number, rather than your name, will be used on all study forms. We will not release or print any information that would disclose the identity of anyone in this study. We will keep study records in a locked filing cabinet at the School of Nursing, Dalhousie University, and only study staff will have access to them. However, portions of your study records may need to be checked by an IWK Health Centre Research Services Office representative, as part of normal monitoring to ensure that research in the Centre is conducted properly. Study records will be kept until your baby is 29 years old, as required by the IWK Research Ethics Board.

**Reimbursement of Participants:**
You will not receive money or other payment for being part of this study.

**Communication of Results:**
If you wish to have a copy of the results from this study sent to you when it is complete, please tell us on page 3 of this form. If you feel that you do not wish to receive that information, but you later change your mind, please contact the researcher, Faith Wight Moffatt, at 902 494-2181 or by email at faith.wightmoffatt@utoronto.ca.

**Continued Access:**
If you agree to take part in the study, your time in it will end within 4 weeks, except for the questionnaire that we will ask you to complete 6 weeks after your baby is born. However, you may wish to continue to use the relaxation method you have been using during this study.

**Contact Person:**
You have a right to ask questions about this study at any time. If you have any questions about the study or about your being in the study, please call me at any time at 902 494-2181 or (902) 499-8252 (cell). My PhD supervisor, Professor Ellen Hodnett, can be reached at (416) 946 8676. You may also contact the IWK Research Office at 470-8765 to receive information about this study from an outside source.

Faith Wight Moffatt, BN, MS(N), RN
Doctoral Candidate, University of Toronto
Study Title: The Relaxation and Blood Pressure in Pregnancy (REBIP) Pilot Study

Participant ID: ___________________  Participant Initials: ___________________

PARTICIPANT CONSENT -

I have read this Information and Consent Form, or had it read to me. I have had the Relaxation and Blood Pressure in Pregnancy (REBIP) study explained to me and I understand this information. I have had a chance to ask questions and to have my questions answered to my satisfaction before signing my name. I know I can ask further questions at any time. I understand that I can withdraw from the study without affecting the health care that my baby and I receive. I freely give my consent to participate in the REBIP study, and I have received a copy of this Information and Consent Form.

________________________________ ___________________ ____________________
Name of Participant (Please print)  Signature of Participant

Date: ___________________  Time: ______________

☐ I would like to receive a summary of the study results

(If YES, please make a tick mark in the box, and write your address below).

Mailing Address: _____________________________________________________________
___________________________________________________________________________
___________________________________________________________________________

STATEMENT BY PERSON PROVIDING INFORMATION ABOUT THE STUDY & OBTAINING CONSENT

I have explained the nature and demands of the research study and judge that the participant named above understands the nature and demands of the study. I have also explained the nature of the consent process to the person named above and judge that they understand the participation is voluntary and that they may withdraw at any time from participating.

________________________________ ___________________ ____________________
Name (Please print)  Position  Date: ____________  Time: _____________

Signature of Participant

Other people present at time of signing:

________________________________ ___________________ ____________________
Name (Please print)  Position  Date: ____________  Time: _____________
Appendix G
Guide to Ambulatory Blood Pressure Monitoring

The REBITP Relaxation and Blood Pressure in Pregnancy Study

GUIDE to AMBULATORY BLOOD PRESSURE MONITORING

Please contact ________________ if you have questions, at Cell phone: _________
Email: ________________
As part of the REBIP (Relaxation and Blood Pressure in Pregnancy) study, you have been asked to wear an ambulatory blood pressure monitor during daytime waking hours one day per week for this and the next four weeks.

Everyone’s blood pressure changes throughout the day, and blood pressure is often higher in a doctor’s office or in a clinic. Collecting several blood pressure readings over daytime hours will give the researchers more information about how your blood pressure responds to rest and relaxation.

You should not change your plans on the day you wear the monitor. Do whatever you would do if you were not wearing it. However, it should be kept dry, so it should not be worn in the shower or bathtub.

An ambulatory blood pressure monitor is a small electronic device with a blood pressure cuff attached to it. It is totally automatic and will take your blood pressure every 30 minutes between the time it is put on your arm until you remove it and turn it off at bedtime.

When it is about to take your blood pressure, you will hear a double beep. Within 5 seconds, you will feel the cuff tighten on your arm.

**VERY IMPORTANT:** At the sound of the beep, hold the cuffed arm across your chest. If sitting in a chair, keep feet flat on the floor, rest your back against the back of the chair, and do not talk or move. If standing, simply stand still, hold arm across chest, and do not talk or move. If you are lying down, it is important that you are not lying flat on your back.

Once the monitor has taken your blood pressure, you may return to what you were doing.

If you are unable to sit or stand or lie still as required, don’t worry about it, because the monitor will try to take your blood pressure again in 2 – 3 minutes. If it is still not able to at that time, it will take your blood pressure again in 30 minutes.
The monitor will not display your blood pressure readings, but stores them in the monitor.

If possible, you should keep the cuff on until bedtime. If you must take it off, you should take it off immediately after it has taken your blood pressure. Try to replace the cuff before the next reading.

When you go to bed at bedtime, you may take the cuff off your arm. **You must then turn the monitor off.** Remove it from the case and move the switch on the bottom of the monitor to the "OFF" position (see the picture below).

The monitor will be picked up by someone from the research study the next day.

**If you have any questions, call ______________**
Appendix H

Written Instructions for Study Group Conditions
Written Instructions for Using Guided Imagery in

Dear _______________________

- We ask that you try and practice the guided imagery exercise **at least twice per day, every day**, over the next 4 weeks.

- The compact disc (CD) you have been given is designed to help you use this guided imagery to relax. Practicing the exercise on the CD may help you get better at relaxing, so if it helps you to listen more frequently than twice per day, feel free to do that.

- You may find that as time goes on, you may be able to use your imagination to relax when you need or want to, without your listening to the CD.

- Choose a place where it is quiet, and where you can be alone and are unlikely to be disturbed for a few minutes. This is important so you will not feel rushed and you can focus on the sessions.

- Set aside times of day that are most convenient or work best for you to practice your Guided Imagery. Some people may choose to listen to the CD before they get up in the morning and at bedtime. Others may choose to listen at other times of day. The times you listen may also change from one day to the next. Also, you may be more comfortable if you go to the bathroom first.

