Support and Reassurance in Antenatal Care: A randomised controlled trial of a telephone support intervention with and without uterine artery Doppler screening for low risk nulliparous women.

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Abstract

Background: The number of routine antenatal visits provided to low risk nulliparous women, has been reduced as recommended (NCCWCH 2008) . It was recognised that this change in care may result in women being less satisfied with care and having poorer psychosocial outcomes. The guidelines identified the need for further research to investigate alternative methods of providing women with information and support during pregnancy.

Objectives: To investigate whether the provision of proactive telephone support with and without uterine artery Doppler screening (UADS) would reduce the total number of antenatal visits required and affect the psychological outcomes measured.

Methods: The study used a mixed methods approach. 840 low risk nulliparous women were recruited to a three arm randomised controlled trial. Women in the control group received standard care, those in the Telephone intervention group (T), received a telephone call from a midwife at 28, 33 and 36 weeks and women in the telephone and Doppler group (T+D) received the telephone support intervention and uterine artery Doppler screening at 20 gestation. The primary outcome measure was the total number of antenatal visits received. Semi structured interviews were undertaken with 45 women to investigate their views of the interventions and the antenatal care they received.

Results: The median number of unscheduled (n=2.0), scheduled visits (n=7.0) and mean number of total visits (n=8.8) were similar in the three groups. Additional support was not associated with differences in clinical outcomes, levels of anxiety, social support or satisfaction with care. Perceptions of antenatal care were affected by women's perceptions of their pregnancy, the structure of care and the way the care was delivered by their midwife.

Conclusion: Further research is required to investigate alternative methods of providing women with support during pregnancy, in particular the utilisation of new technologies.

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Foreword

Researcher's background and research interests

I have been a qualified midwife since 1994 and have worked in all areas of midwifery including a Fetal Medicine Unit. I currently work as a research midwife and midwife sonographer at the Royal Victoria Infirmary, Newcastle upon Tyne.

My research interests include antenatal care, specifically the structure and design of antenatal care provision, the psychological effects and clinical outcomes of antenatal screening and ultrasound during pregnancy. Previous work has focussed on the psychological impact of ultrasound screening for Down's syndrome.

Structure of thesis

The background section (Chapter 1) provides a review of the historical events that have influenced the structure of antenatal care and the present provision of care, with a particular focus on trials that examined the impact of reducing the number of routine antenatal visits. A table of seven trials included in systematic reviews of reduced schedules of care is included. The various components of antenatal care are presented and the factors that affect the utilisation of care discussed. The influence of social support on women's wellbeing and a review of antenatal support interventions designed to affect clinical outcomes is presented. The concept of satisfaction with care is explored and a review of telephone support interventions and uterine artery Doppler screening is discussed.

Chapter 2 provides an overview of the chosen methodology incorporating the rationale for a mixed methods approach, a discussion of the measurement scales used in the questionnaires, followed by a detailed description of the research methods used.

Chapter 3 presents the primary and secondary outcome data from the quantitative data analysis. The analysis and interpretation of the semi-structured interview data is provided in Chapter 4.

The discussion section critically expounds the strengths and weaknesses of the research design including the outcome measures, sample and study interventions. Issues surrounding the implementation of the study interventions are reflected upon and an account of the interview process presented. A discussion of the implications of the research findings on clinical practice and directions for future research are presented.

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List of Tables and Figures

Abbreviations

2D	Two dimensional
4D	Four dimensional
ANOVA	Analysis of variance
BP	Blood pressure
BW	Birthweight
CI	Confidence interval
DCE	Discrete choice experiment
DUFSS	Duke-UNC functional support scale
FGR	Fetal growth restriction
hCG	Human chorionic gonadotrophin
IQR	Interquartile range
IUGR	Intrauterine growth restriction
LBW	Low birthweight
LSCS	Lower section Caesarean section
MAU	Maternity assessment unit
NCCWCH	National Co-ordinating Centre for Women's and Children's Health
NICE	National Institute of Clinical Excellence
PAPP-A	Pregnancy-associated plasma protein A
PE	Pre-eclampsia
PI	Pulsatility index
PIH	Pregnancy induced hypertension
PMD	Placental mediated disease
PPH	Post partum haemorrhage
PROM	Preterm rupture of membranes
PRW	Pregnancy worries
SCBU	Special care baby unit
SD	Standard deviation
SGA	Small for gestation age
SSQ	Six simple questions

STAI	State-trait anxiety inventory
TOP	Termination of pregnancy
TSI	Telephone support intervention
UADS	Uterine artery Doppler screening
UTI	Urinary tract infection
GP	General practitioner
UK	United Kingdom
HIV	Human immunodeficiency syndrome
DfES	Department for Education and Skills
USA	United States of America
APH	Antepartum haemorrhage
NHS	National Health Service
UNICEF	United nations children's fund
mmHg	Milligrams of mercury
CONSORT	Consolidated standards of reporting trials
GCSE	General Certificate of Secondary Education
X^2	Chi square

Chapter 1. Background

1.0 Introduction

The aims of the literature review are to provide an overview of the current structure of antenatal care and a commentary on the history behind its development. The composite parts of antenatal care will be discussed including an in-depth review of the literature pertaining to the frequency of antenatal visits, the implications of parity, telephone support interventions and uterine artery Doppler screening. The concepts of social support, satisfaction with antenatal care and the economic implications of reducing antenatal visits will also be discussed.

1.1Search Strategy

It was expected that relevant studies would incorporate a variety of methodologies, so no limits were placed on the type of studies included. Quantitative, qualitative and mixed methods studies were included in the literature search.

The search strategy primarily involved a search of the following electronic databases:

Medline
Embase
PsychINFO
Cinahl
Scopus

Online and hard copy hand searching of the British Journal of Obstetrics and Gynaecology, Birth, Journal of Reproductive and Infant Psychology, Midwifery, National Institute of Clinical Medicine (NICE), Health Technology Assessment (HTA) and Cochrane database and was undertaken to ensure that no pertinent papers were missed.

1.1.1Search terms

The following search terms were used:

Antenatal

"Antenatal care"

Prenatal

"Prenatal care"

AND history OR background

AND structure OR design OR content

AND purpose OR function OR aims

Antenatal

"Antenatal care"

Prenatal

"Prenatal care"

Pregnancy AND visits

AND schedule

AND appointments

"Women's views" AND "antenatal care"

Satisfaction AND healthcare

AND antenatal care

AND antenatal visits

AND prenatal care

"Measurement of satisfaction"

"Views of health care"

Perceptions of health care OR antenatal care OR prenatal care OR pregnancy

Nulliparous OR "first pregnancy" OR "first time mothers" AND antenatal

AND antenatal visits

AND antenatal care

AND pregnancy

"First pregnancy"

"First time mothers" AND "antenatal care

"Uterine artery Dopplers"

Uterine artery Doppler screening

Uterine arteries

Screening AND “blood pressure” OR hypertension OR pregnancy induced hypertension OR PIH OR pre eclampsia OR pre-eclampsia

AND pregnancy

AND small for gestational age OR intrauterine growth restriction OR small baby OR SGA OR IUGR

“Placental mediated disease”

“Placenta mediated disease”

“Telephone support” OR telephone

AND health

AND intervention

AND pregnancy

AND support

“Telephone support intervention”

Antenatal care AND economic OR costs

Antenatal AND rationalisation

1.1.2 Quality assessment

A quality assessment of the antenatal visit studies was undertaken using a form that had been previously devised for a structured review (Appendix A) (Collins et al. 2004) and utilised in an a Health Technology Assessment systematic review (Green et al. 2004).

1.2 History of Antenatal Care

Before the 1900’s pregnancy was viewed as a normal state of health, which did not require intervention or monitoring from medical staff or midwives (Oakley 1982). There was a poor understanding of the underlying physiology of pregnancy by health professionals and their ability to identify or treat complications during pregnancy was limited (Tew 1990). The advice of a doctor was only sought by the wealthiest women to counteract unpleasant side effects of pregnancy, which were often treated with questionable treatments such as repeated venesection (Oakley 1982)

In the early 1900's there was concern about the persistently high perinatal mortality rate; figures having remained reasonably static for more than 70 years. In comparison to other European countries such as Norway and Sweden, the mortality and morbidity rates were much higher in England and Scotland (Oakley 1982). Education for women during pregnancy was the primary aim of early antenatal care with the provision of information to women of low socio-economic status about the benefits of good nutrition, hygiene and adequate rest during pregnancy. Initially this advice was provided to poor women by more affluent women prior to a formalised approach being introduced in 1915 (Tew 1990).

In 1915 the first clinic for the monitoring of pregnancy complications was opened in the United Kingdom. This development arose following the realisation that it may be possible to treat and prevent some of the causes of death and illness during pregnancy by regular monitoring of the pregnant woman and her fetus (Tew 1990). The clinic was opened in Edinburgh and overseen by Dr J.W Ballentyne whose interest was the wellbeing of the fetus rather than the mother (Oakley 1982).

From around 1915 the perinatal mortality rate began to improve whilst the maternal mortality rate remained high. This resulted in a change of focus with the medical care of the women becoming a more prominent feature of antenatal care (Oakley 1982). Doctors began researching the causes of maternal death and treatments to reduce mortality during pregnancy and childbirth were instigated. The reports that resulted suggested that the provision of antenatal care would have a substantial impact on maternal mortality rate (Oakley 1982).

Although there was mention of the influence of social deprivation on the health of childbearing women and their infants and a need to improve conditions, the widespread provision of antenatal care was largely believed to be the intervention that would dramatically improve mortality and morbidity rates. There was a misconception that the provision of antenatal care would result in vast improvements in health and it was clearly easier than interventions to improve socio-economic factors.

The provision of antenatal care was a national recommendation from 1929. The Ministry of Health produced a memorandum during that year, which set out the suggested number of times a pregnant woman should attend antenatal clinics and the observations that should be recorded during the visits (Tew 1990). The recommendations set out in the document formed the basis of antenatal care in its current form with the number of antenatal visits remaining unchanged for decades and the basic screening tests continuing as a part of the provision of antenatal care to this day (Hall 2001).

By the 1930's it became clear that the introduction of antenatal care had not improved outcomes; the maternal mortality rate was increasing rather than declining (Hall et al. 1985). There were difficulties in persuading all women to attend antenatal appointments; often the clinics were at inconvenient times and locations and involved long waiting times.

During the Second World War the differences between the social classes became more obvious and the role that social deprivation played in the health of childbearing women was recognised as being a major influence. The Government took responsibility for improving the nation's health and ensured the evacuation of pregnant women. As a result of evacuation from inner cities, it became clear that poor living conditions often resulted in major health problems. It was obvious from the physical appearance of the inner city, working class women, that there were vast differences in their lifestyle compared to women living in more rural areas and as a result they were in poorer health (Oakley 1982). The rationing of food had unexpected results; there was a marked improvement in the nutrition of the poor and this together with free vitamin supplements and milk may have contributed to an improvement in the maternal mortality and stillbirth rates (Tew 1990). However, it was not entirely clear exactly which factors contributed to the improvement of the overall health of women and children (Oakley 1982).

The introduction of the National Health Service in 1948 meant that all pregnant women could have free access to a midwife and general practitioner for their care throughout the antenatal period (Tew 1990). During the 1950's there was

an increase in the amount of antenatal care provided by general practitioners rather than by local authorities, as had been the case previously with most women booking a GP to deliver their baby at home instead of a midwife (Oakley 1982).

The provision of antenatal and intrapartum care by GP's was relatively short lived initially; from the 1960's obstetricians and midwives led the majority of antenatal care and there was a gradual move to increase the number of hospital based antenatal visits (Hall et al. 1985). The Short Report (1980) recommended that measures be implemented to encourage earlier uptake of antenatal care and better attendance. These measures were to educate women about the importance of antenatal care, to improve the facilities in clinics and provide a more personalised environment ensuring that women did not feel like they were on a 'production line'. This resulted in there being a move back to community based care for women not requiring specialist intervention (Hall et al. 1985).

1.3 Aims of antenatal care

The overall aim of antenatal care is to prevent, treat and monitor pregnancy complications and thereby ensure the wellbeing of the woman and baby (Villar and Bergsjo 1997). The provision of information and education for women, screening pregnancies for abnormalities and complications and ongoing monitoring are viewed as an effective means of detecting and treating complications, promoting timely medical intervention and promoting health (Petrou et al. 2003). Studies have shown that women who receive antenatal care tend to have better pregnancy outcomes but it remains unclear which interventions are effective and how the various components of the care package interact (Villar et al. 2001a). There have been difficulties in assessing the effectiveness of the composite parts of antenatal care in developed countries because it has been universally accepted as 'usual' care for around 100 years (Carroli et al. 2001b).

A study in Finland showed that women who did not attend for antenatal care or received limited care were more likely to have a placental abruption or chorio-amnionitis and have a preterm delivery. Birthweights were lower (as a result of

preterm birth) than babies of mothers who had attended for antenatal care and the risk of fetal and neonatal death was higher. Demographic factors associated with non or under attendance for care, were low maternal age, grand-multiparity, smoking and excessive alcohol use (Raatikainen et al. 2007). There is evidence to suggest that antenatal care does improve outcomes for women who have 'high risk' pregnancies, defined as such due to previous adverse pregnancy outcome or underlying medical disorders, but its benefit for woman who have 'low risk' pregnancies is not proven (Enkin and Chalmers 1982).

There has been a drive by consumers and health care providers over the last 20 years to ensure that antenatal care has a more scientific basis. This has resulted in a number of studies addressing the optimum number of antenatal visits, antenatal care provider, organisational issues and newly developed screening procedures (Luyben and Fleming 2005). The scope of antenatal care has widened greatly since its inception in the early 1900's. Although the drive to monitor and improve the health of the mother and her fetus as the primary focus of care remains unchanged, there has also been a gradual move to include a greater number of functions as a result of emerging health technologies and evidence from research findings.

The main functions of antenatal care will be presented in the next section under the following headings:

- Monitoring the health of the woman and her fetus
- Screening
- Health behaviour
- Preparation for pregnancy, birth and parenting

1.3.1 Monitoring the health of the woman and her fetus

The routine procedures that are undertaken during antenatal visits such as measurement of blood pressure and testing of urine, abdominal palpation and auscultation of the fetal heart are carried out in a bid to detect the most common complications of pregnancy, namely pre-eclampsia (PE) and fetal growth

restriction (Moos 2006). There is remaining uncertainty as to the best method for the detection and management of hypertensive diseases and other conditions during pregnancy and evidence to show that further research is required to evaluate the content and effectiveness of antenatal visits (Carroli et al. 2001a).

The monitoring procedures which form part of antenatal visits may provide the pregnant women with the reassurance that the health professional is monitoring her health and that of her fetus. Many women regard this as the most important aspect of antenatal care (Hildingsson et al. 2002). The routine procedures undertaken during antenatal visits have changed since its inception as a result of advances in technology and the recognition that unnecessary monitoring can have a detrimental effect on women's psychological wellbeing. For example, routine weighing of women at each visit is no longer recommended because it confers no benefit to women and can result in unnecessary maternal anxiety (NCCWCH 2008).

One of the greatest changes in the provision of care has occurred as a result of advances in biochemical and ultrasound screening techniques. Such advances have meant that women are offered an array of screening opportunities during pregnancy (Hewison 1996). The use of antenatal technologies to monitor pregnancy wellbeing ensures that the health professional's knowledge base is supported by scientific evidence (Harris et al. 2004). This means that women are unable to gain reassurance entirely from their own knowledge or that of significant others and have come to rely on technologies to allay their anxieties during pregnancy (Zechmeister 2001).

1.3.2 Pre-test counselling

There has been a recognition of the importance of providing consumers with appropriate pre-test counselling to ensure that they are aware of the possible benefits and limitations of the test they are considering (National Collaborating Centre for Women's and Children's Health 2003). With conditions such as HIV and Hepatitis B, for which there is no definitive cure for the mother, it is important that women are aware of the implications of a positive diagnosis.

Participation in screening programmes for fetal chromosomal and structural abnormalities can result in the receipt of false negative or false positive results as well as information which is not conclusive about fetal prognosis.

Pregnant women have many choices to make about the screening tests offered to them during the course of the pregnancy and have a definitive time in which to make those decisions. Health professionals therefore have a significant role to play in ensuring that women are provided with timely information and that it is presented in an understandable format to facilitate informed decision making. This is particularly important when new screening tests are introduced into routine practice because women can be susceptible to complying without fully understanding the consequences of the screening process (Thornton et al. 1995).

There are many challenges associated with the provision of information prior to screening tests. Information needs to be provided in a format that is readily understandable and the most appropriate method of provision can differ between individuals, for example it is estimated that 5.2 million people in the UK lack functional literacy (Department for Education and Skills 2003). Women's socio-economic status, educational level, ethnicity, maternal age and parity have been shown to affect knowledge acquisition by women having screening for Down's syndrome (Green et al. 2004). The informed decision making process can result in women experiencing increased levels of anxiety as a result of having to actively consider the consequences of receiving a screen positive result, although there is evidence to show that those making an informed decision are less likely to be falsely reassured and be more satisfied with their decision (Bekker et al. 2003). It has been suggested that the benefits derived from providing women with increased levels of information prior to screening could be achieved by redirecting resources from unnecessary visits later in pregnancy (Thornton et al. 1995).

1.3.3 Ultrasound screening

Ultrasound is one of the most significant technological developments for the monitoring and management of pregnancy over the last three decades (Dooley

1999). The routine use of ultrasound to screen and monitor the fetus during pregnancy has been a prominent feature of antenatal care since the 1970's.The use of ultrasound during pregnancy has a number of applications including confirmation of viability, accurate estimation of gestational age, detection of multiple pregnancies and the identification of pregnancy complications such as placenta praevia. The role of ultrasound in screening for fetal abnormality has progressed rapidly with a particular focus on screening for Down's syndrome and structural abnormality.

It is now a national recommendation that all women are offered screening for Down's syndrome by means of the combined test at 11-14 weeks gestation. This consists of maternal serum PAPP-A and HCG combined with ultrasound measurement of nuchal translucency. Screening for fetal structural abnormality is offered to women at 18 -20 weeks gestation (National Collaborating Centre for Women's and Children's Health 2008).