- On the day of the week that your blood pressure is being measured every half-hour for this study, you may find it will be helpful if you plan to do your guided imagery sessions in between the times your blood pressure is measured. That way, you will not be disturbed or distracted by the cuff pumping up.

- Choose the position you find most comfortable and relaxing, but so you are not lying flat on your back.

- Place the CD in the CD-player (if it isn’t there already), place the earphones in your ears, and start to play the relaxation exercise on the CD. Use of earphones is encouraged to help you focus on the session and cut down on distracting noises while you are listening to the tape.

- Do your best to follow the instructions you hear on the tape. Try to imagine the images with as many of your senses as possible.

- The CD player will automatically turn itself off within a minute or so after the Guided Imagery exercise ends.

- Once a week, either when someone brings the blood pressure monitor, or when she comes to pick it up, she will ask you some questions about how often you rested, and how often you used the guided imagery during the previous week. For that reason, you may want to keep track of this on paper, if you think it will help you remember.

- If you have any questions or problems with using this CD or doing the guided imagery, you can contact me on my cell-phone at _________.

Thank you,

Faith Wight Moffatt, BN, MS(N), RN, PhD Candidate (Nursing Science)
Written Instructions for Women in the Quiet Rest Group of

Dear __________________

We ask that you rest at least 15 minutes at least twice per day, every day, over the next 4 weeks. You may wish to rest more often and/or longer than this. These Quiet Rest periods are not meant to be less than what increased rest your doctor may have recommended for you. These rest periods do not include night-time sleep.

During these rest periods, please lie on your side, or stretch out in a chair with your legs up, so you are comfortable and relaxed. It is important that you do not lie flat on your back.

Please do not read or watch television during these two 15 minute periods each day.

Choose a place where it is quiet, and where you can be alone and are unlikely to be disturbed for a few minutes.

Set aside times of day that are most convenient or work best for you. Some people may choose to have their Quiet Rest periods before they get up in the morning and at bedtime. Others may choose other times of day. The times of day you rest may also change from one day to the next. Also, you may be more comfortable if you go to the bathroom first.

On the day of the week that your blood pressure is being measured every half-hour for this study, you may find it will be helpful if you plan to have your Quiet Rest periods in between the times your blood pressure is measured. That way, you will not be disturbed or distracted by the cuff pumping up.

Once a week, either when someone brings the blood pressure monitor or when she comes to pick it up, she will ask you some questions about how often you rested during the previous week. For that reason, you may want to keep track of this on paper, if you think it will help you remember.

If you have any questions about, or problems with this Quiet Rest, you can contact me on my cell-phone at _________.

Thank you,

Faith Wight Moffatt, BN, MS(N), RN, PhD Candidate (Nursing Science)
Appendix I

Script for Guided Imagery

It is normal to feel uncertain … with the changes in your life right now. … Your listening to this tape … may help take you away from your worries, … or help you manage them, or any stresses you may be feeling. Using this relaxation tape may also help … lower your blood pressure. Lie down, … or recline in a chair, … and make yourself … as comfortable as you can, … with a small pillow … or rolled towel … or blanket under one of your hips. Loosen any clothes that feel too tight, … uncross your legs, … and let your arms rest comfortably.

This relaxation exercise … is a tool that you can use … as a break from any concerns … you may be experiencing right now … Just follow my voice … as you listen to this tape. … Let your eyes close gently, … and follow my voice. … Now, … As you rest your eyes … you may feel yourself start to relax … This time is for you … Feel yourself start to breathe slowly … and deeply … [PAUSE]. With each breath, … feel any discomfort, … tension, … stress … or strain … start to leave you … [PAUSE LONGER] As you breathe out, … you may feel a soothing wave of relaxation … flowing around and through you … with each breath … You may hear occasional sounds in the background, … but they will not be a distraction for you.

These relaxation breaks … may be beneficial to you now … and may also help … as you go through the changes of pregnancy … and of new parenthood. … [PAUSE] By taking this time for yourself, … you are mothering your baby … [PAUSE] You deserve this special time … … Let your tensions go … with each breath you breathe … You feel comforted … feel your burdens … float away … [SLOW, PAUSE]. Release them, … one by one … just allow them to float away … with each breath … [LONGER PAUSE] … Feel, … [PAUSE], imagine, … any concerns, … worries, … uncertainties … flowing away … like bubbles … Or like waves … receding on a shoreline … Let any tension go … with each breath … [BREATH OUT] … You
may feel those breaths ….as if they are gentle waves, ….rocking you, ….comforting you ….Rocking softly, ….slowly,….Calm, ……[PAUSE] peaceful… You may feel yourself lighter, …less heavy, …less burdened…. Remember that … in this relaxed state, …you are still totally… in control………[PAUSE] If any problem were to occur, …you would be able to respond to it…. …You have people who are looking out for you and your baby ..... You are not alone. .....At any time …. you feel you need to stop this tape, …you will be able to open your eyes … and you can emerge … from this relaxed state…feeling calm and comfortable…alert and relaxed….Remember, …in this relaxed state … you are still…fully in control…At some level, …your mind perceives everything…but for the next few minutes, …you can focus, … and enjoy a time away …from the many busy thoughts … of your day.

Sometimes, negative thoughts … may cross your mind. You may wish to just …. put these thoughts aside … for the next little while, …just let them fade away, … you can deal with them …later... Continue to follow my voice …. You feel calm …. [SLOW, PAUSE] ……Calm in mind, …calm in spirit, …calm in body…. … Breathe deeply…. [PAUSE] This is your special time …. Feel your body be comfortable ..... relaxed ..... Enjoy the sense of relaxation …and comfort … you feel ….Notice how you feel yourself lighter, … as you let negative feelings …drift away……

‘This is your time …. to take care of …to nurture ….yourself … and your baby ….Your taking time for yourself … Being kind to yourself… will help you … as you mother this baby…

Continue to focus …on your breathing now… Continue to breathe slowly and deeply …. …Let your mind be at peace ..... Let yourself feel calm, [PAUSE]…very calm….relaxed….strong… With each slow … deep breath out, … you may feel more and more relaxed. …Feel your body relax … from the top of your head …to the tip of your toes … Just follow my voice.
Now, as your body… and mind feel relaxed… as you continue to breath deeply,… perhaps you would like… to imagine that… you are in a special place,… Your own private sanctuary… one where you feel comfortable,… wonderful… nurtured,… safe and sound. …where you can relax… totally… your retreat. …This place… can be a real place,… where you have been before,… or perhaps it is a place you would like to go… Or one that isn’t finished yet… or exists only… in your own imagination. … Any comforting place you want… It can be a natural place,… outside…, or a room or space indoors. … This… nurturing space… in your mind… can be your ‘safe haven’,… one where you can feel ‘safe and sound’,… serene and peaceful. … You can be private… in this space… or… you can imagine bringing someone… that you choose… with you. …

You can experience… all of this scene now,… with all… of your senses… [SLOW] Continue to close your eyes,… but what do you see… in your mind’s eye… as you look around? … What is in this place? … See it… imagine it all… as clearly as you can. … Take in all the details. … What colours do you see? … Enjoy those colours. … Notice,… the objects here,… perhaps trees,… plants,… even a piece of furniture that you love. … Notice how you feel here. … Feel [EMPHASIZE] the environment around you… Perhaps the air on your face,… a breeze across your cheek,… perhaps the gentle warmth of the sun,… It feels good… renewing. … You can feel the textures… of the things there… You may begin to notice… pleasing sounds of that environment,… and smell wonderful smells. [SLOW] Concentrate on this place… Experience it,… explore it… at your own pace… Is there a path you want to wander down? If so, feel free to stroll down that path. Or perhaps… there is something else… that you want to explore here… [EMPHASIZE] Feel the tranquillity here… [SLOW] Take time to feel,[PAUSE]… to enjoy. … Continue to breath slowly,… and follow my voice. [PAUSE] It is tranquil here….
Soothing...peaceful..... Allow yourself .....to enjoy the feelings of comfort and joy ... you may be experiencing....

Explore at your own pace ... Enjoy it with all of your senses ...[PAUSE] ...You may wish to stay in your sanctuary longer .... If you wish .... [EMPHASIZE]. You are in control ....And so ,...when you feel ready to leave, ... and come back to the outside world, ...just count slowly, ... from five ... to four, ... to three,... to two, .....to one ..... At that time, ... leave negative feelings ...and thoughts behind, and ..... bring some of the calm, peaceful feelings with you ... back to the room, ..... As you count, ...you will feel more and more focused ...on your breathing ..... and your sensations

Notice how relaxed you feel,... calm and centred within yourself. This sense of calmness ...is something that you can reach .... at times when you need ...to feel that way. ...You can return ...to your wonderful place ....by following my voice on the tape ... or just by ...closing your eyes....You can keep things as you want in your special place, ... or make changes ...or add things anytime you want. You can go there ...whenever you need a break...or need to take time for yourself ....and experience that sense of relaxation.
Appendix J

Data Entry Forms
Entry Form

(collect immediately before randomization)

Section A: Baseline Characteristics

A1. Gestational Age (must be ≤ 33 weeks, 6 days at randomization)

   [ ] Weeks   [ ] days

A2. What type of hypertension does this woman have? (Hypertension ≥ 140 mmHg systolic AND
     ≥ 90 mmHg diastolic) (mark all that apply)
     ○ Chronic
     ○ Pre-eclampsia (Hypertension & proteinuria > 300 mg/L in any 24 hour collection OR a total of
       500 mg/24 hours, documented at any point during pregnancy, OR a dipstick of
       ≥ 2+ from a clean catch midstream urine)
     ○ Gestational hypertension (Hypertension & no proteinuria, when proteinuria > 300 mg/L in
       any 24 hour collection OR a total of 500 mg/24 hours, documented at any point during
       pregnancy, OR a dipstick ≥ 2+ from a clean catch midstream urine.)
     ○ Unable to determine

A3. Para (# of previous births ≥ 20 weeks or > 500grams)

   [ ] [ ]

A4. Is this a singleton pregnancy?
     ○ YES
     ○ NO

A5. Have you had other complications in this pregnancy?
    a) Diabetes?
       ○ NO
       ○ YES → If YES, type:
         ○ Gestational
         ○ Type 1
         ○ Type 2

    b) Preterm labour (now or previously in this pregnancy):
       ○ NO
       ○ YES

    c) Vaginal bleeding after the first trimester:
       ○ NO
       ○ YES

    d) Other major health pregnancy problem during this pregnancy?
       ○ NO
       ○ YES (please specify): _______________________

    ... please turn the page for more questions
A6. Currently, do you smoke cigarettes?
   ○ Not at all
   ○ Occasionally, not every day
   ○ Daily

A7. When you think of your ethnic or cultural background, which of the following terms applies to you? (please mark all that apply)
   ○ White/Caucasian
   ○ Black
   ○ Aboriginal Canadian/First Nations
   ○ Arab
   ○ Asian
   ○ Other (please specify): __________________________
   ○ Prefers not to answer

A8. Education completed: (mark only one)
   ○ Less than high school
   ○ High school
   ○ Community college/trade school
   ○ University/ 4 year college
   ○ Graduate school or higher
   ○ Prefers not to answer

A9. Paid employment currently?
   ○ No (includes maternity leave)
   ○ Part-time
   ○ Full time

A10. Marital status
   ○ Married or stable relationship
   ○ Other

A11. At time of randomization, woman was
   ○ Hospitalized as inpatient
   ○ On home care program (outpatient)
   ○ Outpatient but NOT on home care program
Section B: Randomization Instructions

2. Call 416-946-0249
   You will be connected to the Computerized Randomization Service.
3. Follow the instructions over the phone to enter the answers to questions B1 to B3, which
   will identify the woman. All answers must be followed by entering the # sign (located on the
   bottom right corner of the telephone key pad.) At the end of each question, your response
   will be repeated back to you for confirmation. If you need to make changes wait for the
   question to begin again before re-entering your answer. After confirming the woman’s date
   of birth, no further changes can be made as the study group has been assigned.
4. Mark the study group assigned by the Randomization Service under question B4 below.
5. Complete question B5.

B1. Study Identifying code
   003#

B2. Study Code Number:

B3. Woman’s Date of Birth

B4. Allocated study group (enter the group assigned by the Randomization Service):
   ○ GUIDED IMAGERY
   ○ QUIET REST

B5. Date & time of randomization:
   year  month  day  24-hour clock
**Baseline Self-Evaluation Questionnaire**

**DIRECTIONS:** A number of statements which people have used to describe themselves are given below. Read each statement and then make a mark in ONE box for each statement to indicate how **you have felt over the past week**. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your feelings best.