Ultrasound can also be used to screen for complications of pregnancy such as preterm delivery by examination of the cervical length (Greco et al. 2011) and pre-eclampsia and growth restricted fetuses by the measurement of uterine artery blood flow velocities (Cnossen et al. 2008). Currently, such techniques are usually confined to screening women who have previously had relevant pregnancy complications. Such screening facilitates appropriate monitoring and planning of care for those found to be at high risk.

The continued advances in ultrasound have had an enormous effect on the experience of antenatal care by consumers. Parents now have the opportunity to exert choice about continuing their pregnancy on diagnosis of fetal abnormality. The option of fetal therapy exists for the treatment of some conditions such as bladder shunt insertion for lower urinary tract obstruction and placental laser treatment for twin-to-twin transfusion syndrome (Deprest et al. 2010). Ultrasound also provides the opportunity for monitoring of the 'at risk' fetus (Lindqvist and Molin 2005), optimising the timing of treatment such as inutero fetal blood transfusion or delivery of the baby. Increasingly, private clinics are offering women 2D and 4D ultrasound examinations which can be

requested without a clinical indication but for a fee. 4D imaging of the fetus may provide greater opportunities for fetal diagnosis inutero as well as providing families with enhanced visualisation of their fetus (Edwards et al. 2010; Ji et al. 2005).

For prospective parents, ultrasound provides them with their first visual encounter with their fetus, which can also provide confirmation of the pregnancy (Clement et al. 1998). In a systematic review, Bricker et al (2000) concluded that women and their partners generally find ultrasound to be a positive addition to their antenatal care because it provides them with reassurance about fetal wellbeing. However, there are many factors that affect women's experience of ultrasound during pregnancy. The quality of interaction between the woman and the sonographer can affect how the scan is perceived; women who feel that the image has been fully explained to them tend to rate the experience more positively (Reading et al. 1988). For women who have a scan which results in a poor outcome, such as a missed miscarriage, the impact of the visualisation of the demised fetus (or absence of the expected image) may result in poorer psychological outcomes (Baillie and Hewison 1999).

There is evidence to suggest that women's expectations of ultrasound screening can differ from the medical and scientific rationale for it being offered. This is partly a result of the ultrasound scan having become an intrinsic part of routine care which is offered as an 'opt out' rather than 'opt-in' procedure (Thorpe et al. 1993). Ultrasound screening for chromosomal and structural abnormalities can result in women receiving false or true positive results and most women who receive a positive result will experience increased levels of anxiety as a result (Marteau et al. 1992) . Studies have shown that for most women undergoing screening for Down's syndrome, anxiety levels are initially increased in those who receive a false positive result, but return to normal after a negative result from diagnostic testing (Abuelo et al. 1991). However, some women will experience elevated levels of anxiety despite a normal diagnostic result and such anxiety may even persist after the birth of the baby (Statham and Green 1993).

Women who have received positive results from screening may modify their reaction to the pregnancy because they no longer believe that they will have a positive outcome (Baillie et al. 2000) . This state has previously been described as a 'tentative' approach and results from women suspending their commitment to the fetus until they have been reassured that the pregnancy is progressing normally (Rothman 1994) . There is evidence to demonstrate that increased anxiety following a screen positive result may manifest as a women having generalised anxiety about other risks to the pregnancy that had not previously been imagined (Baillie et al. 2000). Inappropriate information or insufficient information provided before embarking on a screening test can have an impact on women's levels of anxiety and result in strongly negative responses (Green et al. 2004).

Soft markers are minor structural variations of fetal development, which are rarely of significance when seen in isolation. Examples of soft markers which can be detected at 18-20 weeks scan include increased nuchal fold and echogenic bowel. The detection of more than one soft marker at the time of the anomaly scan increases the likelihood that a fetus is affected by a chromosomal defect. There is evidence to show that women who experience the detection of one soft marker during their scan may have psychological distress that is sustained long after the diagnosis, even when the fetus is completely normal (Carolan and Hodnett 2009). Current guidelines state that choroid plexus cysts, dilated cistern magna, echogenic foci in the heart and a two vessel cord should not be reported to women or prompt referral to a fetal medicine specialist (Kirwin et al. 2010). Ongoing advances in ultrasound technology mean that the detection of anomalies of unknown significance particularly at earlier gestations will be a more frequent occurrence in the future (Getz and Kirkengen 2003).

1.3.4 Blood screening

Pregnant women are familiar with the routine of testing blood during pregnancy and are generally well accepting of the procedure. As well as the traditional blood tests offered such as screening for blood group, red cell antibodies and anaemia, there has been an expansion of the number of blood screening tests available. It is currently recommended that all pregnant women are offered

screening for rubella immunity, syphilis, HIV, Hepatitis B, Thalassaemia and sickle cell disease at the time of their booking appointment and subsequent testing for haemoglobin levels and red cell alloantibodies at 28 weeks gestation (National Collaborating Centre for Women's and Children's Health 2008).

1.3.5 Health behaviour

Antenatal care is recognised as providing ideal opportunities for health promotion in areas such as smoking cessation, diet, exercise and drug/alcohol misuse. Most pregnant women view the acquisition of knowledge to optimise the health of themselves and their fetus as one of the key components of the care they receive during the antenatal period (Luyben and Fleming 2005).

Pregnancy provides health care professionals with the opportunity to introduce interventions to improve health behaviours such as smoking cessation and unhealthy diet because of the repeated contact they have with the pregnant woman and to ensure that pregnant women are appropriately informed of the health risks attributed to different health behaviours (Birdsall et al. 2009; Hajek et al. 2001). The antenatal period is unusual in that it provides contact with healthy women who would otherwise not be seen by health professionals (Rosen et al. 1991).

1.3.6 Preparation for pregnancy, birth and parenting

As well as the promotion of positive health behaviours, contact with health professionals also provides the opportunity for the provision of information relating to pregnancy, birth, infant feeding and parenthood. The information can be presented in a number of different ways including websites and printed literature with the most common being structured group antenatal classes. Classes are particularly popular with nulliparous women; a UK survey of 10,000 women found that 67% of nulliparous women had attended antenatal classes compared with 12% of multiparous women. Of the respondents', 12% arranged private fee paying antenatal education and the majority of these women were nulliparous (85%) (Redshaw and Heikkila 2010).

The content and structure of classes is not standardised and can be provided by midwives or organisations such as the National Childbirth Trust. Evidence has shown that although women appear to receive sufficient information about labour and birth, they feel that they receive insufficient information about postnatal issues and how to care for their baby (Lavender 2000). There is evidence to show that attendance at antenatal classes does increase levels of knowledge about labour and birth (Rolls 2001), although there is no data to suggest that attendance has an effect on clinical outcomes (Gagnon and Sandall 2009).

1.4 Structure of Antenatal Care

1.4.1 Initiation of antenatal care

It has been suggested that the gestation at which antenatal care is initiated may have an impact on health outcomes with earlier attendance conferring benefits to women (McCaw-Binns et al. 1995). In contradiction to this suggestion, a survey to look at the effect of the initiation of antenatal care after 28 weeks gestation found that there was no difference between those women who had delayed attendance when compared to those whose care started before 28 weeks (Thomas et al. 1991). The outcomes measured in this study were severe PE, perinatal mortality, preterm delivery and birthweight. This observational study was not large enough to compare the rate of eclampsia between the two groups and did not aim to examine any psychosocial factors. There is evidence to show that women who continue to smoke during pregnancy are more likely to delay the initiation of antenatal care and/or attend antenatal care less frequently (Mohsin and Bauman 2005), although it is unclear whether antenatal care utilisation has a positive impact on smoking cessation or whether pregnant women who smoke are less likely to attend (Palma et al. 2007).

It has been shown that late initiation of antenatal care is more prevalent for women born outside the UK or not cohabiting with a partner (Rowe et al. 2008), although the majority of women in the UK (95%) have seen a health professional by the time they are 12 weeks pregnant (Redshaw and Heikkila 2010). Despite the fact that most women in the UK do see a health professional early in pregnancy, it has been found that 26% of women who died from causes

directly or indirectly related to pregnancy either booked late for care, had an insufficient number of visits or did not receive any antenatal care at all (Confidential Enquiry into Maternal and Child Health 2011).

Later initiation of antenatal care also impacts on a woman's choices in relation to screening tests for Down's syndrome and fetal abnormality. Late initiation after 24 weeks may also limit women's choices about pregnancy continuation when a fetal anomaly has been detected.

1.4.2 Number of Antenatal Visits

The scheduled number of antenatal visits that a woman in England and Wales attend during her pregnancy had remained unchanged and largely unchallenged since the pattern of care was devised around 1929 until the review of antenatal guidelines (National Collaborating Centre for Women's and Children's Health 2003). The schedule of care consisted of monthly visits up to 28 weeks gestation followed by fortnightly visits until 36 weeks and weekly visits thereafter until delivery. This schedule resulted in women having up to ten planned antenatal visits after 20 weeks gestation. This visit schedule was introduced without any scientific basis and did not necessarily reflect the needs of women (Petrou et al. 2003). Hall et al (1985) was one of the first to challenge the value of this antenatal visit schedule, particularly for women who were considered to be at low risk of developing problems during pregnancy. In a study conducted in Aberdeen, the number of antenatal visits for low risk women was reduced from 10 to 7 visits after 20 weeks gestation and there was no decrease in the detection of the most common complications of pregnancy.

The suggestion that the number of planned visits should be evaluated was again presented in the Changing Childbirth report (Department of Health 1993). Since then there have been a number of studies which have examined the effects of a reduced schedule of antenatal visits for low risk women. Two systematic reviews of seven of these trials concluded that a policy of reduced visits could be implemented without any adverse impact on maternal and perinatal outcomes (Carroli et al. 2001b; Villar et al. 2001b). Both reviews included four trials that were undertaken in developed countries and three trials

in developing countries. The key design features and outcome measures of the seven trials are shown in Table 1. The focus in all of the studies was maternal and perinatal morbidity and five of the seven trials measured women's satisfaction with care. Most of the studies found no difference between groups for the chosen measures of morbidity, although one trial that was undertaken in Zimbabwe found a reduced incidence of preterm delivery in the intervention group (Table 2).

Table 1 - Key design features and outcome measures of antenatal visit trials

Study	Year	Setting	Design	Sample	Participants	Primary outcome measures	Secondary outcome measures	Satisfaction / Quality of care measurement
Binstock et al	1995	USA	Quasi-randomised controlled trial	Low risk women	549	Preterm delivery, LBW, LSCS, Apgar score at 5 minutes < 7, neonatal length of stay, maternal length of stay		Self completion postnatal questionnaire
Majoko et al	2007	Zimbabwe (rural)	Cluster randomised	All women presenting for care	13517	Number of visits; referral for antenatal, intrapartum or postpartum problems, place of delivery and low birthweight	Antenatal diagnosis of hypertension and twin pregnancy, perinatal mortality, operative delivery, preterm delivery (<37weeks) and number of times fundal height measurement recorded.	Not systematically reported
McDuffie et al	1996	USA	Randomised controlled trial	Low risk women	2764	Preterm delivery; pre-eclampsia; LSCS; LBW and satisfaction with care	Rates of LSCS for fetal distress, preterm labour, PPROM, gestational diabetes, multiple pregnancy, chorioamnionitis, placental abruption, placenta praevia, PPH, birthweight, SGA, very LBW, Apgar score and stillbirth	Self completion questionnaire at 6 weeks postpartum
Munjanja et al	1996	Zimbabwe (urban)	Cluster randomisation	Low risk women	15994	Preterm delivery, LBW, small for gestational age, perinatal and maternal mortality, maternal morbidity	Length of gestation, low birthweight, referral patterns during the antenatal period and during labour, and obstetric interventions.	Not measured
Sikorski et al	1996	UK	Randomised controlled trial	Low risk women	2794	Caesarean section rate for pregnancy related hypertensive disorders	Measures of maternal and fetal morbidity; health service use, psychosocial outcomes, maternal and professional satisfaction	Self completion questionnaire at 34 weeks and 6 weeks postnatal
Villar et al	2001	Argentina Cuba Saudi Arabia Thailand	Randomised controlled trial	All women presenting for care	24526	LBW (<2500g), pre-eclampsia/ Eclampsia, severe postpartum anaemia, urinary tract infection	Fetal mortality, neonatal mortality, maternal antenatal complications, preterm delivery, PROM, very LBW (<1500g), Apgar score, admission to neonatal unit	Focus groups In-depth interviews Self completion questionnaire
Walker and Koniak-Griffin	1997	USA	Prospective randomised trial	Low risk women	81	Number of visits, gestational age at birth, birthweight, mode of delivery, Ballard score, IUGR, admission to neonatal unit, neonatal complications. Maternal complications: preterm labour, anaemia, UTI, hypertension, fetal malposition, substance misuse, postdates.		Self completion questionnaire 36-38 weeks

Table 2 – Implementation of interventions loss to follow up rate and outcomes in trials of antenatal

Study	Year	Control group		Intervention group		Loss to follow up rate		Clinical outcomes	Satisfaction with care	Quality assessment score
		Proposed no. visits	Median no. visits	Proposed no. visits	Median no. visits	Intervention (%)	Control (%)			
Binstock et al	1995	13	11.3	8 (focussed content)	8.2	29	24	No differences in rates of preterm delivery; LBW: LSCS; Apgar score	Overall satisfaction with care was similar in two groups. Higher satisfaction with continuity of care in intervention group	-1
Majoko et al	2007	9	4	5 goal orientated visits	4	22	22	No difference in rates of preterm delivery, LBW or detection of hypertensive disorders	Proportion of nulliparous and low parity women dissatisfied with spacing of visits in intervention group	5
McDuffie et al	1996	14	14.7	9	12	16	16	No differences in rates of preterm delivery, pre-eclampsia	No differences in satisfaction with quality of care	10
Munjanja et al	1996	14 scheduled (but only 7 achieved before trial)	6	6 goal orientated visits	4	3	3	Rate of preterm delivery lower in the intervention group. No difference in LBW and perinatal morbidity and mortality	Not reported	8
Sikorski et al	1996	13	10.8	7 for nulliparous women and 8 for multiparous women	8.6	5	2	No difference in rate of LSCS for hypertensive disorders, pre-eclampsia, maternal or perinatal morbidity	Women in intervention group were less satisfied with number and spacing of visits	11
Villar et al	2001	8	8	4 goal orientated visits	5	2	2	No differences in birthweight, preterm delivery or pre-eclampsia	Women in the intervention group were more satisfied with care. Anxiety levels were that same in both groups	13
Walker and Koniak-Griffin	1997	10	10.8	8	7.6	30	38	No differences in birthweight, preterm delivery or pre-eclampsia	Women in the intervention group were more satisfied with care. Anxiety levels were the same in both groups	4

LBW=low birthweight, LSCS=lower section caesarean section, PPROM= preterm premature rupture of membranes, PPH=post partum haemorrhage, SGA=small for gestational age, IUGR= intrauterine growth retardation, UTI=urinary tract infection

The selection of the outcome measures in these studies is questionable and appears to be based on the cost effectiveness of visits. In two of the trials the differentiation between the primary and secondary outcome measures is unclear (Walker and Koniak - Griffin 1997; Binstock and Wolde-Tsadik 1995). Sikorski et al (1996) focussed on morbidity resulting from the failure to detect or late detection of hypertensive disorders and used the rate of Caesarean section as a proxy measure. This choice of outcome measure is interesting because it does not accurately reflect the long or short term morbidity associated with pre-eclampsia, with the mode of delivery being affected by many other clinical variables. Although most of the results from the trials reviewed are reassuring and suggest that a reduced number of antenatal visits do not increase the incidence of the most common antenatal complications, the list of clinical outcomes is by no means exhaustive. There remains the possibility that there are other significant outcomes that were not included and reported in the trials or outcomes were so unusual that a trial would need to be of greater size to detect a difference in incidence between the control and intervention groups.

Villar et al (2001) included a study of disease diagnosis and recorded whether women were referred to other sources of care i.e. hospital clinics to determine whether a reduction in visits affected the detection rate of complications and resulted in women being referred for extra care. The findings showed that a greater number of women who received a reduced schedule of visits were referred for additional antenatal care but that fewer were admitted to hospital when compared to the standard model of care. It is expected when considering the results of the trials discussed, that a reduction of visits would not increase the incidence of complications but could affect the timely treatment and management of care.

Although all the trials in the review aimed to reduce the number of visits, there were difficulties ensuring that the new and in some cases, the traditional patterns of care were adhered to. Two of the studies conducted in developing countries achieved fewer visits in the intervention group than proposed (Majoko et al. 2007; Munjanja et al. 1996) and three of the five trials undertaken in developed counties had a greater number of antenatal visits in the intervention groups than planned (Table 2). These results suggest that there are difficulties

enforcing a new schedule of antenatal visits and does raise questions over whether the intervention was actually achieved. The difference in the number of antenatal visits between the trial groups was less than intended; therefore the outcomes were similar in each group (Villar et al 2001). This finding has obvious implications for service provision planning and the economic evaluation of new patterns of care.

The three trials which were conducted in developing countries showed the largest reduction in number of visits from standard care and had significantly fewer visits in the intervention arm than the trials undertaken in developed countries (Majoko et al. 2007; Villar et al. 2001a; Munjanja et al. 1996) . The results of the trials in developing countries provide reassurance that a more moderate reduction of visits in developed countries is unlikely to be associated with significant differences in maternal and perinatal morbidity.

There was a relatively high loss to follow up rate in four trials (Majoko et al. 2007; Walker and Koniak - Griffin 1997; McDuffie et al. 1996; Binstock and Wolde-Tsadik 1995). The study by Binstock and Wolde-Tsadik (1995) had significant methodological limitations, in particular women were randomised on the basis of their date of birth leading to a high likelihood of bias and the groups were intentionally unbalanced in terms of recruitment to each trial group (more women were allocated to the study group). The study by Walker and Koniak-Griffin (1997) had a relatively small sample of women (n=81) which could impact on the reliability of the results (shown in Table 2) and reduce the ability to make meaningful conclusions about clinical outcomes.

1.5 Influence of parity

The seven trials in the review included both nulliparous and multiparous women in the sample population and although one study did advocate more visits for nulliparous women in their intervention group, none of the trials differentiated between these groups of women when presenting the results. This means that the actual clinical and economic impact of a reduced schedule of visits in nulliparous women specifically, is unknown.