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Expectancy Scale

DIRECTIONS:

Think of the study group you were given and the form of relaxation you have been asked to use. Please circle one number between 0 and 10 as your rating for each of the following 5 questions, with 0 being "not at all" and 10 being the highest rating possible, "very much so". There are no right or wrong answers.

1. How logical does this form of relaxation seem to you?

   0   1   2   3   4   5   6   7   8   9   10
   Not at all
   very much so

2. How confident would you be that this form of relaxation would be successful in helping to lower your blood pressure?

   0   1   2   3   4   5   6   7   8   9   10
   Not at all
   very much so

3. How confident would you be that this form of relaxation would be successful in helping to lower your anxiety?

   0   1   2   3   4   5   6   7   8   9   10
   Not at all
   very much so

4. How successful do you think this form of relaxation would be in improving other problems?

   0   1   2   3   4   5   6   7   8   9   10
   Not at all
   very much so

5. At this point, how confident would you be in recommending this form of relaxation to a friend who suffered from similar problems?

   0   1   2   3   4   5   6   7   8   9   10
   Not at all
   very much so
## Patient Information

- **Patient Name:**
- **Address:**
- **City:**
- **State:**
- **Zip:**
- **I.D. #:**
- **Soc Sec #:**
- **Insurance #:**
- **Medicare #:**
- **Scan #:**

- **Reason for Test:** Baseline
- **Medication:** None
- **Dose:**
- **Time:**

## Physician Information

- **Physician:** F. Wight Moffatt
- **Address:** School of Nursing Dalhousie University
- **Phone:** (902) 494-2181

## Technical Data

- **Scan Start Date:** 12/03/2004
- **Scan Start Time:** 11:34
- **Scan End Date:** 12/03/2004
- **Scan End Time:** 22:03

- **Scan Total Time:** 10:29
- **Successful Readings:** 23
- **Percent Successful:** 95%
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</table>

**Legend:**
- **R** = Auto Retry
- **M** = Manual Initiated
- **AE** = Auto Edit
- **EE** = Event Edit
- **ME** = Manual Edit
- **< >** = Estimated

---

### ABP Raw Data

<table>
<thead>
<tr>
<th>Day &amp; Time</th>
<th>Systolic</th>
<th>Diastolic</th>
<th>MAP</th>
<th>Heart Rate</th>
<th>Event Code</th>
<th>Status</th>
<th>Diary Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 M 1-11:43</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td></td>
<td>EE</td>
</tr>
</tbody>
</table>

**Legend:**
- **R** = Auto Retry
- **M** = Manual Initiated
- **AE** = Auto Edit
- **EE** = Event Edit
- **ME** = Manual Edit
- **< >** = Estimated
## SUMMARY

<table>
<thead>
<tr>
<th></th>
<th>MIN</th>
<th>MEAN</th>
<th>MAX</th>
<th>STD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic</td>
<td>121 (1-11:34)</td>
<td>135</td>
<td>153 (1-19:03)</td>
<td>6.41 mmHg</td>
</tr>
<tr>
<td>Diastolic</td>
<td>70 (1-11:34)</td>
<td>88</td>
<td>97 (1-12:33)</td>
<td>7.24 mmHg</td>
</tr>
<tr>
<td>MAP</td>
<td>95</td>
<td>103</td>
<td>111</td>
<td>4.77 mmHg</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>73</td>
<td>87</td>
<td>101</td>
<td>6.89 BPM</td>
</tr>
</tbody>
</table>

Percent of Systolic Readings above period limits: 43.5%
Percent of Diastolic Readings above period limits: 39.1%
Percent of time Systolic was above period limits: 45.3%
Percent of time Diastolic was above period limits: 40.5%

## SUMMARY PERIOD: 6:00 to 18:00

<table>
<thead>
<tr>
<th></th>
<th>MIN</th>
<th>MEAN</th>
<th>MAX</th>
<th>STD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic</td>
<td>121 (1-11:34)</td>
<td>135</td>
<td>141 (1-17:33)</td>
<td>5.84 mmHg</td>
</tr>
<tr>
<td>Diastolic</td>
<td>70 (1-11:34)</td>
<td>83</td>
<td>97 (1-12:33)</td>
<td>7.16 mmHg</td>
</tr>
<tr>
<td>MAP</td>
<td>95</td>
<td>101</td>
<td>109</td>
<td>4.37 mmHg</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>82</td>
<td>90</td>
<td>101</td>
<td>6.36 BPM</td>
</tr>
</tbody>
</table>

Percent of Systolic Readings > 140 mmHg 7.1%
Percent of Diastolic Readings > 90 mmHg 14.3%
Percent of time Systolic > 140 mmHg 4.2%
Percent of time Diastolic > 90 mmHg 16.7%

## SUMMARY PERIOD: 18:00 to 6:00

<table>
<thead>
<tr>
<th></th>
<th>MIN</th>
<th>MEAN</th>
<th>MAX</th>
<th>STD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic</td>
<td>127 (1-20:33)</td>
<td>136</td>
<td>153 (1-19:03)</td>
<td>7.24 mmHg</td>
</tr>
<tr>
<td>Diastolic</td>
<td>72 (1-20:03)</td>
<td>85</td>
<td>95 (1-21:03)</td>
<td>7.42 mmHg</td>
</tr>
<tr>
<td>MAP</td>
<td>96</td>
<td>103</td>
<td>111</td>
<td>4.94 mmHg</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>73</td>
<td>86</td>
<td>96</td>
<td>7.37 BPM</td>
</tr>
</tbody>
</table>

Percent of Systolic Readings > 120 mmHg 100.0%
Percent of Diastolic Readings > 80 mmHg 77.8%
Percent of time Systolic > 120 mmHg 100.0%
Percent of time Diastolic > 80 mmHg 81.3%
Weekly Assessment Form for Women in the Guided Imagery Group

@ end of: ☐ 1st week; ☐ 2nd week; ☐ 3rd week; ☐ 4th week
(Please identify study week by marking one of the circles above)

SECTION A: Self-Evaluation Questionnaire

**DIRECTIONS:** A number of statements which people have used to describe themselves are given below. Read each statement and then make a mark in ONE box for each statement to indicate how you have felt over the past week. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your feelings best.

<table>
<thead>
<tr>
<th></th>
<th>NOT AT ALL</th>
<th>SOMEWHERET</th>
<th>MODERATELY SO</th>
<th>VERY MUCH SO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel calm</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. I feel secure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. I am tense</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. I feel strained</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>5. I feel at ease</td>
<td></td>
<td></td>
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<td>6.</td>
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<td>16.</td>
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</tr>
<tr>
<td>17.</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

... please turn the page for more questions
SECTION B:
It is important for the research team to find out how your participation in this study is going for you. All of these questions have to do with your experience this PAST WEEK. There are no right or wrong answers and honest responses are important.

B1. Are you currently taking prescription medication for your blood pressure?
   ○ NO
   ○ YES

The next 2 questions are about your experiences in trying to rest this week. By "rest" we mean sitting quietly in a chair or lying down, without using any special relaxation techniques, for at least 15 minutes at a time.

B2. How many DAYS during this past week did you rest for at least 15 minutes at one time (other than night time sleep)?
   ○ None at all
   ○ One
   ○ Two
   ○ Three
   ○ Four
   ○ Five
   ○ Six
   ○ Seven

B3. In the past week, in general, how many TIMES per day have you rested for at least 15 minutes at one time (other than night time sleep)?
   ○ Not at all
   ○ Once per day
   ○ Twice per day
   ○ More often than twice per day

... please turn the page for more questions
These next questions are about your use of a specific relaxation technique.

B4. How many **DAYS** during the past week did you use guided imagery?
   ○ None at all
   ○ One
   ○ Two
   ○ Three
   ○ Four
   ○ Five
   ○ Six
   ○ Seven

B5. In the past week, in general, how many **TIMES per day** have you used guided imagery?
   ○ Not at all
   ○ Once per day
   ○ Twice per day
   ○ More often than twice per day

**SECTION C:**
Based on your use of guided imagery over the past week, please rate each of these 5 statements on a scale of 0 to 5, if “0” is “never” and “5” is “all of the time”. There are no right or wrong answers and honest responses are important.

C1. My mind wandered during the imagery
   Never 0 1 2 3 4 5 all of the time

C2. The images appeared real
   Never 0 1 2 3 4 5 all of the time

C3. I had difficulty concentrating on the imagery
   Never 0 1 2 3 4 5 all of the time

C4. I enjoyed the imagery
   Never 0 1 2 3 4 5 all of the time

C5. I had difficulty picturing the images.
   Never 0 1 2 3 4 5 all of the time

...please turn the page for more questions
Please think about your use of the guided imagery over the past week, and please answer these 2 questions:

C6. When you did guided imagery, how often did you use the CD you were given?
   ○ Not at all
   ○ Occasionally
   ○ Most of the time
   ○ Always

C7. How easy or difficult was it for you to do the guided imagery exercise?
   ○ Very easy
   ○ Somewhat easy
   ○ Neither easy nor difficult
   ○ Somewhat difficult
   ○ Very difficult

This last question is about the LAST TIME you used guided imagery.

C8. Please rate how relaxed you were immediately after using the guided imagery the last time by circling one of the numbers between 0 to 10, if “not at all relaxed” is 0 and “completely relaxed” is 10.

0  1  2  3  4  5  6  7  8  9  10  
not at all relaxed  completely relaxed
Weekly Assessment Form for Women in the Quiet Rest Group

@ end of: ○ 1st week; ○ 2nd week; ○ 3rd week; ○ 4th week  
(Please identify study week by marking one of the circles above)

SECTION A: Self-Evaluation Questionnaire

DIRECTIONS: A number of statements which people have used to describe themselves are given below. Read each statement and then make a mark in ONE box for each statement to indicate how you have felt over the past week. There are no right or wrong answers. Do not spend too much time on any one statement but give the answer which seems to describe your feelings best.

<table>
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<th></th>
<th>NOT AT ALL</th>
<th>SOMEWHAT</th>
<th>MODERATELY SO</th>
<th>VERY MUCH SO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. I feel calm ..................</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>2. I feel secure ...............</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>3. I am tense ....................</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>4. I feel strained ..............</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>5. I feel at ease ...............</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>6. .............................</td>
<td>○</td>
<td>○</td>
<td>○</td>
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<tr>
<td>7. .............................</td>
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<td>8. .............................</td>
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<td>9. .............................</td>
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<td>13. .............................</td>
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<td>14. .............................</td>
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<td>15. .............................</td>
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<tr>
<td>16. .............................</td>
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<tr>
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B2. How many DAYS during this past week did you rest for at least 15 minutes at one time (other than night time sleep)?
   ○ None at all
   ○ One
   ○ Two
   ○ Three
   ○ Four
   ○ Five
   ○ Six
   ○ Seven

B3. In the past week, in general, how many TIMES per day have you rested for at least 15 minutes at one time (other than night time sleep)?
   ○ Not at all
   ○ Once per day
   ○ Twice per day
   ○ More often than twice per day

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These next questions are about your use of a specific relaxation technique.

B4. How many **DAYS during the past week** did you use guided imagery?
   - None at all
   - One
   - Two
   - Three
   - Four
   - Five
   - Six
   - Seven

B5. In the past week, in general, how many **TIMES per day** have you used guided imagery?
   - Not at all
   - Once per day
   - Twice per day
   - More often than twice per day
Outcomes Data Form

Pregnancy

1. Antihypertensive medication since randomization (choose only 1 answer)
   ○ NO
   ○ YES → If YES, then:
     ○ Initiated during pregnancy
     ○ Initiated during labour
     ○ Initiated during postpartum hospitalization

2. Admitted to prenatal care unit for pregnancy complication after randomization and prior to admission to the Birth Unit for delivery?
   ○ NO
   ○ YES → If YES, number of days? __________
     → If YES, reason(s) for hospitalization (mark ALL that apply):
     ○ Hypertension
     ○ Abruptio placenta
     ○ Diabetes
     ○ Preterm labour
     ○ Placenta previa
     ○ Other (please specify):