The need for antenatal visits is greater for women having their first baby for a number of reasons. Fetal growth restriction (FGR), PE and placental abruption are conditions of pregnancy that are grouped under the term placental mediated disease (PMD). Pathological evidence suggests that PMD is caused by inadequate trophoblastic invasion of the spiral arteries resulting in abnormal placentation. It is the most significant cause of maternal and fetal morbidity in pregnancy and the group of conditions are known to be more prevalent in nulliparous women; PE affects 2-5% of all pregnancies and is 3-6 times more likely to affect nulliparous women than multiparous (Subtil et al. 2003). A review of risk factors for FGR found that nulliparous women had an risk ratio of 1.23 (Kramer 1987) and a later study showed an adjusted odds ratio for small for gestational age at birth of 1.6 in nulliparous women (Lang et al. 1996).

Because the incidence of PMD is higher in nulliparous women than multiparous, screening and diagnosis of PE and FGR are a fundamental focus of antenatal care for such women (Shennan 2003). The identification of a woman as having a 'low risk' pregnancy is determined by a number of factors. For those women who have previously had a baby, their obstetric as well as their medical history is taken into consideration. This assists the clinician to determine the likelihood of recurrence of PE and FGR and tailor their antenatal care accordingly. The assessment of a nulliparous woman's risk of such complications is less straightforward with the clinician having only the previous medical history as a guide.

There are also differences between nulliparous and multiparous women's psychosocial needs during pregnancy. A study of 1302 primiparous and 1759 multiparous women in Sweden found that primiparous women had different expectations and requirements of antenatal care. Nulliparous women viewed the opportunity to gain information and attend antenatal classes as very important whereas multiparous women did not place such emphasis on this component of antenatal care (Hildingsson et al. 2002).

It has been shown that the lack of previous experience of pregnancy results in nulliparous women requiring reassurance that their individual experience is 'normal'. Reassurance has been found to be particularly relevant for women

experiencing their first pregnancy because it is a time of physical and emotional transition (Earle 2000). The differences in the expectations and requirements of antenatal care are important considerations in light of the recent recommendations for the provision of antenatal care. The results of two systematic reviews (Carroli et al. 2001b; Villar et al. 2001b) led the National Institute of Clinical Excellence (NICE) to recommend that nulliparous women with 'low risk' pregnancies should have 7 visits rather than the traditional pattern of 10 visits after 20 weeks gestation. The differences between the traditional and NICE recommended schedule of antenatal visits for nulliparous women is shown in Table 3.

Table 3 - Traditional and NICE antenatal visit schedule for nulliparous women

	Gestation in weeks											
	24	25	28	30	31	32	34	36	37	38	39	40
Traditional visits	✓	×	✓	✓	×	✓	✓	✓	✓	✓	✓	✓
NICE visit schedule	×	✓	✓	×	✓	×	✓	✓	×	✓	×	✓

1.6 Satisfaction with a reduced schedule of antenatal visits

There is evidence to suggest that a reduction in the number of antenatal visits when compared with a traditional visit schedule results in women feeling less satisfied with their care. In the study by Sikorski et al (1996) that included both nulliparous and multiparous women, it was found that women's psychological needs were not met as effectively with fewer visits. The study used a self-completion questionnaire, which included measures of postnatal depression, attitudes to the fetus and experiences of maternity care. The response rates for the antenatal and postnatal questionnaire were 70% and 63% respectively. The study demonstrated that women in the intervention group were more worried about the babies antenatally and postnatally and had more negative attitudes towards their baby during pregnancy; in addition women wanted more information about feeding their babies. The women did not feel that their concerns were listened to, wanted more time to talk during visits and felt they received too few visits.

In contrast a study by McDuffie et al (1996) of 2764 women found there was no difference in levels of satisfaction experienced by women in the two study groups. In this study satisfaction with antenatal care was assessed by means of a self completion questionnaire that comprised of items measuring the women's perception of the quality of care, the education they received during antenatal visits and their satisfaction with the number of visits. The return rate for the satisfaction questionnaire was low (51%), leading to concerns about the generalisability of the findings.

Both studies included both nulliparous and multiparous participants and the authors did not provide information about whether there was any difference in levels of satisfaction with care between the two groups of women. It is relevant that the women in the intervention groups received less care than those in the traditional care groups. Thus the reduced levels of satisfaction could have been exhibited because the participants were aware that they were receiving less care and this may not be the case when a reduced schedule of visits is implemented as routine care provision (Hall et al. 1985).

A follow up of the Sikorski study (1996) examined the long term psychological consequences of receiving a reduced number of antenatal visits and concluded that there was no evidence of adverse effects 2.7 years later. The follow up study included only 40% of the initial sample so the findings may not be representative and it is possible that women experienced significant negative consequences prior to the follow up data being collected (Clement et al. 1999).

1.6.1 Measurement of 'satisfaction' with care

There are inherent difficulties in measuring satisfaction with healthcare; it is a multi-dimensional construct that is affected by many different factors including expectations, individual experience, health outcomes and demographic variables (Sitzia 1999) . A wide range of different methods have been utilised in an attempt to obtain meaningful information on patients views about the healthcare they have received including direct observation, questionnaires, interviews and the analysis of complaints (Crow et al. 2002). The measurement of satisfaction does, however, provide a valuable insight into women's experiences and perceptions of their care during pregnancy and may provide

health professionals with the knowledge to modify care accordingly to improve quality (Redshaw 2008).

In order to improve care, it is necessary to identify the different factors that may affect women's perception of care and therefore levels of satisfaction. Women's individual circumstances can influence how they feel about the care they receive as well as the quality of care and the manner in which it is organised and provided.

Self completion questionnaires are generally easy to administer to large numbers of consumers and so are cost effective methods of eliciting views. Postal questionnaires also have the advantage of reducing the likelihood of respondents being affected by interviewer bias. Qualitative interviews provide a more in depth insight into consumers' perceptions of the healthcare system and the factors which contribute to their experience but can result in respondents giving answers which they deem to be more socially acceptable. The use of a combination of qualitative and quantitative methods has been suggested as the optimum approach to provide reliable and valid data (Crow et al. 2002).

1.7 Social Support

Social support is a concept that has been extensively investigated in relation to health care over the last few decades. However, due to varying definitions of support, interpretation of research findings has been problematic. There is substantial evidence to suggest that effective social support has a positive association with the health and wellbeing of individuals (Uchino 2006) and this association may be independent of other variables such as health behaviours, socio-economic status and frequency of utilisation of health services (Wiggins et al. 2004; Kaplan et al. 1977). It has also been reported that effective social support can have a 'buffering' effect against high levels of stress thereby reducing negative impacts (Glazier et al. 2004; Cobb 1976).

Social support has been defined as the individual's perceptions that they are cared for and valued within a network, involving communication and mutual obligation. This support can be provided from a number of sources including family, partner, friends and social and community contacts (Stroebe 2000)

The functions of social support are often separated into four distinct categories (Stroebe 2000):

- Emotional - being provided with empathy, love care and trust
- Instrumental – provision of practical, direct help
- Informational – the offer of information that helps the individual cope with their specific situation
- Appraisal – the ability to self evaluation in comparison with significant others.

The provision of psychosocial support for women has been described as a vital component of antenatal care and an inherent part of the role of the midwife (McCourt 2009; Langer et al. 1996) frequency of contact between the midwife and pregnant woman ensures that midwives have a unique opportunity to provide women and their families with individualised psychosocial support. This has been highlighted as an area which is important for the future development of the role of the midwife (Midwifery 2020 UK Programme Board 2010). The importance of the inclusion of social support in antenatal care has arisen as a result of studies in other areas of health research that show a positive correlation between levels of social support and positive health outcomes (Uchino 2004).

A wide range of observational studies have been undertaken to determine whether pre- existing low levels of social support are correlated with detrimental health outcomes in relation to pregnancy. A study of 9208 pregnant women concluded that perceived emotional and instrumental social support reduced a woman's vulnerability to depression (Baker and Taylor 1997). This finding is supported by a study that explored the relationships between social support, stressful living conditions and depression in women of low socio-economic status (Seguin et al. 1995). Unavailability of social support was strongly associated with depressive symptoms, particularly for those women of low socioeconomic status. Low levels of social support during early pregnancy have also been associated with lower birthweight in infants born after 37 weeks gestation (~200g on average), increased depressive symptoms and reduced quality of life (Elsenbruch et al. 2007)

Other studies have reported contrary results; Dole et al. (2003), in a study of 1962 pregnant women, reported no association between social support and either depression or preterm delivery. Baker et al (1997) found that levels of social support did not impact on the physical health outcomes measured (backache and urinary infection).

A systematic review of randomised controlled trials of the impact of the provision of social support in addition to routine care for women at increased risk of having preterm or low birthweight (LBW) babies was published in 2003 and updated in 2010 (Hodnett et al. 2010). A summary of the key design features, interventions and outcomes are shown in Table 4.

Table 4 - Key design features of randomised controlled trials of support interventions during pregnancy for women at increased risk of pregnancy complications

Lead authors/Year	Intervention group	Setting	Sample size	Interventions	Main outcome measures	Outcomes
Blondel et al (1990)	Women with threatened preterm labour between 26-36 wks gestation.	France	158	1-2 home visits/week by midwives and access to telephone contact	Hospital admission, < 37wks at delivery, lengths of hospital stay.	No difference in number of hospital admissions, length of stay or preterm delivery rates
Brooten et al (2001)	High risk of preterm labour, diabetes or chronic hypertension	USA	173	Home visits by nurse specialists	Antenatal hospitalisation, length of postpartum stay in hospital, readmission	Lower rate of antenatal admission. No difference between length of postpartum stay or readmission.
Bryce et al (1991)	1 or more: preterm births, LBW babies, perinatal death, second trimester miscarriage, 3 or more 1st trimester miscarriages or previous APH	Australia	1970	Home visits at 4-6 wk intervals and telephone calls	Gestational age at delivery, stillbirth, neonatal death, method of delivery	No significant difference in preterm birth rate between groups. Trial was underpowered.
Dawson et al (1989)	Risk factors for LBW baby	Wales	60	11 home visits and telephone domiciliary fetal monitoring system	No. of and length of admissions, gestation at delivery, obstetric interventions, anxiety, postnatal depression and perinatal mortality	Reduction in admission rate for women in the intervention group. No differences observed in other outcome measures
Dawson et al (1999)	High risk for adverse pregnancy outcome	Wales	81	Domiciliary fetal monitoring via telephone calls and home support from community midwives	Mean gestation at delivery, induction of labour, method of birth, birthweight, Apgar scores, depression, anxiety, postnatal depression and satisfaction.	No difference in gestation at delivery or neonatal outcomes. No difference between groups for psychological outcomes.
Heins et al (1990)	Risk factors for or previous LBW baby	USA	1458	Weekly/biweekly antenatal care including counselling, education and cervical screening	Birthweight	No difference in infant birthweight
Klerman et al (2001)	African American, increased risk of complications	USA	656	Health behaviour education visits every 2 weeks and group educational session	Women's perceptions of care, rate of LSCS and neonatal outcomes	Women in intervention group rated care more highly. No differences in rate of LSCS or neonatal outcomes.
McLaughlin et al (1992)	Low income women at risk of child maltreatment	USA	428	Focussed prenatal care, meeting with psychologist and prenatal support groups	Birthweight, miscarriage and termination of pregnancy	Higher infant birthweight for primiparous women in intervention group
Moore et al (1998)	Increased risk of low birthweight baby	USA	1554	Education, 3 telephone calls/week until 37 weeks	LBW, gestational age <37weeks	No differences in LBW or preterm delivery rates
Norbeck et al (1996)	Low income, African American women identified as having poor social support	USA	114	4 standardised face-to-face sessions at home and telephone contacts in between.	Rates of LBW (< 2500g)	Significant difference in LBW <2500g,9.1% in intervention group compared to 22.4% in control group

Table 4 continued

Oakley (1990)	History of low birthweight baby (<2500g).	UK	509	3 home visits and 2 telephone contacts. Semi structured interview guides for midwives. Midwife on call for 24hrs day.	Length and no. hospital admissions, hypertension, depression labour outcomes, neonatal outcomes. Postnatal psychological outcomes.	Infants in the intervention group had mean birthweight 38g higher than control group infants and were healthier during perinatal period. Fewer very LBW babies in the intervention group. Higher rate of hospital admission for women in control group. Women in intervention group rated care highly
Olds (1986)	One or more of following criteria: <19years, single parent, low socioeconomic group, nulliparous.	USA	379	Three intervention groups comprising a combination of: transport for appointments, home visits antenatally and/or postnatally.	Child abuse/neglect, mother's assessment of babies behaviour, objective assessment of parenting, birthweight, length of gestation, stillbirth	No overall differences between groups. Higher birthweight and lower incidence of preterm delivery in women <17 years of age and those who smoked.
Rothberg (1991a)	Black women with hypertension, < 26 wks gestation	S. Africa	80	Counselling by social worker 4 times during pregnancy	Birthweight, gestation at delivery, admissions, LSCS, miscarriage/stillbirth, LBW rate.	Significant reduction in number of babies with birthweight <3000g in intervention group.
Rothberg (1991b)	Caucasian women, low risk for preterm delivery of LBW. High levels of life stress.	S. Africa	104	20 minutes of individualised counselling at each visit or by telephone	Birthweight < 300g, LBW, preterm delivery rate	Significant reduction in number of babies with birthweight < 3000g but no difference in number of LBW babies.
Spencer (1989)	Increased risk of LBW baby	UK	1288	1- 2 visits per week by lay family worker	Birthweight, length of gestation, SGA, preterm delivery, terminations, miscarriages and still births.	No significant differences between groups.
Villar (1992)	One or more of following: LBW or preterm delivery, fetal or infant death, <18 years, <50kg, <150cms, low income, < 3 years school, smoking, alcohol use, single parent	Argentina Brazil Mexico	2235	4 - 6 home visits by social worker or nurse and access to support office.	LBW, preterm delivery, IUGR, mode of delivery, stillbirth, perinatal death, Apgar score, admission to neonatal unit	No significant differences between groups.
LBW = low birthweight, LSCS = lower section Caesarean section, APH = Antepartum haemorrhage, IUGR = Intrauterine growth restriction, SGA=small for gestational age. All differences in outcomes stated are statistically significant.						

The support interventions used in the studies reviewed involved various combinations of extra home visits by health professionals (Brooten et al. 2001; Klerman et al. 2001; Dawson et al. 1999; Norbeck et al. 1996; Villar et al. 1992; Bryce et al. 1991; Rothberg and Lits 1991; Rothberg et al. 1991; Blondel et al. 1990; Oakley et al. 1990; Dawson et al. 1989; Olds et al. 1986) or lay workers (Spencer et al. 1989) and/or clinic visits (McLaughlin et al. 1992; Heins et al. 1990), group sessions (Klerman et al. 2001; McLaughlin et al. 1992), telephone calls (Moore et al. 1998; Norbeck et al. 1996; Blondel et al. 1990; Oakley et al. 1990; Dawson et al. 1989), telephone help lines (Villar et al. 1992; Oakley et al. 1990) and a telephone fetal monitoring system (Dawson et al. 1999; Dawson et al. 1989).

The authors of the systematic review concluded that overall there was no association between increased social support and the incidence of preterm delivery or LBW. One of the reviewed studies found a significant difference in the incidence of LBW in the intervention group (Norbeck et al. 1996) and another study showed that the psychosocial intervention had a positive impact on birthweight for primiparous women only, although the number of primiparous women in the intervention group was relatively small in this study (n=86) (McLaughlin et al. 1992). A trial of 509 women with a history of having a low birthweight baby, where the intervention comprised of extra home visits and had access to a 24 hour telephone contact lines, found that the women in the intervention group had heavier babies (38 grams heavier) and were admitted to hospital less frequently during the pregnancy. Women had better physical and psychosocial health when compared to those in the control group and used health services less frequently (Oakley et al. 1990).

The systematic review stated that there was a positive association between the support interventions and a reduction in the number of antenatal hospital admissions and Caesarean section delivery. The review focussed on studies that used clinical outcomes such as birthweight, preterm delivery rates and length of hospital stay. The authors concluded that although the results did not show a significant change in all of the clinical outcomes used, pregnant women do deserve to be provided with effective support during what is a significant life

event and this sentiment is reiterated further in a WHO commentary paper (Langer 2003).

In light of the NICE recommendations to reduce the number of antenatal visits for low risk nulliparous women with the recognition that this may have a negative impact of women's psychological wellbeing, it is possible that the introduction of a support intervention may have beneficial effects. In order to maintain the recommended number of antenatal visits, it is important that a support intervention is delivered by a method other than face-to-face contact with a health care professional e.g. telephone delivered intervention.

1.8 Economic factors

The provision of fewer antenatal visits has been shown to result in lower costs for health care providers and to women for out-of-pocket costs (Villar et al. 2001a). The study by Sikorski et al (1996) only examined costs to the National Health Service (NHS) and concluded that such costs were marginally lower with a reduced schedule of care. The costs for traditional antenatal care were estimated at £544 per woman with the antenatal element being £251 and the reduced schedule of care costs were £563 with £225 incurred antenatally. These estimates demonstrate that although the antenatal portion of care was more economical, the overall costs were greater. This was as result of more neonatal admissions in the reduced visit group, although the authors suggest that this is most likely to be a chance finding. It has been suggested that the NHS would be unlikely to realise the cost savings resulting from fewer visits but rather that there would be a more effective distribution of costs within the antenatal care structure with resources being more effectively redirected to women with greater needs.

There is a concern that a reduction in the number of planned antenatal visits could also increase the utilisation of acute services thereby negating possible cost savings. This would also result in a reduced ability to plan care provision and would exert pressure on other services. It has been found that a reduction in the number of routine antenatal visits for low risk women did not result in an increase in the uptake of other healthcare services (McDuffie et al. 1997).

However, although the proposed number of visits was 9, the participants in the intervention group actually received 12 visits. The true reduction in visits received was 2 when compared with the control group. Thus it remains unclear what the impact of a greater reduction of visits would be on other services. In two trials women who received fewer antenatal visits also had significantly fewer ultrasound scans (Sikorski et al. 1996; Binstock and Wolde-Tsadik 1995). A reduction in the number of ultrasound examinations would also mean lower costs and/ or a more effective use of resources. This could facilitate the introduction of scans specifically targeted to screen for predetermined conditions such as preterm labour and PMD which would ensure that clinicians could provide antenatal care tailored to individual women's needs and clinical risk.