3. Clinical BP values for the 4 weeks of study participation (closest to ABPM session that week):
   - Baseline __________ / __________ mmHg:
     - Using:
       ○ Mercury/manual
       ○ Oscilometry/automatic monitor
       - Location:
         ○ Clinic/office
         ○ Home
         ○ Hospital
   - Week 1: __________ / __________ mmHg:
     - Using:
       ○ Mercury/manual
       ○ Oscilometry/automatic monitor
       - Location:
         ○ Clinic/office
         ○ Home
         ○ Hospital
   - Week 2: __________ / __________ mmHg:
     - Using:
       ○ Mercury/manual
       ○ Oscilometry/automatic monitor
       - Location:
         ○ Clinic/office
         ○ Home
         ○ Hospital
   - Week 3: __________ / __________ mmHg:
     - Using:
       ○ Mercury/manual
       ○ Oscilometry/automatic monitor
       - Location:
         ○ Clinic/office
         ○ Home
         ○ Hospital
   - Week 4: __________ / __________ mmHg:
     - Using:
       ○ Mercury/manual
       ○ Oscilometry/automatic monitor
       - Location:
         ○ Clinic/office
         ○ Home
         ○ Hospital
Labour & Birth

4. Date and time of hospital admission for delivery:

   year  month  day  24-hour clock

5. Length of gestation at birth:

   Weeks  days

6. Date and time of delivery:

   year  month  day  24-hour clock

7. Type of Labour:
   ○ Spontaneous only
   ○ Augmented
   ○ Induced
   ○ No labour

8. Mode of delivery (as identified on birth record) (check ONE only)
   ○ Vaginal (check ONE only)
     ○ Spontaneous
     ○ Forceps
     ○ Vacuum extraction
     ○ Cesarean section

9. Did the mother receive MgSO4 (during either antepartum, intrapartum or postpartum)?
   ○ NO
   ○ YES

10. Did mother have an eclamptic seizure(s) during either antepartum, intrapartum or postpartum
    (as diagnosed by physician)?
    ○ NO
    ○ YES  → If YES, did woman receive anti-seizure medication(s) (other than MgSO4)?
      ○ NO
      ○ YES

11. Was there a diagnosed abruptio placenta (as documented by physician)?
    ○ NO
    ○ YES
Newborn Outcomes

12. Gender
   ○ Male
   ○ Female
   ○ Ambiguous

13. Birth Weight

   in grams

14. Birth
   ○ Live
   ○ Stillbirth

15. Apgar Score at 1-minute: 

16. Apgar Score at 5-minutes: 

17. Admission to special care nursery (SCN):
   ○ NO
   ○ YES → If YES, reason(s) (check all that apply):
       ○ Nonreassuring fetal heart rate pattern(s)
       ○ Resuscitation in Birth Unit
       ○ Respiratory distress
       ○ Premature
       ○ Small for gestational age
       ○ Maternal diabetes
       ○ Maternal hemorrhage
       ○ Maternal fever during labour or birth
       ○ Other (please specify): ________________________________

18. Date and time baby's discharge to home (if time of discharge not known, write “12:00”):

   year  month  day  24-hour clock

19. Neonatal death prior to 6 weeks of age:
   ○ NO
   ○ YES → If YES, date and time of death:

   year  month  day  24-hour clock
Postpartum

20. Date and time of woman’s discharge to home (if time of discharge not known, write “12:00”):

| year | month | day | 24-hour clock |

21. Was the woman still hypertensive at postpartum discharge to home (when $BP \geq 140$ mmHg systolic AND $\geq 90$ mmHg diastolic documented at least twice in a 24-hour period)?

- NO
- YES
- Unable to determine
Postpartum Questionnaire for Women in the Guided Imagery Group

Your opinions about your study participation are very important.

Participant Satisfaction

The first 3 questions are about your experiences as a participant in the REBIP Study.

1. What I liked about being in study (mark all that apply)
   - Contacts with study nurse
   - Randomized to the group I wanted
   - Being in this study helped me feel reassured
   - There were few or no extra demands on my time, energy
   - Helped to find answer to an important research question
   - Liked nothing
   - Other

2. What I disliked about being in study (check all that apply)
   - Contacts with study nurse
   - Not randomized to the group I wanted
   - Being in this study caused me to feel worried
   - Disliked the extra demands on my time, finances, energy
   - Disliked nothing
   - Other

3. If you had the decision to make again, would you choose to be in the study? (choose only one)
   - Definitely yes
   - Probably yes
   - Probably not
   - Definitely not
   - Not sure

Ambulatory Blood Pressure Monitor

The next questions are about your experiences with the Ambulatory Blood Pressure Monitor. Based on your use of the ambulatory blood pressure monitor for 1 day per week for the time you were in this study, please rate each of these statements on a scale of 0 to 5, if “0” is “not at all” and “5” is “very much so”.

1. Instructions about the monitor were easy to follow
   not at all  0  1  2  3  4  5  very much so

2. The monitor caused me discomfort
   not at all  0  1  2  3  4  5  very much so

... please turn the page for more questions
3. Wearing the monitor interfered with my activities
   not at all 0 1 2 3 4 5 very much so

4. Wearing the monitor interfered with my resting during the day
   not at all 0 1 2 3 4 5 very much so

5. I was bothered by the noise from the monitor
   not at all 0 1 2 3 4 5 very much so

6. Wearing the monitor caused me worry
   not at all 0 1 2 3 4 5 very much so

7. I had problems with the machine not working properly
   not at all 0 1 2 3 4 5 very much so

Comments

____________________________________________________________________________________
____________________________________________________________________________________

Guided Imagery

These next questions are about your use of guided imagery
Based on your use of the guided imagery over the 4 weeks, Please rate each of these statements on a scale of 0 to 5, if “0” is “not at all” and “5” is “very much so”.

1. The CD was easy to use.
   not at all 0 1 2 3 4 5 very much so

2. The instructions were easy to follow.
   not at all 0 1 2 3 4 5 very much so

... please turn the page for more questions
3. I enjoyed using the guided imagery
   not at all  0  1  2  3  4  5  very much so

4. I would recommend guided imagery like this to other women with high blood pressure in pregnancy.
   not at all  0  1  2  3  4  5  very much so

5. It was easy for me to imagine a restful, calming place when I used the guided imagery
   not at all  0  1  2  3  4  5  very much so

6. I am now able to imagine a restful, calming place when I need to, without having to listen to the CD.
   not at all  0  1  2  3  4  5  very much so

7. I would have liked different choices of CDs to use over the 4 weeks I was in the study
   not at all  0  1  2  3  4  5  very much so

8. I would use guided imagery again in the future (mark all that apply)
   ○ No
   ○ If I had high blood pressure in pregnancy another time.
   ○ For times when I am feeling stressed
Postpartum Questionnaire for Women in the Quiet Rest Group

Your opinions about your study participation are very important.