1.9 Uterine artery Doppler screening

Uterine artery Doppler screening (UADS) is a non-invasive ultrasound technique that measures downstream impedance and correlates with inadequate trophoblastic invasion and deficient spiral artery remodelling (Sagol et al. 1999). UADS is achieved using standard Doppler ultrasound technology and is a relatively straightforward, non-invasive procedure that takes approximately 5 minutes to complete. It effectively predicts poor placentation and therefore PE, FGR and fetal death (Cnossen et al. 2008; Papageorghiou et al. 2002).

A review of fifty-two studies of the predictive accuracy of uterine artery Doppler screening (UADS) concluded that it is more accurate when performed during the second trimester than the first trimester. An increased pulsatility index (PI) with diastolic notching was the best predictor of PE (positive likelihood ratio (LR) 7.5, 95% CI 5.4-10.2; negative LR 0.59, 95% CI 0.47-0.71) and FGR (positive LR 9.1,95% CI 5.0-16.7); negative LR 0.89, 95% CI 0.85-0.93) in a low risk population (Cnossen et al. 2008).

Studies have demonstrated that UADS is more effective at predicting preterm PMD rather than term disease. It was found in one study that the sensitivity of uterine artery screening for predicting PE was 45% overall but for predicting PE

requiring delivery before 34 weeks gestation the sensitivity was increased to 90% (Albaiges et al. 2000).These findings were similar to those of other studies (Papageorghiou et al. 2001; Kurdi et al. 1998). The onset of PE prior to 34weeks is more likely to result in adverse outcomes for the mother and infant with PE at term being less likely to result in FGR or placental abruption (Yu et al. 2008).

Women who have normal uterine artery Doppler indices constitute a lower risk group for the development of problems associated with abnormal placentation. UADS therefore provides the opportunity to screen low risk nulliparous women for the major causes of maternal and fetal morbidity. For women, the knowledge that they have a reduced chance of developing these complications could provide reassurance and allay anxieties during the pregnancy although being deemed at high risk for PMD may cause women increased levels of anxiety in the absence of a proven treatment for the condition (Cnossen et al. 2008).

1.10 Telephone support intervention

The provision of social support intervention by telephone has been used in a variety of healthcare fields and has a number of possible benefits for healthcare providers and recipients. The increase in the number of telephone delivered interventions has occurred partly as a response to a need to reduce resource use with an ever expanding demand for health care (McBride and Rimer 1999). Access to a telephone is almost universal; this means that utilisation of this technology to deliver healthcare and support is a feasible, low-cost option (Mair and Whitten 2000).

Telephone contact has been described as one of the most underutilised resources in healthcare (Bullock et al. 2002). It provides an immediate, convenient form of contact that allows the patient to receive support and advice whilst in their own surroundings. This means that barriers to accessing healthcare such as transport and geographical difficulties are reduced (Creedy 2003). Contact by telephone can actually improve communication because clients feel more at ease and confident in their own home when compared to a

clinical setting, this can facilitate discussions about personal or private issues (Bullock et al. 2002).

Studies have shown varied effects on psychosocial outcomes from the use of telephone delivered healthcare. A randomised trial that examined the effects of providing scheduled telephone contact following traumatic brain injury found that the intervention group had an improved composite outcome including functional status and quality of wellbeing (Bell et al. 2005). In the study by Bell et al (2005) the intervention was successfully completed in 79 out of 83 participants. However, a study focussing on a scheduled telephone intervention for women following a cardiac event (myocardial infarction, coronary artery bypass grafts, coronary angioplasty or stable angina) found that there was no difference between the groups in levels of anxiety or depression at 12 weeks after discharge from hospital, although the intervention was acceptable to women. In this study the telephone intervention was fully delivered on only a third of the 93 participants suggesting that the study was underpowered to detect a difference between the groups (Gallagher et al. 2003).

A telephone delivered support intervention has also been used in an attempt to improve pregnancy outcomes. A prospective randomised trial of 1554 women, found that twice weekly nurse initiated telephone contact reduced the rate of low birthweight babies in African American women by 26%. The same study did not find any reduction in rates of low birthweight babies in Caucasian women (Muender et al. 2000). In a relatively small sample of women (n=21) at increased risk of preterm birth, daily telephone contact was not found to have any impact on the rate of preterm delivery although due to the small sample size it is difficult to draw any meaningful conclusions from the results. The intervention was successfully delivered to all of the participants (Boehm et al. 1996).

The use of proactive telephone contact by health professionals may therefore be beneficial. It has been found that most patients who have significant concerns will not initiate a telephone contact with professionals but will ask questions when they are contacted at home by a health professional (Bostrom

et al. 1996). A review of studies utilising telephone contact as a means of delivering health care concluded that telephone contact may be useful for the proactive contact of those with limited access to services and can reduce the number of face to face encounters with patients (McBride and Rimer 1999)
In a study of a reduced antenatal visit schedule, it was found that 86% (1560/1818) of participants would like extra telephone support with a midwife as a means of maintaining support during the pregnancy (Clement at al 1997). This type of support can be provided whilst maintaining the visit schedule proposed in the NICE guidelines (National Collaborating Centre for Women's and Children's Health 2003).

1.11 Summary of previous literature

In summary, the review of the literature identified a number of important concepts:

1. The number of antenatal visits for low risk women can be reduced without a significant impact on major clinical outcomes but there is no evidence to determine whether these findings are influenced by parity.

2. There is no literature to suggest whether or not nulliparous and multiparous women differ in the level of satisfaction they express about reduced schedules of care.

3. Social support interventions may reduce anxiety levels, improving satisfaction with care and reducing worries. This could be achieved by a proactive, telephone support intervention

4. Screening for PE and FGR can be successfully achieved by uterine artery Doppler screening. A negative result means that a woman has a reduced risk of developing early onset PMD which may be reassuring for women.

1.12 Study rationale

In making the recommendation to reduce the number of antenatal visits for low risk women it was recognised that this change in care may result in women being less satisfied with their antenatal care and having poorer psychosocial outcomes. The guidelines identified the need for further research to address gaps in the current research evidence which included studies to investigate alternative methods of providing women with information and support during pregnancy. A further recommendation was for research to be conducted to explore how to ensure that women are satisfied with fewer antenatal visits as proposed in the guideline (NCCWCH 2003).

1.13 Aims and Hypotheses

The aims of this trial were to assess the impact of two antenatal interventions on the total number of visits that low risk nulliparous women had with health professionals after 20 weeks gestation, when compared to usual antenatal care. Specifically the project was designed to test the following hypotheses:

The provision of a telephone support intervention to low risk nulliparous women will reduce the total number of antenatal visits, reduce anxiety and increase social support and satisfaction with antenatal care when compared with usual antenatal care.

The provision of a telephone support intervention with supplemental UADS to low risk nulliparous women will reduce the total number of antenatal visits, reduce anxiety and increase social support and satisfaction with antenatal care compared to a telephone intervention and usual care.

Chapter 2. Methods

2.1 Introduction

The following chapter will discuss the rationale for the study design including the mixed methods approach, setting and the assessment scales utilised. A detailed description of the research methods is provided.

2.2 Rationale for Methodology

2.2.1 Mixed methods approach

It is recognised that there are substantial challenges in evaluating complex healthcare interventions, particularly those which encompass a significant social component such as a telephone support intervention (Medical Research Council 2008; Campbell et al. 2000). A pragmatic approach was therefore taken and the most appropriate methods of investigation utilised to answer the research questions in a bid to yield the most informative and reliable data. The chosen study design employed a mixed methods approach (Blackwood et al. 2010), which was a 'complementary quantitative, qualitative follow –up' as described by a mixed methods typology (Morgan 1998). The primary study involved a three arm randomised controlled trial (RCT) with a smaller qualitative interview study in a parallel design to provide a greater depth and breadth of data than could be generated from using one approach in isolation (Teddlie and Tashakkori 2009).

2.2.2 Randomised controlled trial

A RCT was selected because it is the optimum method for the investigation of health care interventions, although it is accepted that all research methods have their limitations (Tilling et al. 2005). The RCT design was used in a bid to reduce bias by having a randomly selected, comparable control group (Oakley 2007). This facilitates an evaluation of the outcomes of participants who received the intervention compared with a comparable group of participants who did not. To minimise allocation bias, an external organisation (Centre for Health Service Research, Newcastle University) was used to design and operationalise the randomisation procedure and a web based randomisation was used. Those individuals involved directly with the study had no control over

the allocation of participants or knowledge of the allocation methods. It was not possible to blind the participants, investigators or care givers due to the nature of the interventions.
The quantitative data was analysed using an 'intention to treat' approach to minimise the chance that there were systematic differences between the groups. It was expected and accepted that a proportion of women in the intervention groups would not receive part or all of the allocated intervention.

Consideration of the ethical implications of not providing the interventions to those women in the control group was given. Because the women who were to be recruited were at low risk of developing pregnancy complications and additionally and the benefits of the interventions in this population specifically were unknown, it was considered to be ethical and desirable to use random allocation of participants. It was accepted that a proportion of women may decline to take part in the study and a decision was made to record their predominant reason for not taking part in order to evaluate whether this had an impact on the results. It was also accepted that the interventions may result in women experiencing additional anxiety, particularly those women who received a positive result from uterine artery Doppler screening. In order to address these issues, women were provided with contact numbers for the research midwives involved in the study and encouraged to contact them with any queries relating to this.

2.2.3 Qualitative interviews

It was recognised that although the RCT design offered the best option for assessing the effectiveness of the interventions, the use of qualitative semi-structured interviews would provide valuable information regarding contextual factors that might impact on effectiveness and compliance with the interventions. In addition, the interviews provided information to increase the depth of understanding in relation to the evaluation of the interventions. The analysis provided greater understanding and insight into women's views of the care they received and the issues that were salient to them.

Face-to-face, semi-structured interviews were undertaken in participants' own homes to generate the qualitative data, this approach was used to ensure that all of the relevant questions relating to issues such as the acceptability of the interventions and women's views on the number of antenatal visits they received were addressed whilst giving participants the chance to discuss anything else that arose during the course of the interview (Creswell 2007) . An interview guide was developed and used to ensure that the interviews were all conducted in a similar manner and to ensure rigour in the research process (Appendix N). The participants were purposefully selected based on their study group, age, ethnic origin and highest educational level in order to elicit the views of a broadly representative sample.

The interview data was analysed using a 'Thematic Framework' approach. This approach was developed for applied policy research and was selected for use in this project because its key features made it suitable considering the research questions being posed. The method has been designed to be suitable for use in conjunction with quantitative statistical analysis, which makes it ideal for the mixed methods approach of this research project (Ritchie and Spencer 1994). It is a systematic approach that has specific stages and a clear analytic process but at the same time is flexible and can be changed or amended throughout the analysis. This methodology facilitates a full review of all of the interview data and allows comparisons between and within cases. Framework analysis is useful for research that has a defined timescale, as in the case of this project, and it provides a transparent analysis process that can be viewed by others (Ritchie and Spencer 1994).

It was accepted that the interviewer's background as a midwife and sonographer might impact on both the interview process and the inferences made as a result. In order to minimise the impact on the interviewees, a discussion took place prior to the commencement of the interview during which the researcher acknowledged their professional background. She explained to the woman she was not employed by the NHS trust at that time and any information provided would be treated confidentially and would not affect their

care. A biography of the researcher is provided in the foreword to help achieve reflexivity (Donovan and Sanders 2005).

2.2.4 Setting

The research was undertaken in the Royal Victoria Infirmary, Newcastle upon Tyne in collaboration with Newcastle University. The hospital is a regional referral unit with approximately 7500 deliveries per annum; because of the high number of women booking for care at the hospital the population is more diverse than that of smaller units within the local geographical area. Recruitment to the study was undertaken in the Antenatal Ultrasound department. This was deemed the most appropriate location because most of the care for low risk nulliparous women was based in the community setting and they only attended the hospital for routine ultrasound scans. Recruitment to the study in the community setting would have provided significant logistical difficulties and may have introduced bias into the sampling strategy.

2.2.5 Questionnaire data collection

Postal questionnaires, provided with prepaid envelopes, were used to collect data on selected outcomes; this method of data collection was used because it provided the option of administering a number of scales to the entire study sample at multiple time points. This facilitated a cost effective examination of the outcome data across the duration of the second and third trimesters and postnatally. Postal questionnaires have the benefit of reducing respondents' susceptibility to social desirability and interviewer bias but it was accepted that response rates can be affected (Bowling 2009). In an attempt to optimise the response rate, a repeat questionnaire was sent out two weeks after the initial questionnaire, if it was not returned.

2.3 Assessment scales

2.3.1 Anxiety measurement

Anxiety was assessed using the State-Trait Anxiety Inventory (STAI) (Spielberger et al. 1970). The measure comprises of two 20 item scales; one scale is designed to measure trait anxiety and the other to measure state

anxiety. Trait anxiety is described as the general level of anxiety experienced by an individual that determines how they react to perceived threatening situations. State anxiety reflects how the individual feels at the time the measure is completed (Hundley et al. 1998). The STAI was chosen because it has been shown to have good internal consistency (r = 0.86) (Spielberger et al. 1970), content (Spielberger et al. 1970) and construct validity (Okun et al. 1996). The STAI has been suggested to be the most appropriate tool for the measurement of anxiety in a perinatal sample of women in a research setting (Meades and Ayers 2011) and a recent study demonstrated that the STAI is valid for use during pregnancy when results were compared to women's answers to open ended questions about their anxiety levels (Gunning et al. 2010). Furthermore, it was found to be the most frequently used measure of anxiety in a meta-analysis of studies exploring the relationship between anxiety during pregnancy and association with perinatal outcome (Littleton et al. 2007).

The STAI scores range from 20-80 for both the trait and the state subscales with a higher score indicating higher levels of anxiety (Spielberger et al. 1970). A score of ≥40 was the cut off used to determine high levels of anxiety (Barnett and Parker 1986). Both the trait and state subscales were administered at the time of recruitment (20 weeks gestation) to obtain a baseline assessment of women's anxiety. Subsequently, questionnaires at 28, 36 and 6 weeks postnatally included only the state subscale.

2.3.2 Pregnancy Worries

In order to supplement the results of the STAI with a pregnancy specific scale, the Pregnancy Worries scale (PWS) was selected for inclusion in the questionnaires. The PWS was developed to measure anxiety specific to pregnancy (Thornton et al. 1995). The validity and consistency of this scale have not been reported.

The Cambridge Worries scale (Statham et al. 1997b) was also considered as an alternative. However, the Pregnancy Worries scale was chosen because it had previously been used in a study examining the effects of providing women

with information about screening for Down's syndrome and includes an item to determine how worried women were about the ultrasound scan.

The PWS is a 15 item Likert scale with possible scores ranging from 15 – 90 and a higher score indicating greater pregnancy worries. The possible responses range from 'not at all' to 'extremely'. The scale was completed at 36 weeks gestation.

2.3.3 Social support

Levels of social support were measured using the Duke/UNC Functional Social support (DUFSS) questionnaire, designed to measure functional aspects of social support within a primary care setting (Broadhead et al. 1988). The scale comprises of two subscales measuring Affective and Confidant support.

The DUFSS scale is an eight item Likert scale which has five possible responses ranging from a score of one corresponding to 'as much as I would like' to a score of five, corresponding to 'much less than I would like'. The total scores range from 8 to 40, a low score indicates higher levels of social support. The reliability and validity of the DUFSS has been found to be acceptable although when the scale was devised, it was not tested on a pregnant population specifically.(Broadhead et al. 1988). The scale has acceptable average test–retest reliability (Pearson's coefficient 0.66) and internal consistency has been demonstrated (Cronbach's alpha 0.80) (McDowell 2006).

There are a significant number of social support scales available such as the Social Support Questionnaire (SSQ) (Sarasan et al. 1983), Maternity Social Support Scale (MSSS) (Webster et al. 2000) and the Norbeck Social Support Questionnaire (NSSQ) (Norbeck et al. 1981). The DUFSS was selected because it effectively measures two dimensions of support, it is not overly long or complicated for respondents to complete and has been has been previously used a in range of studies of pregnant and postnatal women (Hoddinott et al. 2009; Castle et al. 2008; Cox et al. 2008; Kutz Landy et al. 2008; Wiggins et al.

2004; Watt et al. 2002; Morrell et al. 2000). The scale was administered at 20, 28, 36 weeks gestation and 6 weeks postnatally.

2.3.4 Satisfaction with care

Due to the difficulties acknowledged in the definition and measurement of satisfaction with health care, it was expected that the most appropriate way to gain a comprehensive understanding of women's views of the care they received would be from the analysis of both the questionnaire data and data obtained from semi- structured interviews (Crow et al. 2002). It was judged that a short, simple quantitative measure of satisfaction could provide a broad overview of the experience of the sample population as a whole.

Satisfaction with maternity care has been assessed, in past research, using a wide range of tools with many having been designed for specific research projects (Britton 2012). This has resulted in the lack of a validated tool that has been widely used in the relevant literature. The Six Simple Questions satisfaction scale (SSQ) was developed specifically for use in the perinatal period, to provide data on the issues that are most likely to impact on women's perception of the care they receive (Harvey et al. 2002) .The scale has been shown to have content validity when scores were compared to scores from The Labour and Delivery Satisfaction Index (LADSI) (Lomas J et al. 1987) and internal consistency has been demonstrated (Cronbach's alpha 0.86). The scale has been shown to have to capacity to reflect changes in satisfaction levels over time, which was a requirement for the present study.

The scale comprises of six items which are scored on a Likert scale with seven options ranging from a score of one corresponding to 'strongly disagree' to a score of seven corresponding to 'strongly agree'. Total scale scores range from 6 – 42, with a higher score indicating a greater level of satisfaction with care. The SSQ was administered as a self completion scale at 36 weeks gestation and six weeks postnatally.

2.4 Study design

The design was a three-arm randomised controlled trial involving low risk nulliparous women. Participants were randomly allocated to one of three groups as shown:

Control

Participants received standard antenatal care as defined below.

Telephone support intervention

Participants received standard care supplemented by the telephone support intervention as described in the following section. The telephone calls were made when the women were 29, 33 and 37 weeks gestation as determined by dating at their first ultrasound scan.

Telephone support and UADS intervention

Participants received standard antenatal care supplemented by UADS undertaken at 20 weeks gestation and the telephone support intervention at 29, 33 and 37 weeks as determined by dating at their first ultrasound scan.

2.4.1Standard antenatal care

All participants received usual antenatal care which followed the recommended visit schedule for low risk nulliparous women after twenty weeks gestation. The pattern and purpose of visits is shown below in Table 5 (NCCWCH 2003)

Table 5 - Recommended visit schedule for low risk nulliparous women after 20 weeks gestation

Timing of visits (weeks)	Function of visit
25	Measure and plot symphysis-fundal height Measure BP and test urine for proteinuria Give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information.
28	Offer a second screening for anaemia and atypical red cell alloantibodies. Investigate a haemoglobin level of less than 10.5g/100ml and consider iron supplementation. Offer Anti-D to Rhesus negative women. Measure and plot symphysis-fundal height. Measure BP and test urine for proteinuria. Give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information.
31	Measure and plot symphysis-fundal height. Measure BP and test urine for proteinuria. Give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information. Review, discuss and record the results of screening tests undertaken at 28 weeks; reassess planned pattern of care for the pregnancy and identify women who need additional care
34	Offer second dose of Anti-D to Rhesus negative women Measure and plot symphysis-fundal height. Measure BP and test urine for proteinuria. Give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information. Review, discuss and record the results of screening tests undertaken at 28 weeks; reassess planned pattern of care for the pregnancy and identify women who need additional care
36	Measure and plot symphysis-fundal height. Measure BP and test urine for proteinuria. Check position of baby For women whose babies are in the breech presentation, offer external cephalic version Review ultrasound scan if placenta extended over the internal cervical os at previous scan Discuss breastfeeding technique and good management practices , refer to the UNICEF Baby Friendly Initiative Give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information.
38	Measure and plot symphysis-fundal height. Measure BP and test urine for proteinuria. Give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information.
40	Measure and plot symphysis-fundal height. Measure BP and test urine for proteinuria. Give information, with an opportunity to discuss issues and ask questions; offer verbal information supported by antenatal classes and written information.
41	A membrane sweep should be offered Induction of labour should be offered, measure BP and test urine for proteinuria. Measure and plot symphysis-fundal height. Information should be given, including further discussion about management for prolonged pregnancy, with an opportunity to discuss issues and ask questions, verbal information supported by written information.

Standard antenatal care for low risk nulliparous women included the following components:

- Antenatal care was provided by an identified midwife or team of community midwives who were aligned to the woman's GP surgery.
- The majority of visits took place in community based midwife-led clinics with occasional home visits being made.
- All women were offered routine antenatal screening ultrasound scans at 12 weeks and 20 weeks gestation (not incorporating UADS).
- Women were referred to an obstetrician or the Maternity Assessment Unit (MAU) if the midwife considered the pregnancy to have deviated from normal
- Community or hospital based antenatal classes were offered to all women. These classes provided information on labour and pain relief, complications of labour, infant feeding and postnatal issues. The classes included a visit to the maternity unit. A separate, additional class was offered to women who wanted to breastfeed.

2.5 Sample

The participants were a sample of low risk nulliparous women booked for care at the Newcastle upon Tyne Hospitals NHS Foundation Trust between 1st February 2004 and 7th January 2007. Low risk status was determined by the criteria set out in the NCCWCH (2003) guidelines which stated a number of conditions that excluded women from being considered as 'low risk' and required nulliparous women to receive antenatal care additional to the recommended visit schedule. The conditions are listed below:

- Cardiac disease, including hypertension
- Renal disease
- Endocrine disorder or diabetes requiring insulin
- Psychiatric disorder (on medication)
- Haematological disorder, thromboembolic disease, autoimmune disease such as antiphospholipid syndrome
- Epilepsy requiring anticonvulsant drugs
- Malignant disease

- Severe asthma
- Drug use such as heroin (including crack cocaine) and ecstasy
- HIV or hepatitis B virus (HBV) infected
- Autoimmune disorders
- Obesity (body mass index(BMI) ≥ 35 kg/m^2 at first contact) or underweight (BMI ≤ 18 at first contact)
- Women who may be at higher risk of developing complications e.g. women 40 years and older and women who smoke
- Women who are particularly vulnerable (e.g. teenagers) or who lack social support.

Women who were over 40 years of age and those who smoked were not excluded from the trial unless they had been referred for additional antenatal care; it was not standard practice at the hospital at the time of the study for such women to automatically receive additional input. Similarly, women were not routinely assessed to identify those with poor social support as part of routine care and therefore such women were not excluded from the trial. Teenage women were included providing they were not receiving care from the teenage pregnancy service that was provided at the hospital during the duration of the trial. The teenage pregnancy service is a multidisciplinary group who provide additional one-to-one visits, antenatal classes and a telephone contact line. This service encompassed the majority of women under the age of 18 years who resided in Newcastle upon Tyne at the time of their early scan, but did not include those who lived outside of the city.

2.6 Exclusion criteria

A proportion of women who were considered to have a low risk pregnancy were excluded from the trial. They were as follows:

- Women who were unable to understand the English language without the help of an interpreter. The financial and time constraints of the project meant that it was only possible to provide the telephone support intervention in English.

- Women who planned to relocate to a different geographical area during their pregnancy, because of the difficulties involved in providing the interventions and obtaining outcome data.

2.7 Recruitment

Nulliparous women who were identified as having a low risk pregnancy were booked for their 20-week anomaly scans on one of three designated ultrasound scan lists to facilitate recruitment.

The women eligible for recruitment were given a patient information sheet (Appendix B) at the time of their first trimester scan by the ultrasonographer. For those women who did not attend for an early scan an information sheet was sent out in the post with their anomaly scan appointment by the antenatal clinic clerical staff. This ensured that women had a reasonable period of time to read the information sheet and discuss it with their partner before attending for their 20-week anomaly scan.

Eligible women were approached about the opportunity to take part in the study by a research midwife when attending for their 20 week anomaly scan. The women were provided with another information sheet if required and a full verbal explanation of the study was given. The women were informed that participation in the trial would involve the completion of postal questionnaires and they may be approached to take part in an interview after delivery. Women and their accompanying partner/friend/family member were encouraged to ask questions about the study at this time.

Following a decision to participate in the study, written consent was obtained and a copy of the consent form was filed in both the woman's handheld and hospital maternity notes (Appendix C). A study sticker was attached to the women's handheld notes to clearly identify that the woman was taking part in the research. For those women booked for care at the Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH) but who lived outside the Newcastle area, an information sheet for their community midwife was filed in their notes (Appendix D). This was to ensure that out of area midwives were aware of the

aims and purpose of the study and had the contact details of the research co-ordinator if required.

2.8 Randomisation

Randomisation was undertaken by three research midwives following informed consent by the use of a web based randomisation package provided by the Centre for Health Services Research based at Newcastle University. This process was conducted within the clinical antenatal ultrasound department where Internet access was readily available.

2.9 Design and development of telephone support intervention discussion guide

It was recognised that a vital function of the TSI was that it was individualised and centred on the specific needs of the woman. This means that as well as giving women the option of what time of day the calls were made it was important that there was flexibility in the actual dialogue that took place between the woman and the midwife. Although the midwife initiated the dialogue, the aim was that it was subsequently driven by the concerns of the woman with the expectation that this would vary between individuals. It was also felt that it was desirable that there was consistency in the way in which the midwives conducted the telephone calls. For this reason the TSI discussion guide was developed (Appendix D).

The development process began with an in-depth examination of the current literature to elicit the specific areas which were of concern to nulliparous women during the third trimester of pregnancy. The informational needs of nulliparous women and the influence of social support on women's experience of pregnancy is discussed in greater depth in the introduction section.

From this review four main topic areas were identified:

- Maternal physical health
- Practical support
- Emotional support and wellbeing
- Fetal wellbeing

In order to ensure the validity of the document it was circulated to the trial steering committee for discussion and modification. Following this the intervention guide was distributed to 10 pregnant women via the service users' representative and to 10 clinical midwives working within the hospital and community. Once feedback had been received from the reviewers the document was amended.

The intervention was designed to enable women in their first pregnancy to have contact with a midwife when they were not planned to have a routine appointment according to the pattern of visits recommended by the antenatal care guidelines (NCCWCH 2003).

The calls were scheduled in the third trimester because the recommended schedule of care proposed a greater reduction in the number of visits during the third trimester than during the first and second trimesters (NCCWCH 2003). As well as the impact of the reduction of routine antenatal visits, it is during third trimester that women are most likely to develop complications of pregnancy such as PE and FGR.

A second attempt to contact women was made if the first was unsuccessful. The justification for only making a maximum of two attempts at each time point was that should the intervention be found to have a significant impact, the most likely health professional to undertake it in clinical practice would be the woman's allocated midwife. It was felt that it was reasonable for midwives to make two attempted calls if required but any further calls may compromise their existing.

2.10 Implementation of theTelephone Support Intervention (TSI)

The participants who were randomised to receive the TSI were asked when they were most likely to be at home or available to take a call at work or on a mobile telephone. They were given the option of morning, afternoon or evening calls on any day of the week to accommodate work patterns and personal commitments and to ensure that the intervention was tailored around their needs.

Participants were encouraged to provide more than one contact number to optimise the chance of the research midwife securing a successful contact and asked to inform the research team if they were moving house or changing their contact details. The telephone contact number(s) and convenient time of day for the women to receive the intervention were recorded on a Microsoft Excel database designed for this purpose.

The majority of the calls were made by one clinical midwife (funded by NHS resources) with leave/ sickness cover provided by the trial co-ordinator. The midwife who delivered the intervention had significant experience in providing advice to pregnant women via the telephone as a result of working within the hospital Maternity Assessment Unit (MAU). The midwife was also provided with specific training about how to deliver the intervention and record details during conversations with participants.

The midwife conducted the TSI at 29, 33 and 37 weeks' gestation. These specific time points were chosen because nulliparous women did not routinely have an antenatal appointment with their midwife at these gestations. The midwife attempted to contact the women twice within the pre-arranged time frame; if both calls were unsuccessful this was recorded and calls attempted at the next gestational time point. Women were asked during the telephone calls if they had required any extra contact with their midwife or other health care professional and if they intended to go to antenatal classes or if they had already attended. This information was recorded on the women's telephone discussion guide (Appendix E). If the woman reported concerns that the study midwife felt required further investigation by another health professional, an appropriate referral was made in the usual way as per the hospital guidelines. The midwife also directed women to alternative sources of information such as books and online resources e.g. to obtain information about maternity benefits.

During the course of the telephone intervention, notes were made on the women's telephone discussion guide sheet (Appendix E) to record the general

topic areas discussed and any specific difficulties or worries experienced by each woman.

If the study midwife referred the women to any other health professional or source of information as a result of their discussion, this was also recorded. A blank telephone discussion guide sheet was used for each TSI time point and the sheets were stapled together and filed. This ensured that when subsequent telephone calls were made the midwife could refer back to the previous conversation and discuss whether prior concerns had been resolved or if the woman required any further advice or information. The sheet also acted as a prompt for the midwife when she needed to action points raised during the call e.g. arrange antenatal classes for the woman. This aided the development of a positive relationship between the woman and the midwife making the calls.

2.11 Implementation of UADS

Prior to the commencement of the trial, the majority of the sonographers working within the antenatal ultrasound department were already competent in obtaining uterine artery Doppler waveforms. Those who were not, were provided with appropriate in-house training and the organisation of staff ensured that there was always a senior sonographer available to provide assistance if required.

All of the ultrasound machines in the department had the functionality to provide pulsed wave Doppler and colour flow mapping. The ultrasound examinations during the trial were undertaken on two machines: Aloka 5000 and Philips HD 11XE. UADS was undertaken at the end of the participant's routine 20 week anomaly scan. The sonographer used colour flow to identify each of the uterine arteries at the crossover with the external iliac arteries and the sample volume was adjusted and positioned over each uterine artery and pulsed wave Doppler was used to collect the waveforms (Lees et al. 2001).

The pulsatility index (PI) is a measure of blood flow velocity and demonstrates the amount of blood flow impedance distal to the uterine artery (Gosling and King 1975). The PI on each of the uterine arteries was measured over five cycles (by the ultrasound machine software) and the mean of the left and right uterine artery PI was calculated manually (Lees et al. 2001).

The presence of unilateral or bilateral waveform notching was noted. This information was recorded on the women's record in the ultrasound examination database provided by Viewpoint; this database was used to record all ultrasound examinations in the department. A normal uterine artery Doppler was defined as a mean PI of both uterine artery waveforms of <1.45 with no notch or unilateral notch (Albaiges et al. 2000). The participants who had normal uterine Doppler indices received explicit verbal and written information (Appendix F) about their reduced risk of developing significant PE and of having a growth restricted baby.

An abnormal UADS was defined as a mean PI of ≥1.45 and/or bilateral notching (Albaiges et al. 2000). Those who had abnormal waveforms were provided with a verbal and written explanation of the findings (Appendix G) and were offered a repeat ultrasound assessment at 24 weeks gestation (Appendix F). They were encouraged to contact a study midwife for further discussion if they had any concerns about the results. If at the time of the 24 week ultrasound examination, the uterine artery Doppler indices were within normal limits the women were informed of their low risk status for the development of PE and FGR and given an information sheet (Appendix H). The remainder of their antenatal care followed the usual care schedule supplemented by the telephone support intervention.

If the UADS result remained abnormal (i.e. a mean PI of >1.45 and/or bilateral notching), a further ultrasound assessment was arranged for 30 weeks gestation. This ultrasound examination involved measurement of fetal size, umbilical artery Doppler PI and amniotic fluid index. If any of the parameters

measured were outside of the normal range follow up was arranged as per the current hospital guidelines. The participants in this group received the TSI irrespective of the result of their uterine artery Doppler screening.

2.12 Outcome measures

2.12.1 Primary outcome measure

The primary outcome measure was the number of antenatal visits that women had after 20 weeks gestation. For the purpose of this study, antenatal visits were defined as a scheduled or unscheduled attendance at a medical, midwife or GP clinic within the community or hospital setting, attendance at a maternity day assessment unit, home visit by a community midwife or general practitioner and attendance at any other location for the receipt of antenatal care such as the fetal medicine unit or hospital ward. This was to ensure that the total number of visits made by participants incorporated all of the 'face to face' contacts women accessed including those additional to the scheduled visits provided by their midwife. All antenatal contacts were included provided they were recorded in either the women's hospital or handheld antenatal notes and irrespective of whether the contact was initiated by the woman, her midwife or other health professional.

2.12.2 Secondary outcomes

1. Number of hospital admissions

Hospital admissions were recorded if a participant spent > 5 hours in hospital and were categorised as either day case admission or overnight stay. If an overnight stay occurred, the number of nights spent in hospital was recorded.

2. Anxiety, worries and social support

The data was collected by the administration of psychological scales.

3. Satisfaction with care

Satisfaction with care was assessed using a scale administered by postal questionnaire and the analysis of semi-structured interviews.

4. Costs of interventions and antenatal care

5. Major clinical outcomes:

PE was defined as a diastolic blood pressure (BP) ≥90mmHg and/or a systolic blood pressure ≥140 mmHg on at least two consecutive readings and proteinuria (proteinuria of ≥ 2+ measured by urine dipstick at least 4 hours apart and/or ≥ 300mg/day on 24 hour urine collection) (Brown et al. 2001). PE resulting in delivery at less than 34 weeks gestation was classified as severe PE. Pregnancy induced hypertension was defined as a diastolic BP ≥90mmHg and/or a systolic blood pressure ≥140 mmHg on more than one occasion at least 4 hours apart +/- proteinuria but not reaching the threshold for classification as PE or severe PE..

Small for gestational age (SGA) infants were classified in the following two categories based on birthweight for sex and gestational age according to local population standards: 5^{th} - 10^{th} percentile and < 5^{th} percentile (Tin et al. 1997).

Stillbirth was defined as babies born after 24 weeks gestation, which did not show any signs of life.

2.13 Sample size and power calculation

Based on a standard deviation (SD) of 2.7 visits (McDuffie et al. 1996; Sikorski et al. 1996), a sample size of 196 women in each group would give a 90% power to detect a difference in the number of visits of 1.0. The significance level was set at 2.5% to allow for multiple comparisons between groups. Anticipating a 30% attrition rate, 840 participants were required.

The decision to power the study to detect a difference of 1 antenatal visit (as defined below) was made because of the possible economic implications of an increase or decrease of 1 visit per woman when considered on a national scale

The attrition rate included participant withdrawal and unsuccessful retrieval of women's hospital and hand-held notes from the records department. The

figures were derived from previous research undertaken with pregnant women within the same hospital.

2.14 Data Collection Methods

2.14.1 Number of Visits, Telephone Calls and Clinical Outcomes

The details of all of the antenatal visits that women made during their pregnancy after 20 weeks gestation were extracted from the handheld and hospital notes of each participant after delivery. The data from both sets of notes was entered into a specifically designed Microsoft Access database.

This outcome data incorporated the following information:

1. The total number of antenatal visits made to health care professionals
2. Whether the visits were scheduled or unscheduled (as per the antenatal guidelines)
3. Pregnancy gestation at time of visit
4. Health professional participant visited/ telephoned
5. The location of the visit
6. The reason for the visit
7. Any further action taken as a result of the contact

Clinical outcomes of interest (as listed previously) were also extracted from the women's notes and recorded in the same way. The reliability of this method of data collection was confirmed by the cross checking 20 sets of notes by a second research midwife.

2.14.2 Questionnaire data

All of the participants in the study were asked to complete a postal questionnaire at 20, 28 and 36 weeks gestation and at 6 weeks post delivery (Appendices I - L). The 20-week questionnaire was given at the time of recruitment. The other questionnaires were sent out by post at the other time points. Questionnaires were sent with a stamped addressed return envelope and accompanying letter (Appendix M).

2.14.3 Demographic information

It is accepted that there are inherent difficulties in accurately assessing social status; in view of this a number of demographic variables were collected from the study participants. These were: age, educational attainment, age when finished education, marital status and occupation. The aim of collecting this data was to provide a description of demographic variability of the sample population.