Participant Satisfaction

The first 3 questions are about your experiences as a participant in the REBIP Study.

1. What I liked about being in study (check all that apply)
   ○ Contacts with study nurse
   ○ Randomized to the group I wanted
   ○ Being in this study helped me feel reassured
   ○ There were few or no extra demands on my time, energy
   ○ Helped to find answer to an important research question
   ○ Liked nothing
   ○ Other ____________________________

2. What I disliked about being in study (check all that apply)
   ○ Contacts with study nurse
   ○ Not randomized to the group I wanted
   ○ Being in this study caused me to feel worried
   ○ Disliked the extra demands on my time, finances, energy
   ○ Disliked nothing
   ○ Other ____________________________

3. If you had the decision to make again, would you choose to be in the study? (choose only one)
   ○ Definitely yes
   ○ Probably yes
   ○ Probably not
   ○ Definitely not
   ○ Not sure ____________________________

Ambulatory Blood Pressure Monitor

The next questions are about your experiences with the Ambulatory Blood Pressure Monitor. Based on your use of the ambulatory blood pressure monitor for 1 day per week for the time you were in this study, please rate each of these statements on a scale of 0 to 5, if “0” is “not at all” and “5” is “very much so”.

1. Instructions about the monitor were easy to follow
   
   not at all 0 1 2 3 4 5 very much so

2. The monitor caused me discomfort
   
   not at all 0 1 2 3 4 5 very much so

... please turn the page for more questions
3. Wearing the monitor interfered with my activities
   
   | not at all | 0 | 1 | 2 | 3 | 4 | 5 | very much so |

4. Wearing the monitor interfered with my resting during the day
   
   | not at all | 0 | 1 | 2 | 3 | 4 | 5 | very much so |

5. I was bothered by the noise from the monitor
   
   | not at all | 0 | 1 | 2 | 3 | 4 | 5 | very much so |

6. Wearing the monitor caused me worry
   
   | not at all | 0 | 1 | 2 | 3 | 4 | 5 | very much so |

7. I had problems with the machine not working properly
   
   | not at all | 0 | 1 | 2 | 3 | 4 | 5 | very much so |

Comments
   
   _________________________________________________________________
   _________________________________________________________________
   _________________________________________________________________


Appendix K

Table.
*Group comparison: Antihypertensive medication use post-randomization*

<table>
<thead>
<tr>
<th>Antihypertensive medication</th>
<th>Guided imagery group (n = 34)</th>
<th>Quiet rest group (n = 35)</th>
<th>$\chi^2$</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received</td>
<td>16 (47.0%)</td>
<td>13 (37.1%)</td>
<td>0.74*</td>
<td>.46</td>
</tr>
<tr>
<td>Not received</td>
<td>16 (47.0%)</td>
<td>20 (57.1%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing data</td>
<td>2 (5.9%)</td>
<td>2 (5.7%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Fishers exact test*
Table.

*Reported frequency of guided imagery uses by week for Guided Imagery group*

<table>
<thead>
<tr>
<th>Uses per day</th>
<th>Week 1 (n = 30)</th>
<th>Week 2 (n = 24)</th>
<th>Week 3 (n = 20)</th>
<th>Week 4 (n = 16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Once</td>
<td>10</td>
<td>9</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Twice</td>
<td>20</td>
<td>15</td>
<td>11</td>
<td>8</td>
</tr>
<tr>
<td>&gt; twice</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of days used per week</th>
<th>Week 1 (n = 30)</th>
<th>Week 2 (n = 24)</th>
<th>Week 3 (n = 20)</th>
<th>Week 4 (n = 16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
<td>4</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Total Uses mean (SD)</td>
<td>9.7 (3.8)</td>
<td>10.1 (4.1)</td>
<td>9.3 (3.8)</td>
<td>8.9 (4.5)</td>
</tr>
</tbody>
</table>
Appendix M

Table.
Summary of correlations between totaled guided imagery evaluation scores and guided imagery effectiveness on mean arterial pressure (MAP) at last week of study participation (N = 31)

<table>
<thead>
<tr>
<th>At last week of study participation</th>
<th>Difficulty concentrating on imagery</th>
<th>Difficulty picturing images</th>
<th>Enjoyed imagery</th>
<th>Images appeared real</th>
<th>Mind wandered</th>
<th>MAP change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty concentrating on imagery</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficulty picturing images</td>
<td>.64**</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enjoyed imagery</td>
<td>-.20</td>
<td>-.29</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Images appeared real</td>
<td>-.07</td>
<td>.10</td>
<td>.57**</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mind wandered</td>
<td>.63 **</td>
<td>.42 *</td>
<td>-.25</td>
<td>-.09</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>MAP change</td>
<td>.32</td>
<td>.27</td>
<td>-.23</td>
<td>-.07</td>
<td>.10</td>
<td>1</td>
</tr>
</tbody>
</table>

Pearson R
** Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).
## Appendix N