Table 6 - Data Collection

	Demographics	STAI	Worries scale	DUFSS	SSQ
20 weeks	✓	✓		✓	
28 weeks		✓		✓	
36 weeks		✓	✓	✓	✓
6 weeks postnatal		✓		✓	✓

2.14.4 Data collection time points

Table 6 shows the time points at which the questionnaire scales were administered. The initial time point at 20 weeks gestation was used to collect baseline data from all trial participants (Appendix I). The timing of the second questionnaire (Appendix J) (28 weeks) was chosen because it was after the second uterine artery Doppler screen at 24 weeks for those women who were initially found to have a positive result but before the TSI had commenced at 29 weeks gestation which allowed a comparison of the effect of the interventions on the psychological outcomes measured.

The third time point (36 weeks) was chosen because it represented a point where the majority of antenatal care has been experienced but most women would not have given birth, thereby maximising the questionnaire response rate (Appendix K).

The final questionnaire was sent 6 weeks after the birth; this was felt to be sufficiently close to the pregnancy to allow women to recall the antenatal experience whilst giving them time to adjust to motherhood and hopefully have time to complete and return the questionnaire (Appendix L).

2.15 Ethical approval

Newcastle and North Tyneside Local Research Ethics Committees granted ethical approval for the study and amendments (Appendix N). The document included in Appendix M refers to the present study under its first title which was subsequently amended through the appropriate process (although subsequent documentation from the Ethics Committee continued to refer to the study by its prior title). The study was sponsored by Newcastle Hospitals NHS Foundation Trust with granted approval for conduct of the study.

2.16 Communication to clinical staff

Meetings were arranged with clinical staff at the community midwife bases and within the maternity unit with hospital based midwives and sonographers to discuss the research design before recruitment commenced. This process facilitated the dissemination of information about the forthcoming trial so that it was familiar to staff and they knew how to obtain further information if required. It also provided a useful forum for the discussion of any anticipated problems. This was a vital part of the research planning process that helped to ensure that the research was conducted with minimum disruption to clinical care. The excellent support for the project by staff in the clinical areas was partly attributed to doing this preparatory work and the undertaking of regular staff updates. These factors contributed significantly to the success of the research trial.

2.17 Trial Steering Group

A project management group was set up for the design, implementation and monitoring of the project. The group comprised of a consultant obstetrician, health economist, maternity services lay representative, head of the antenatal ultrasound department, senior antenatal receptionist, research midwife and trial co-ordinator. The group met monthly in the initial planning and implementation

stages of the project and quarterly once the project was established. This forum was also used to monitor rates of recruitment, the implementation of the interventions and to discuss and resolve any difficulties as they arose. The formation of the group was in keeping with the recommendations made by the Medical Research Council (MRC 1998).

2.18 Economic Evaluation

A detailed costing of each of the trial interventions was undertaken. The TSI costs were calculated by taking the call charges per minute and the mean duration of the calls at each of the three time points, plus the staff costs required administering the calls. The cost of uterine artery Doppler screening was assessed by obtaining cost data on staff, the mean duration of the examination together with any resulting scans or appointments.

2.19 Quantitative data analysis plan

A flow diagram was produced to show the progression of trial participants through each stage of the research process. This followed the CONSORT guidelines and shows numbers of participants who were randomised to each group, the total of participants who received the interventions and the number where the primary outcome measure data was obtained (Moher et al. 2001).

The primary outcome measure was the mean number of antenatal visits that women received after twenty weeks gestation (as previously defined). The analytic strategy was to do an overall test of variance between the three groups and perform a pairwise comparison if there was a significant difference to determine where the differences were.

The secondary analyses were undertaken to compare the mean/median scores of the scales used to measure anxiety, social support, satisfaction and worries between women in the control group , the telephone group and the telephone + Doppler group at each of the questionnaire time points (20, 28 and 36 weeks gestation and 6 weeks postnatal). Further analysis was undertaken to compare the number of hospital admissions and the major clinical outcomes (as stated)

in the three groups. A comparison of demographic variables across the three trial groups was also undertaken.

All of the questionnaire data were double entered by an independent data entry service and analysed using SPSS for Windows 14.0. The trial data was analysed using an intention to treat approach. The data tables presented provide the results of both parametric and non parametric analysis depending on whether or not the data was normally distributed. For normally distributed data, a one-way ANOVA was conducted to compare means; for this type of data the tables provide the mean and standard deviation (SD). In the case of non-normally distributed data, an independent samples Kruskel-Wallis test was performed when three groups were compared and a Mann-Whitney test was used for the comparison of two medians. These are reflected in the tables by the presentation of the median and the interquartile range (IQR). The analysis of categorical variables was achieved by conducting crosstabulation using Pearson's Chi squared test and Fisher's exact test for small samples.

2.20 Qualitative data collection

2.20.1 Methods

The inclusion of interviews as a method of gathering data for the project was discussed with the participants at the time of recruitment. Women were informed that with their consent, they might be contacted after the birth of their baby to see if they would agree to be interviewed to discuss their experiences of antenatal care. The participants were informed that the interview would be digitally recorded and subsequently transcribed. They were reassured that any information they provided would be treated confidentially and that the sound files and transcripts would not be identifiable in any way. The participants were informed that small sections of the transcribed interview may be used in the final research report or in papers resulting from it, but that their name or any other identifiable data would not be used.

2.20.2 Interview sample

From those who agreed a purposive sample of fifteen women in each group were selected on the basis of their trial group, age and highest educational level. The women were interviewed at 8 to 10 weeks post delivery in their own home and the discussion digitally recorded and transcribed verbatim. The interview was semi structured and an interview guide was developed and used during the interviews to act as a prompt to the interviewer (Appendix O). All of the interviews were undertaken by the author.

The interview process provided the opportunity for further discussion and explanation of the aspects of care that were useful and those that could be improved and provided clarification of women's sources of support during pregnancy. Women were also asked their views on the TSI and UADS and asked if given the choice, whether they would include these interventions in their care during a subsequent pregnancy.

2.21 Analysis of Qualitative Interviews

2.21.1 Familiarisation

All of the interviews were undertaken by the same researcher which resulted in a degree of familiarisation with the data at the time of data collection. In order to enhance this process further, all of the transcripts were read in full and notes made on emerging concepts and themes.

2.21.2 Identifying a thematic framework

The thematic framework was initially constructed using the a priori themes which were included in the interview guide:

- Expectations of antenatal care
- Content of antenatal care
- Sources of information during pregnancy
- Antenatal education classes
- Provision of support
- Possible improvements to care provided

- Views of telephone support intervention
- Views of uterine artery Doppler screening

As the familiarisation process was undertaken new themes emerged which were also incorporated into the framework:

- Personality of midwife
- Importance of individualised approach to antenatal care
- Normalising of pregnancy experience
- Acknowledgement of pregnancy as an event
- Overall impact of ultrasound examinations during pregnancy

2.21.3 Indexing

The data was examined using the thematic framework and indexing was done by making notes on the interview transcripts. This part of the process allowed the construction of the first stage charts where sections of text were copied from the transcripts and inserted under broad theme headings. This made viewing of the relevant text more straightforward due to the relatively large number of interviews included in the analysis (Appendix P)

2.21.4 Charting

The charting stage of the analysis was achieved by the creation of individual charts for each broad theme. The themes were then further defined by being broken down into a number of subheadings. A brief synopsis of the verbatim text was entered for each participant who had contributed an opinion or experience which was relevant to the theme subheading (Appendix Q).

2.21.5 Mapping and Interpretation

For each theme subheading the interpretation of the data was achieved by the identification of commonalities between participants' responses and themes that emerged in order to appreciate the range of women's experiences. An assessment of the salience of the themes was also sought to allow an appreciation of the relevance to the individual women. On occasions it was necessary to refer back to the original transcripts to ensure that individual

quotations were understood in context with the remainder of the interview. This process required a lengthy and in depth review of the thematic charts.

The themes were examined across the trial groups and different age and educational level groupings to determine whether these factors had an influence of women's experiences (Appendix R).

Chapter 3. Results of Randomised Controlled Trial

3.1 Introduction

The following chapter will present the results of the quantitative research data. This will incorporate a RCT flow chart, participant demographic information, the number of antenatal visits, clinical outcomes, questionnaire response rates, intervention rates, psychological questionnaire results and an economic evaluation of the study interventions

3.2 Recruitment and participation

Women were recruited to take part in the trial from February 2004 to January 2007. During the trial recruitment phase, a total of 1363 nulliparous women attended for their 20 week ultrasound scan and were considered for inclusion. Of these, 237 (17.3%) women were ineligible for recruitment and therefore excluded. This group comprised of 170 (71.7%) women who were not low risk as defined by the NICE antenatal guidelines; 49 (20.6%) required an interpreter; 17 (7.1%) women were planning to move out of the area/country during their pregnancy and one (0.42%) woman had learning disabilities which precluded her from giving informed consent. Of the remaining 1141 women who were approached to take part in the trial, 840 (75%) women consented and 286 women declined. The reasons stated for not wishing to take part in the trial were as follows: 226 (79%) women did not want to be involved in research; 34 (12%) women stated that they felt that they may be worried by the extra information provided by the uterine artery Doppler screening; 11 (3.8%) women didn't want any additional antenatal care or support and 15 (5.2%) women were too busy to commit to completing questionnaires or receiving the TSI.

Throughout the duration of the trial, five women chose to withdraw from the study; two from the Control group (C), one woman from the Telephone group (T) and two from the Telephone + Doppler (T+D) group. One woman stated she disliked answering the items in the questionnaires, one woman withdrew after receiving a risk positive uterine artery Doppler result and the remaining three women did not express a reason. The number of participants where primary outcome data was obtained is shown in Figure 1. There was no difference between the trial groups in the number of participants where primary outcome

data was obtained. The actual attrition rate was 7.1% which was lower than the anticipated 30%. Failure to obtain the primary outcome data was due to an inability to obtain the women's hospital and/or handheld notes because they had been misfiled.

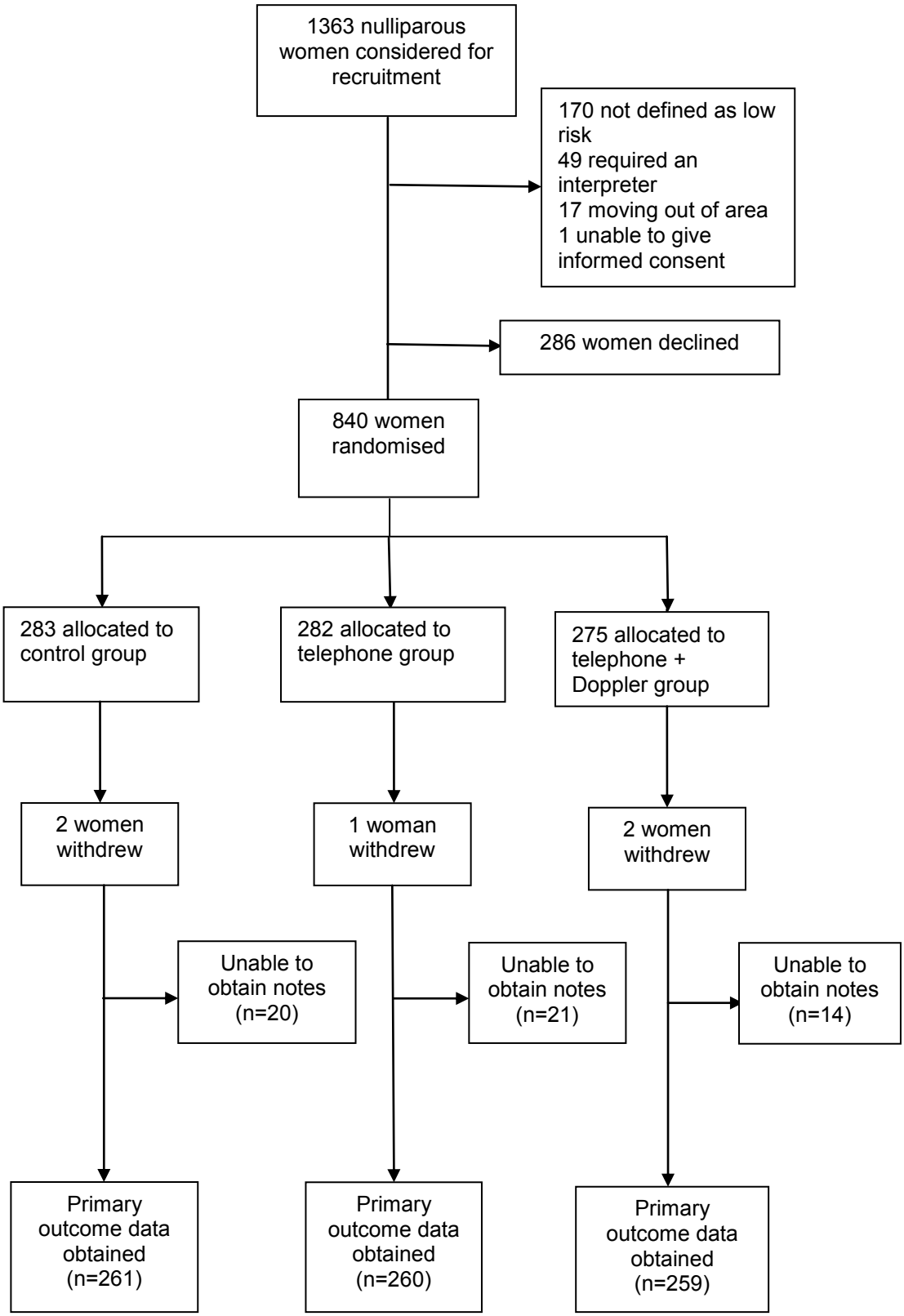

Figure 1-Trial flow chart

3.3 Demographic Characteristics

Table 7 demonstrates that there were no statistically significant differences between the three trial groups for any of the demographic characteristics measured. Most women in the study were married or cohabiting with a partner and the mean age at recruitment was 27 years of age. The proportion of women in the trial who described their ethnic group as white was 91-93% across the three groups.

Table 7 - Demographic characteristics of participants in each group

C = Control; T = Telephone intervention; T+D = Telephone + Doppler intervention				
		Group		
		C n=283	**T** n= 282	**T + D** n= 275
Age at recruitment	**Mean(SD) years**	27.4 (5.8)	26.9 (5.4)	27.8 (5.8)
Married/Co-habiting	**n (%)**	237(83.7)	236 (83.7)	230 (83.6)
White		258(91.2)	262 (92.9)	262 (93.1)
Highest educational attainment		n=252	n=261	n=265
	None	14 (5.6)	18 (6.9)	13 (4.9)
	GCSE	73 (29.0)	64 (24.5)	76 (28.7)
	A level	64 (25.4)	69 (26.4)	69 (26.0)
	First degree	72 (28.6)	86 (33.0)	82 (30.9)
	Higher degree	29 (11.5)	24 (9.2)	25 (9.4)

3.3.1 Demographic characteristics of interviewed participants

The highest educational attainment, ethnic origin and age of the subsample of participants who were interviewed are shown in Table 8.

Table 8 - Demographic characteristics of participants in each group

		Group		
		C n=15	T n=15	T+D n=15
Age at time of interview (years)	16-19	0	1	1
	20-25	3	6	1
	26-30	2	5	4
	31-36	10	3	7
	36-40	0	0	2
Highest educational attainment	GCSE	6	7	6
	A level	3	4	6
	Degree	5	4	2
	Higher degree	1	0	1
Ethnic origin	White British	13	14	14
	Indian	1	0	0
	Pakistani	1	0	1
	White-Czech	0	1	0

C = Control; T = Telephone intervention; T+D = Telephone + Doppler intervention

3.4 Primary outcome – Routine and unscheduled antenatal visits

A one-way ANOVA was used to test whether there was a difference in the total number of visits received after 20 weeks (routine plus unscheduled antenatal visits). In line with the overall analytic strategy, the analysis or variance indicated that there was no difference between the groups; therefore pairwise analysis was not undertaken (Table 9).

Table 9 - Total number of antenatal visits after 20 weeks gestation

		Group				
		C	**T**	**T + D**		
		n=261	**n=260**	**n=259**	**F**	**p value**
Routine + extra visits	Mean (SD)	8.7 (2.7)	8.9 (3.2)	8.8 (2.9)	0.29	0.74

There was also no difference between the groups in the median number of unscheduled antenatal visits that women received after 20 weeks gestation (Table 10) which was 2 visits.

Table 10 - Number of unscheduled and scheduled antenatal visits after 20 weeks gestation

		Group				
		C	**T**	**T + D**		
Type of visit		**n=261**	**n=260**	**n=259**	**X^2**	**p value**
Unscheduled	**Median (IQR)**	2.0 (1.0-4.0)	2.0 (1.0-4.0)	2.0 (1.0-3.0)	1.14	0.56
Routine		7.0 (6.0-7.0)	7.0 (6.0-7.0)	6.0 (6.0-7.0)	1.63	0.44

Women in the both the C and T groups received seven routine antenatal visits which is in keeping with the NICE antenatal care recommendations (NCCWCH 2003); women in the T + D group received six visits. The difference between the three groups in the number of routine visits received was not statistically significant (p=0.44) (Table 10).

The majority of extra unscheduled visits took place in the maternity assessment unit (Table 11). Visits to the MAU where active labour was diagnosed were not included in the figures for unscheduled visits. The reasons stated in the notes for the unscheduled visits and the location in which the visits took place is shown in Table10. The most frequently stated reasons for accessing additional antenatal care as assessed by reviewing the women's notes were reduced fetal movements, raised blood pressure and possible onset of labour which was subsequently not confirmed.

Table 11 - Location and reason stated for unscheduled antenatal visits after 20 weeks gestation

		Group		
		C	**T**	**T+D**
		n=591 n (%)	**n=667** n (%)	**n=650** n (%)
Location of visit	Maternity Assessment Unit	326(55.2)	395(59.2)	391(60.2)
	Community midwife	177(29.9)	143(21.4)	159(24.5)
	General practitioner	4(0.7)	7(1.0)	4(0.6)
	Hospital antenatal clinic	46(7.8)	71(10.6)	53(8.2)
	Home	17(2.9)	15 (2.2)	23(3.5)
	Other	21(3.6)	36 (5.4)	19(2.9)
Reason for visit	Reduced fetal movements	72(12.2)	59(8.8)	66(10.2)
	Raised blood pressure	81(13.7)	58(8.7)	96(14.8)
	Premature rupture of membranes	12(2.0)	24(3.6)	17(2.6)
	Unwell	17(2.9)	9(1.3)	18(2.8)
	Vaginal bleeding	19(3.2)	47(7.0)	34(5.2)
	Itching/ Obstetric Cholestasis	19(3.2)	31(4.6)	21(3.2)
	? Onset of labour	89(15.1)	81(12.1)	100(15.4)
	Abdominal pain	18(3.0)	34(5.1)	22(3.4)
	Breech/External cephalic version	37(6.3)	28(4.2)	36(5.5)
	Preterm labour	1(0.2)	6(0.9)	7(1.1)
	Suspected SGA* fetus	10(1.7)	27(4.0)	23(3.5)
	Monitoring of SGA* fetus	5(0.8)	49(7.3)	7(1.1)
	Other	88(14.9)	97(14.5)	91(14.0)
	No reason specified	123(20.8)	117(17.5)	111(17.1)

SGA* - Small for gestational age

Only a small number of women received no routine antenatal visits at all (n=5); this generally occurred because the women had a very preterm delivery or they developed a significant pregnancy complications. Around a fifth of women in each group received five or less routine antenatal visits (19.8 % vs. 19.0% vs. 21.1%) and approximately a fifth of women in the trial (23.7% vs. 24.3% vs. 20.7%) received eight routine antenatal visits (Table 12). Women who received eight routine visits did so because they had not given birth prior to 41 weeks and therefore required a further postdates review by their midwife.

Table 12 - Total number of routine visits received by women in each group

		Group		
		C	T	T+D
		n (%)	n (%)	n (%)
Number of routine antenatal visits	**0**	3 (1.1)	1(0.4)	1(0.4)
	1	0(0.0)	0(0.0)	0(0.0)
	2	0(0.0)	2(0.8)	1(0.4)
	3	3(1.1)	8(3.0)	5(2.0)
	4	12(4.6)	13(4.9)	9(3.5)
	5	34(19.8)	26(9.9)	38(14.8)
	6	72(27.5)	77(29.3)	84(32.8)
	7	76(29.0)	72(27.4)	65(25.4)
	8	62(23.7)	64(24.3)	53(20.7)

There was no correlation between the number of unscheduled antenatal visits received, the number of telephone support calls received and the STAI-state mean scores at 20 weeks gestation.

A random sample of twenty hospital notes were cross-checked by a research midwife who was not involved in the study, to assess the reliability of the data pertaining to the number of antenatal visits received. In all cases the total numbers of visits were judged to be the same by both the researcher and the person cross checking. In three cases there was a discrepancy between whether a visit was classified as a routine or unscheduled visit.

3.5 Secondary outcomes

3.5.1 Telephone support intervention

Table 13 presents a comparison of the delivery rate of the telephone support intervention (three successful calls) in the trial intervention groups at 29, 33 and 37 weeks gestation. The rate at each time point was similar in the two groups at 29 weeks (59.5% vs. 59.6%) and 33 weeks (60.2% vs. 59.2%) with the success rate dropping in both groups at 37 weeks gestation (53.5% vs. 50.7%).

Table 13 - Number of women who successfully received telephone intervention calls

		Group			
		T	**T+D**		
		n =282 (%)	n=275 (%)	**95 % CI**	**p value**
Antenatal time points	**29 weeks**	168 (59.5)	167 (60.7)	-0.06-0.09	0.78
	33 weeks	170 (60.2)	166 (60.3)	-0.08-0.08	0.98
	37 weeks	150 (53.5)	143 (52.0)	-0.09-0.07	0.77

A comparison of the number of intervention calls received by women in each group is shown in Table 14. The mean number of calls received by women in both groups was 1.6 and there was no difference in the total number of calls received. The majority of women (~80%) received at least one telephone support intervention call during their pregnancy.

Table 14 - Number of telephone intervention calls received by women

		Group			
		T	**T+D**		
		n = 282 (%)	n=275 (%)	**t**	**p value**
Mean number of calls (SD)		**1.60 (1.08)**	**1.69 (1.07)**	0.92	0.35
				X^2	**p value**
Total number of calls	**0**	53 (18.8)	56 (20.4)		
	1	63 (22.3)	67 (24.4)	0.97	0.80
	2	85 (30.1)	82 (29.8)		
	3	81 (28.7)	70 (25.5)		

Crosstabulation analysis was undertaken to ascertain whether the number of intervention calls received by women in the two intervention groups was affected by their marital status or highest educational level. For the purposes of this analysis the number of calls received was grouped into 0 -1 call and 2-3 calls. There was no difference in marital status or educational level between women who received 0-1 call or 2-3 calls and no difference in the age of women who received 0-1 call or 2-3 calls.

3.5.2 Uterine artery Doppler screening

Uterine artery Doppler waveforms were successfully achieved for all but one woman (1/275); this occurred because the women felt unwell and requested cessation of the ultrasound examination. Of the 274 women who had screening at 20 weeks gestation, 237 (87%) women had a negative result and 37 had a positive result. One woman who received a positive result at 20 weeks gestation withdrew from the study prior to the 24 week follow up scan. Of the 36 women who had a repeat Doppler, five women had a persistently abnormal uterine artery Doppler (shown in Figure 2).

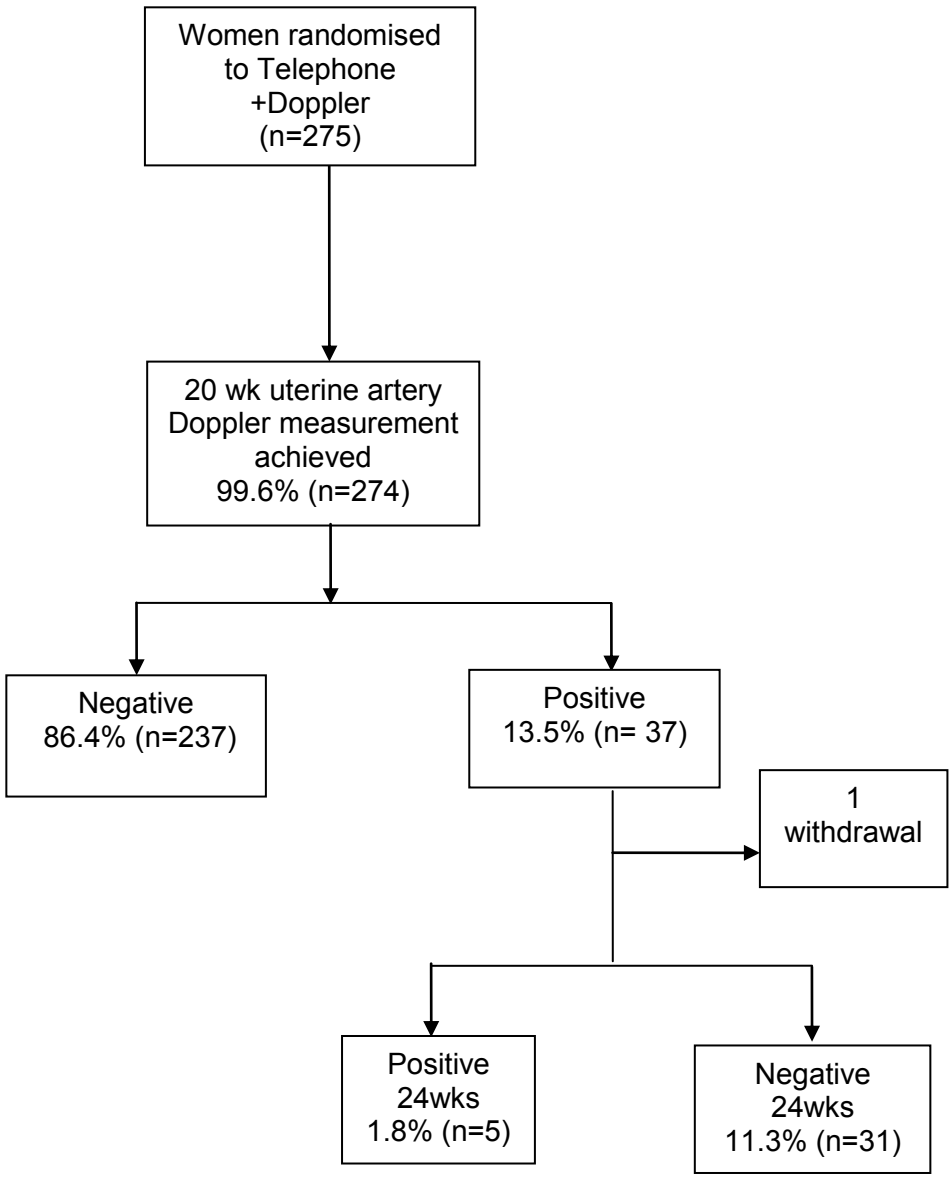

Figure 2 – Results of uterine artery Doppler screening

The incidences of hypertension and SGA in the Doppler group are shown in Table 15. Three out of five women who were screen positive at 24 weeks gestation had babies that were small for gestational age and two of these women also had PIH. There was no statistically significant difference in the proportion of women who had a SGA baby (BW <5th centile + BW 5th -10th centile) in the group of women who had negative UAD screening at 20 weeks compared to those who had a positive result at 20 weeks and then a negative result at 24 weeks (p=0.14).

There was a difference in the incidence of SGA babies (BW <5th centile + BW 5th -10th centile) born to women who had negative UADS at 20 and 24 weeks gestation when compared to those who had a positive result at 20 and 24 weeks (p=0.003). As the number of women with a positive result was very small, no prediction statistics have been calculated (Table 19)

Table 15 - Incidence of small for gestational age infants, PE and pregnancy induced hypertension in women who had uterine artery Doppler screening.

Complication	**Negative UADS (n= 237)**	**Positive UADS at 20wks only (n=31)**	**Positive UADS at 20 & 24 wks (n=5)**
BW <5th centile* (n)%	6 (2.6)	2 (6.3)	1 (20.0)
BW 5th- 10th centile$^{\#}$	8 (3.5)	3 (9.4)	2 (40.0)
Preeclampsia	5 (2.1)	2 (6.3)	0 (0.0)
PIH^{+}	21 (9.0)	1 (3.1)	2 (40.0)

*BW <5th – birthweight below 5th percentile for infant weight, gestational age and sex
$^{\#}$BW 5th – 10th – birthweight between 5th and 10th percentile for infant weight, gestational age and sex
$^{+}$PIH – Pregnancy induced hypertension

3.5.3 Hospital admissions

The number of women who were admitted to hospital after 20 weeks gestation was also similar in the three groups (Table 16). The reasons stated for admission (in the hospital notes) are presented in Table 16. PE, preterm labour and vaginal bleeding were the most common reasons for admission to hospital. The category 'other' included a variety of medical and pregnancy complications such as shortness of breath, chest pain, suspected pulmonary embolism, deep vein thrombosis, diarrhoea and vomiting, feeling generally unwell, perianal abscess, unstable lie and symphysis pubis dysfunction.

Table 16 - Number of antenatal hospital admissions and primary cause of admission

		Group				
		C	T	T+D		
		n=278 n (%)	n=276 n (%)	n=268 n (%)	X^2	p value
Number of women admitted	**Total**	**20(7.1)**	**32(11.3)**	**39(14.2)**	**7.42**	**0.24**
Number of admissions	**Total**	27	42	45		
Number of nights	**Median (IQR)**	2.0 (1.0-5.0)	2.0 (1.0-2.0)	1.0 (1.0-3.0)		
Reason for admission	Pre eclampsia	8 (29.6)	5 (11.9)	9 (20.0)		
	PROM*/Preterm labour	1 (3.7)	10 (23.8)	9 (20.0)		
	Vaginal bleeding	2 (7.4)	10 (23.8)	9 (20.0)	16.9	0.76
	Placenta praevia	2 (7.4)	1 (2.4)	1 (2.2)		
	Abdominal pain	2 (7.4)	8 (19.0)	4 (8.9)		
	Other	12 (44.4)	8 (19.0)	13 (28.9)		

PROM* - Premature Rupture of Membranes < 37 weeks gestation

3.5.4 Delivery outcomes

Table 17 shows the labour and delivery outcomes. The mean gestation at delivery was 40 weeks gestation in each group and there were no statistically significant differences between the groups for onset of labour, reason for induction of labour, mode of delivery or delivery related complications. The majority of women in the trial had a spontaneous onset of labour and most women achieved a vaginal delivery. Labour was induced mainly because of post dates. Postpartum haemorrhage (>500mls) was the most common delivery related complication.

Table 17 - Labour and delivery outcomes

		Group				
		C	**T**	**T + D**	**X^2**	**p**
		n=278	**n=276**	**n=268**		
Gestation at delivery (days)	**Mean (SD)**	279.3 (16.0)	279.9 (14.9)	279.3 (13.4)	2.59	0.30
Onset of labour	n (%)					
	Spontaneous	236 (84.9)	221 (80.1)	211 (78.7)		
	Induced	34 (12.2)	48 (17.4)	50 (18.7)	4.74	0.31
	No labour	8 (2.9)	7 (2.5)	7 (2.6)		
Reason for induction						
	Postdates	21 (61.8)	29 (60.4)	24 (48.0)		
	Pre eclampsia	6 (17.6)	8 (17.0)	9 (18.0)	4.06	0.67
	Fetal concern	4 (11.7)	3 (6.4)	6 (12.0)		
	Other	3 (8.8)	8 (16.7)	11 (22.0)		
Mode of delivery						
	Normal vaginal	121 (43.5)	114 (41.3)	113 (42.2)		
	Assisted vaginal	97 (34.9)	92 (33.3)	90 (33.6)	1.53	0.95
	Emergency LSCS*	52 (18.7)	63 (22.8)	58 (21.6)		
	Elective LSCS*	8 (2.9)	7 (2.5)	7 (2.6)		
Delivery related complication						
	PPH# (> 500mls)	36 (21.6)	32 (19.2)	39 (23.4)		
	Shoulder dystocia	4 (2.4)	4 (2.4)	5 (3.0)	2.54	0.86
	3rd/4th degree tear	9 (5.4)	12 (7.2)	8 (4.8)		
	Other	4 (2.4)	6 (3.6)	8 (4.8)		

LSCS* - Lower section Caesarean section; PPH# – Postpartum haemorrhage

3.5.5 Infant outcomes

Table 18 shows the outcomes for babies born to women participating in the trial. Two pregnancies ended in stillbirth, one in the control group and one in the telephone intervention group. One woman experienced a miscarriage after

recruitment to the trial which occurred at 23 weeks gestation and one participant opted for termination of pregnancy due to fetal abnormality.

Table 18 - Comparison of infant outcomes

		Group				
		C	**T**	**T+D**		
		n=275	**n=275**	**n=270**		
	n (%)				**X^2**	**p value**
Infant outcome	**Live birth**	274 (99.3)	274 (99.6)	269 (99.6)		
	Stillbirth	1 (0.4)	1 (0.4)	0 (0.0)	1.99	0.73
	Miscarriage/ TOP#	1 (0.4)	0 (0.0)	1 (0.4)		
Infant sex	**Male**	138 (50.2)	141 (51.3)	132 (49.3)		
	Female	137 (49.8)	134 (48.7)	136 (50.7)		
Birthweight (grams)	**Mean (SD)**	3395 (530.7)	3346 (555.9)	3356 (546.7)	0.60	0.55
	n (%)					
Small for gestational age	**5th-10th percentile**	12 (4.4)	15 (5.5)	13 (4.9)	0.72	0.94
	<5th percentile	12 (4.4)	10 (3.6)	9 (3.4)		
Preterm < 37 weeks		9 (3.2)	17 (6.2)	14 (5.2)	2.66	0.26
Congenital abnormality		7 (2.5)	5 (1.8)	2 (0.7)		
Admission to SCBU*		12 (4.3)	9 (3.3)	8 (3.0)	0.89	0.64
Number of nights SCBU*	**Median (IQR)**	5.5 (2.5-26.7)	5.0 (2.0-34.0)	3.0 (2.0-21.2)		
SCBU* - Special care baby unit; TOP# - Termination of pregnancy						

There was no statistically significant difference in the mean birthweight of babies born to women in the three groups or the proportion of infants who had weights below the 5th percentile (4.4% vs. 3.6% vs. 3.4%) for their sex and gestation.

There was no significant difference between the groups in the number of babies who had a congenital abnormality or required admission to the Special Care Baby Unit (SCBU) (Table 18). The median number of nights that babies spent in the SCBU did not differ significantly between the three groups (5.5 vs. 5.0 vs. 3.0).

Women's intended method of infant feeding was similar in the three groups. Antenatal intention to breastfeed was higher in all groups (~72%) than the actual rate of breastfeeding at the time of discharge from hospital (~45%).

3.5.6 Incidence of pre-eclampsia

Only one woman developed severe PE underscoring the low risk nature of the study population (Table 19). The prevalence of PE (2.2% vs. 2.2% vs. 2.6%) and pregnancy induced hypertension (10.1% vs. 6.5% vs. 8.9%) were also relatively low. There was no statistically significant difference between the groups in the prevalence of hypertensive disorders (Table 19).

Table 19 - Incidence of confirmed hypertensive disorders of pregnancy

		Group				
		C	T	T+D		
		n= 242(%)	n= 247(%)	n= 238(%)	F	p value
Severe pre-eclampsia	n (%)	0 (0.0)	1 (0.4)	0 (0.0)		
Pre- eclampsia		6 (2.2)	7 (2.2)	6 (2.6)	7.8	0.45
Pregnancy induced hypertension		28 (10.1)	18 (6.5)	24 (8.9)		
Pregnancy induced proteinuria		0 (0.0)	3 (1.1)	1 (0.4)		

3.5.7 Anxiety

There was no statistically significant difference between the three groups in the level of trait anxiety as measured by the State-trait Anxiety Inventory at 20

weeks gestation with the mean scores being as expected for the sample (Table 20).

Table 20 - STAI - Trait mean scores at 20 weeks gestation

Group	n	Mean score (SD)	95% CI	F	p value
C	221	36.6 (8.9)	35.4-37.8		
T	221	35.7(9.0)	34.5-36.9	0.64	0.53
T+D	238	36.3(8.9)	35.2-37.4		

The levels of state anxiety were also similar in the three trial groups at all of the time points measured (Table 21).