Table.  
*Pregnancy Outcomes/Events after Randomization*

<table>
<thead>
<tr>
<th>Event</th>
<th>Guided Imagery (n = 32)</th>
<th>Quiet Rest (n = 33)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. (%)</td>
<td>no. (%)</td>
</tr>
<tr>
<td>Antihypertensive medication after randomization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>16 (50.0%)</td>
<td>20 (60.6%)</td>
</tr>
<tr>
<td>Yes</td>
<td>16 (50.0%)</td>
<td>13 (39.4%)</td>
</tr>
<tr>
<td>Initiated in pregnancy</td>
<td>9 (26.5%)</td>
<td>6 (17.1%)</td>
</tr>
<tr>
<td>Received medication in week 1</td>
<td>4 (12.9%)</td>
<td>1 (3.4%)</td>
</tr>
<tr>
<td>Received medication in week 2</td>
<td>4 (16.7%)</td>
<td>1 (4.0%)</td>
</tr>
<tr>
<td>Received medication in week 3</td>
<td>4 (20.0%)</td>
<td>1 (4.5%)</td>
</tr>
<tr>
<td>Received medication in week 4</td>
<td>3 (18.7%)</td>
<td>2 (12.5%)</td>
</tr>
<tr>
<td>Initiated after week 4</td>
<td>2 (6.2%)</td>
<td>4 (12.1%)</td>
</tr>
<tr>
<td>Initiated during labour</td>
<td>4 (12.5%)</td>
<td>3 (9.1%)</td>
</tr>
<tr>
<td>Initiated postpartum</td>
<td>3 (9.4%)</td>
<td>4 (12.1%)</td>
</tr>
<tr>
<td>Had prenatal admission(s) after randomization</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>20 (62.5%)</td>
<td>25 (75.7%)</td>
</tr>
<tr>
<td>Yes</td>
<td>12 (37.5%)</td>
<td>8 (24.2%)</td>
</tr>
<tr>
<td>Prenatal hospital days after randomization, mean (SD)</td>
<td>3.13 (5.22)</td>
<td>3.85 (6.85)</td>
</tr>
</tbody>
</table>

*GI group n = 31; QR group n = 29; GI group n = 24; QR group n = 25  
GI group n = 20; QR group n = 22; GI group n = 16; QR group n = 16  
2 sets of data not available for each group
Appendix O

Table.

Labour and Birth Outcomes/Events after Randomization

<table>
<thead>
<tr>
<th>Event</th>
<th>Guided Imagery</th>
<th>Quiet Rest</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 32</td>
<td>n = 33</td>
</tr>
<tr>
<td>Gestation at delivery (weeks), mean (SD)</td>
<td>37.6 (2.4)</td>
<td>37.8 (2.5)</td>
</tr>
<tr>
<td>&lt; 28</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>28&lt;sup&gt;0&lt;/sup&gt;-32&lt;sup&gt;6&lt;/sup&gt;</td>
<td>2 (6.2%)</td>
<td>2 (6.1%)</td>
</tr>
<tr>
<td>33-36&lt;sup&gt;6&lt;/sup&gt;</td>
<td>7 (21.9%)</td>
<td>9 (27.3%)</td>
</tr>
<tr>
<td>≥ 37</td>
<td>23 (71.9%)</td>
<td>22 (66.7%)</td>
</tr>
<tr>
<td>Time between randomization and delivery (days), Mean (SD)</td>
<td>47.62 (54.2)</td>
<td>34.55 (28.0)</td>
</tr>
<tr>
<td>Labour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spontaneous only</td>
<td>5 (15.6%)</td>
<td>4 (12.1%)</td>
</tr>
<tr>
<td>Induced</td>
<td>14 (43.7%)</td>
<td>18 (54.5%)</td>
</tr>
<tr>
<td>Augmented</td>
<td>4 (12.5%)</td>
<td>7 (21.2%)</td>
</tr>
<tr>
<td>Caesarean, no labour</td>
<td>9 (28.1%)</td>
<td>4 (12.1%)</td>
</tr>
<tr>
<td>Mode of delivery ⊳</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spontaneous</td>
<td>14 (43.7%)</td>
<td>12 (36.4%)</td>
</tr>
<tr>
<td>Forceps</td>
<td>3 (9.4%)</td>
<td>4 (12.1%)</td>
</tr>
<tr>
<td>Vacuum extraction</td>
<td>1 (3.1%)</td>
<td>2 (6.1%)</td>
</tr>
<tr>
<td>Cesarean section</td>
<td>14 (43.7%)</td>
<td>15 (45.4%)</td>
</tr>
<tr>
<td>Magnesium sulfate administered</td>
<td>6 (18.7%)</td>
<td>4 (12.1%)</td>
</tr>
<tr>
<td>Eclampsia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Anti-seizure medication not MgSO4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Abruptio placenta</td>
<td>0</td>
<td>1 (2.9%)</td>
</tr>
<tr>
<td>Maternal postpartum length of stay (days), Mean (SD)</td>
<td>3.4 (1.1)</td>
<td>3.9 (1.6)</td>
</tr>
<tr>
<td>Hypertensive at hospital discharge</td>
<td>9 (28.1%)</td>
<td>11 (33.3%)</td>
</tr>
</tbody>
</table>

⊕ In the one instance in which 1 twin was born spontaneously and the second twin was born with forceps, the case has been labeled as a forceps delivery.
Two women in each group did not have perinatal outcomes data available.
### Appendix P

*Newborn Outcomes/Events *

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Guided Imagery (n = 32)</th>
<th>Quiet Rest (n = 36)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>20 (62.5%)</td>
<td>19 (52.8%)</td>
</tr>
<tr>
<td>Male</td>
<td>12 (37.5%)</td>
<td>17 (47.2%)</td>
</tr>
<tr>
<td><strong>Birth weight (in grams) Mean (SD)</strong></td>
<td>2984.19 (751.5)</td>
<td>3000.25 (817.20)</td>
</tr>
<tr>
<td>Live Birth</td>
<td>32 (100%)</td>
<td>35 (97.22%)</td>
</tr>
<tr>
<td>Stillbirth</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Neonatal Death §</td>
<td>0 (0.0%)</td>
<td>1 (2.78%)</td>
</tr>
<tr>
<td>Apgar Score less than 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>at 1 minute</td>
<td>5 (15.6%)</td>
<td>9 (25.0%)</td>
</tr>
<tr>
<td>at 5 minutes</td>
<td>1 (3.1%)</td>
<td>1 (2.8%)</td>
</tr>
<tr>
<td>NICU admission</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>23 (71.9%)</td>
<td>19 (52.8%)</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (28.1%)</td>
<td>17 (47.2%)</td>
</tr>
<tr>
<td>Reasons:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonreassuring fetal heart rate</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Resuscitation</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Respiratory distress</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Preterm</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Small for gestational age</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Maternal diabetes</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Maternal hemorrhage</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Maternal fever</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>5</td>
</tr>
</tbody>
</table>

**Newborn length of stay in days, M (SD)** 6.90 (11.65) 6.75 (8.77)

* All outcomes are reported for individual newborns. In the Guided Imagery group, there were 32 women with available outcome data and 32 infants; in the Quiet Rest group, there were 33 women and 36 infants (3 sets of twins)

§ death of infant prior to 6 weeks of age; 1 in this study was due to cardiac and other anomalies