Table 21 - STAI -State score

Time point	Group	n	Mean score (SD)	95% CI	F	p value
20 wks	**C**	216	36.2 (10.5)	34.8-37.6		
	T	217	36.9 (10.9)	35.4-38.3	0.72	0.48
	T+D	236	35.7 (10.0)	34.4-37.0		
28 wks	**C**	194	36.5 (11.0)	34.9-38.0		
	T	181	35.9 (10.5)	34.3-37.4	0.94	0.38
	T+D	189	37.4 (11.2)	35.8-39.0		
36 wks	**C**	166	36.7 (10.9)	35.0-38.4		
	T	159	37.1 (10.3)	35.5-38.8	0.37	0.68
	T+D	170	36.2 (9.9)	34.7-37.7		
6 wks PN	**C**	128	32.5 (9.6)	30.8-34.2		
	T	151	31.6 (8.4)	29.9-33.2	0.41	0.66
	T+D	162	31.9 (9.4)	31.0-32.8		

3.5.8 Pregnancy worries

Table 22 shows the scores from the Pregnancy Worries Scale in each group at 36 weeks gestation.

Table 22 - Worries scale mean scores at 36 weeks gestation

Group	n	Median (IQR)	X^2	p value
C	94	39.2 (11.7)		
T	90	39.7 (12.0)	0.16	0.92
T+D	98	39.7 (11.5)		

There was no statistically significant difference in how worried women were during their pregnancy between the trial groups. The response rate for this scale was reduced in comparison to the other scales due to an administration error which involved an incorrect version of the scale being included in a proportion of the questionnaires.

3.5.9 Social Support

There were no differences in the reported levels of social support as measured by Duke-UNC Functional Support Scale between the three groups at any of the antenatal time points or at six weeks postnatally. The levels of social support did not alter during pregnancy or six weeks after birth with mean scores indicating high levels of support throughout the women's involvement in the trial (Table 23).

Table 23 - Total DUFSS scores

Time point	Group	n	Median (IQR)	X^2	p value
20 wks	C	227	11 (7.0)		
	T	229	10 (6.0)	0.75	0.68
	T+D	244	11 (6.7)		
28 wks	C	196	10 (7.0)		
	T	191	11 (6.0)	2.21	0.33
	T+D	196	11 (8.0)		
36 wks	C	172	10 (6.0)		
	T	167	10 (7.0)	2.00	0.36
	T+D	171	11 (7.0)		
6 weeks postnatal	C	140	10 (8.0)		
	T	161	11 (7.0)	0.15	0.92
	T+D	175	11 (7.0)		

3.5.10 Satisfaction with Antenatal Care

There was no difference in levels of satisfaction between the three trial groups. The scores suggest high levels of satisfaction with the antenatal care the participants received across all three trial groups (Table 24).

Table 24 -Comparison of total SSQ scores at 36 weeks gestation

Time point	Group	n	Median (IQR)	X^2	p value
36 wks	C	109	29.0 (6.5)		
	T	110	28.0 (5.2)	2.55	0.27
	T+D	116	29.0 (6.0)		
Postnatal	C	134	35.5 (9.0)		
	T	139	35.0 (8.0)	1.30	0.52
	T+D	154	35.0 (9.0)		

3.6 Questionnaire response rates

The questionnaire response rates were similar in the three groups at each time point except postnatal rates which were significantly lower in the Control group (Table 25). The return rate was high at the 20 week time point and decreased as the pregnancy progressed with the lowest response rate at 6 weeks postnatal. There was a statistically significant difference between the return rates for the control group compared with the two intervention groups postnatally.

Table 25 - Questionnaire response rate

		Group				
		C	**T**	**T+D**	**X^2**	
	Total	n =282	n =283	n =275		**p value**
Time points	**20 weeks**	232 (82.2)	229 (80.9)	242 (88.0)	5.75	0.06
	28 weeks	199 (70.5)	193 (68.1)	194 (70.5)	0.49	0.99
	36 weeks	173 (61.3)	168 (59.3)	175 (63.6)	1.07	0.58
	6 weeks postnatal	131 (46.4)	166 (58.6)	155 (56.3)	9.53	0.001

3.7 Intervention costs

3.7.1 Uterine artery Doppler screening

In order to calculate the costs of implementing uterine artery Doppler screening it is assumed that the majority of hospitals undertaking routine anomaly ultrasound scans already have ultrasound machines that have the capacity to measure uterine artery Doppler waveforms. There are no additional consumables costs over and above those required for the routine anomaly scan.

The additional cost of incorporating uterine artery Doppler screening is determined by the operator's salary and the length of the time taken to undertake the examination. This was calculated using the following information:

Band 7 Sonographer/ midwife sonographer salary per annum (mid scale point): £32,704

For women who receive a risk positive result, additional discussion and the arrangement of follow up is required as well as extra ultrasound examination(s). The costs for each of the screen positive and negative scenarios are shown in Table 26.

Table 26 - Uterine artery Doppler screening costs

Item	Resources	Unit cost	Total Cost
UADS in addition to routine anomaly scan	Ultrasonographer time x 5 minutes	0.28 per min	1.40
Risk negative result	**Total**		**1.40**
Risk positive result (+discussion of results)	Ultrasonographer time x 15 minutes	0.28 per min	4.20
Fetal growth scan and UADS at 24 weeks	Ultrasonographer time x 20 minutes	0.28 per min	5.60
Risk positive at 20 weeks/ Risk negative at 24 weeks	**Total**		**9.80**
Fetal growth scan at 34 weeks	Ultrasonographer time x 15 minutes	0.28 per min	4.20
Risk positive at 20 weeks and 24 weeks	**Total**		**14.00**
Additional growth scans	Ultrasonographer time x 15 minutes	0.28 per min	**4.20**

3.7.2 Telephone support intervention calls

The cost of implementing the telephone support intervention comprising of three intervention calls has been calculated using midwife time and call costs. In addition, the call attempts made where the women were not reached are also included in Table 27. This accounted for 20% of women at each time point. Thirty percent of women requested calls to mobile phone numbers. The costs are calculated utilising the information below:

- Midwife Band 6 salary per annum (mid scale point): £27,388

- Telephone unit costs (per min) depending on time of calls and whether to land line or mobile phone.

Table 27 - Cost of telephone intervention calls

Item	Resources	Unit cost/per min	Total Cost
Telephone support intervention call	Midwife (Band 6) x 8 minutes	0.23 pence	**£1.84**
	Cost of call to landline (evening)	1.47 pence	**£0.11**
	Cost of call to mobile (evening)	11.54 pence	**£0.92**
Unsuccessful call on first attempt (20% of sample)	Midwife (Band 6) x 2 minutes	0.23 pence	**£0.46**

In order to determine the approximate cost of providing the intervention calls, Table 28 shows the total intervention costs based on 100 women, taking into account the distribution of mobile and landline calls. For the purposes of the calculation the costs have been based on evening call charges.

Table 28 - Total telephone call cost per 100 women

Item	Total cost per call	Total cost per woman	Total cost per 100 women
3 x landline (evening) calls	£1.95	5.85	**£585**
3 x mobile (evening) calls	£2.76	8.28	**£828**
60 unsuccessful calls (20% women x 3 time points)	£0.46		**£27.60**
		Total cost (100 women)	**£1440.60**

Chapter 4. Analysis and Results of Qualitative Interviews

4.1 Introduction

The results of the analysis of the semi-structured interview data is presented in the following sections. Six major themes were identified relating to women's experiences of the antenatal care they received and how they perceived the research interventions: quantity of antenatal visits, content and focus of antenatal visits, organisation and work issues, relationship with community midwife, antenatal classes and preparation for postnatal period and alternative sources of support.

4.2 Themes

4.2.1 Quantity of antenatal visits

One of the a priori aims of the interview process was to explore how the participants felt about the routine antenatal visits they received. Some women said that they had received fewer antenatal visits than they expected and they felt there were times during their pregnancies when they could have benefitted from seeing their midwife more often.

'Probably a few more (visits) because I was a bit confused to be honest. I was kind of the opinion that once you got, later on, that it was every week you are seeing the Midwife, it was every 2 or 3 weeks, that I seen her, and obviously the nerves start kicking in and things like that, because of the time and making sure he is alright and whatever, and I would have been maybe a bit better if I had been able to go every week.'

(T group: 9, 28 years old. Received 6 routine visits and 0 extra visits)

Of the women who were interviewed, 5 out of 15 women in each trial group felt that they would have preferred more visits with their community midwife. The women who were unhappy with the quantity of antenatal visits they received more frequently described their relationship with the midwife as being suboptimal compared to those women who were content with the number of visits (Control: 2/5 women; T: 4/5 women; T+D: 3/5 women). Only one woman

in each group who said that they had received an adequate number of visits stated that their relationship with their midwife could have been improved (Control: 1/10; T: 1/10; T+D: 1/10). This suggests that women who had a positive relationship with their midwives and felt supported were more content with fewer antenatal visits.

Women's own perceptions of their pregnancy also impacted on their view of the appropriateness of the number of antenatal visits received. Women who described their pregnancy as being difficult in some way also felt that they could have benefitted from a greater number of visits with their midwife (Control: 4/6 women; T: 1/6 women; T+D: 3/6 women). The difficulties women discussed were varied and included physical pregnancy complications such as symphysis pubis dysfunction and back pain, psychological factors in which women described feeling worried, scared and depressed and social issues such as homelessness.

I thought, the last couple of weeks I thought I could have done with a couple more because she said to go every fortnight and I really wanted, I was, my greatest concern was the problems of having the symphysis pain around would caused during labour, because I wanted to have a natural birth'
(T: 13, 27 years old. Received 7 routine visits and 0 extra visits)

'I had a difficult situation because I was like homeless…I had nowhere to live, because my partner was a in a flat and it wasn't, our relationship was on the rocks as well, I was there on my own so it was like…if somebody asked me how I was feeling I wanted to cry. So I didn't really say how I felt.'
(T: 6, 27 years old. Received 7 routine visits and 4 extra visits)

Women who were content with the number of visits they received frequently stated that they had 'straightforward' pregnancies and that they knew how to contact their midwife easily if they needed to, thereby having the opportunity to access more care if required. Two women felt that they had seen their community midwife too often but one of these women had access to a midwife through her work environment and the other had a friend who was a midwife.

'The amount that I got was fine. And they had said in between visits if there was anything bothering us all I had to do was phone them on their mobiles or phone the surgery and they would get a message to them and they would phone us back or whatever.'
(C: 10, 34 years old. Received 6 routine visits and 5 extra visits).

4.2.2 Content and focus of antenatal visits

The content and focus of the antenatal visits with the midwife seemed to vary, with some women describing consultations that focussed solely on physical aspects of health whilst other midwives incorporated discussions about emotional wellbeing.

'She was good like that, yeah it was really more sort of you know and how work were being with me and she gave me lots of advice and sort of websites and stuff for where I should be legally with work and things so no she was very good like that, you know she was very informative.'
(C: 1, 32 years old. Received 8 routine visits and 1 extra visit).

Women varied on their views of the content of their antenatal visits. Those who hadn't experienced any particular difficulties during their pregnancy were happy with care that concentrated on the physical health of themselves and their fetus. For women who had experienced emotional or physical concerns, their expectations of the content of their antenatal care were greater and more varied.

'I think there should be more midwives coming out to visit you whilst you are pregnant because you do get pretty worried with being pregnant and you know just the little things. '
(C: 7, 22 years old. Received 7 routine visits and 2 extra visits).

4.2.3 Organisation and Work issues

The way in which routine antenatal visits are delivered does vary somewhat between individual midwives but for most women there is little flexibility in the day and time of day that visits are available.

'There wasn't really much room for any discussion or anything, they did Mondays between nine and half past ten, and that was it.'
(C: 9, 23 years old. Number of visits not known)

The majority of women interviewed did not have any problems with their employers giving them time off work for appointments but some women who held senior employment positions did have difficulty in extricating themselves from their own work responsibilities. Some women described self imposed constraints where they didn't feel that they wanted to leave work to attend appointments because they felt they had responsibilities to their work colleagues. For such women, the opportunity to attend evening or more flexible appointment times would be helpful. Even for women who did not have pressures from work, the lack of choice of appointment times with the midwife was not ideal.

'I know some people like to get away but for me, it's alright at this time of year, because it's dead quiet but in peak times it's a bit of a nightmare. And then everybody goes 'you're entitled to it' that's not it; it's just the fact that you're trying to get out the door. Anything from six o'clock would probably have been better.'
(T+D: 15, 37 years old. Received 5 routine visits and 0 extra visits)

Overall, most women were happy with the way in which their antenatal visits were organised although that did depend on individual circumstances.

4.2.4 Relationship with community midwife

Women's perceptions of their antenatal care were greatly influenced by the way they viewed their relationship with their community midwife or midwives. This relationship appeared to be a complex theme that incorporated a number of interconnected factors.

- Personal characteristics of midwife
- Normalising of pregnancy experience
- Information provision

- Individualised approach
- Continuity of carer
- Acknowledgement of pregnancy event

Women who discussed their relationship in a positive manner used descriptions of their midwives that highlighted how approachable, pleasant and easy to talk to they were and some women felt that being able to identify with the midwife as an individual facilitated the relationship.

'She was like, like myself she reminded us you know she was like very approachable but giggly and nice you know you could chat to her about anything and she'd use like she wouldn't use like medical words she'd use words that you'd understood you know what I mean? And it's like we went to her antenatal classes and she was brilliant and she knew who you were when she'd seen you like she'd seen you out and about she'd wave she was lovely.'
(C: 2, 31 years old. Received 6 routine visits and 5 extra visits)

For a small proportion of the women interviewed, the poor relationship they had with their midwife was viewed as having a negative impact on the antenatal care they received (Control: 3/15 women; TI: 5/15 women; T+D: 4/15 women). These women described midwives as being unhelpful, difficult to talk to and dismissive of their concerns.

'She wasn't very helpful shall I say as far as being a first time mum obviously you don't know what to expect. And she didn't…Like a lot of the time she just made you feel a bit stupid or feel in some way or asking is this normal, she wasn't ideal. She's not somebody I really liked to speak to.'
(T+D: 10, 26 years old. Received 5 routine visits and 4 extra visits).

This resulted in women being self-conscious about asking questions that they felt might be viewed as stupid or trivial and the manner in which their midwife dealt with such concerns seemed to have a major impact on the way the women viewed their midwives personality. It was important for women to feel sufficiently at ease to voice concerns so that the midwife could reassure them

that it was a ‘normal’ part of the pregnancy process. This was particularly important for this sample of women because it was their first pregnancy and they described not knowing what to expect and not being certain of what was a normal part of pregnancy.

‘Even if it's nothing really, it's just nice to have somebody tell you, it's nothing for you to worry about.’

(T+D: 1, 31 years old. Received 8 routine visits and 3 extra visits)

How confident women felt about asking questions that might be viewed as not being of sufficient importance by the midwife was also determined by whether they felt there were time constraints on their consultation and if the midwife just wanted them ‘in and out’.

‘I was in and out. And that was it. And I thought you just feel like a single person, not getting treated properly.’

(T: 14, 20 years old. Received 6 routine visits and 4 extra visits)

‘It’s kind of the case of, sometimes you could be waiting, you had your appointment, you'd be waiting half an hour. And then when you finally got in it was like she was trying to rush you back out again. So had no time really talk to you, chat to you.’

(T+D: 10, 26 years old. Received 5 routine visits and 4 extra visits).

Women valued midwives who took the time to become familiarised with their notes before they were seen and found that having to repeat themselves to different midwives was a frustrating experience. This was often compounded by seeing a number of different midwives over the course of the pregnancy resulting in a lack of continuity of care. It was important for women to be treated as individuals and the relationship was further enhanced when they felt that the midwife had made an effort to get to know them as a person. This allowed women to feel more at ease and able to discuss their worries during the pregnancy.

'I felt like I was explaining myself over and over again. And they said 'hang on, I'll just read through your notes.' And then you have to sit there while they read through your notes.'
(C: 9, 23 years old. Number of visits not available).

'I got to know a bit more and she remembered what I did for work and she remembered me as a person, so yeah she was nice.'
(T+D: 6, 32 years old. Received 6 routine visits and 3 extra visits)

For some women, the concerns that they had during pregnancy were of a personal nature and they found it difficult to bring up sensitive issues with the midwife if they did not feel comfortable with her.

'So every week, every time it was someone different, it felt a bit like…When I was having the bleeding and stuff and having a lot of internals I didn't feel so comfortable.'
(C: 9, 23 years old. Number of visits not available).

This was also a problem for one woman who felt that the presence of a different student every week made her reluctant to discuss how she felt with her midwife with whom she generally had a very positive relationship.

'There was another student there of course and I just came out with it but I felt a bit it's hard to bare your soul when there's two people in the room. But it was a different one every week and you know I understand that but I'm not the sort of person who would say I don't want the student in, not when you are asked in front of them and you've gone in and you know you just wouldn't say no.'
(Control: 11, 32 years old. Received 8 routine visits and 0 extra visits)

Some women felt that the presence of a midwifery student enhanced the care they received because the midwife then discussed what she was doing in greater detail than usual, providing the women with more comprehensive information.

It was evident that a proportion of women felt that it was important that there was an acknowledgement of their first pregnancy as being a significant event. This theme was interwoven with the number of visits that women received. Women who felt that they did not receive sufficient antenatal visits sometimes described this in terms of the midwife not recognising how important the pregnancy was to the woman.

'I think I think it's just nice it would have been nice I think specifically the first pregnancy just to somebody just to sort of acknowledge you're pregnant and are you excited? Are you scared? Are you, you know how are things going? Like that but from the moment you are booked, to the first check up I think it was sixteen weeks or something.'
(C: 11, 32 years old. Received 8 routine visits and 0 extra visits)

Women valued greatly the opportunity to develop a good relationship with their community midwife or midwives. Midwives who encouraged women to feel relaxed and valued were viewed as supportive and having positive personality traits.

4.2.5 Antenatal classes and preparation for postnatal period

How women viewed their antenatal classes was determined by the way in which the classes were presented and the relevance of the information provided. The women interviewed had varying experiences of antenatal classes with some women finding them extremely useful while others felt they offered little 'new' information.

The presentation of the classes was described in terms of the approach taken by the midwives leading the classes. Sessions that were described positively were led by midwives who exhibited enthusiasm and were viewed as friendly and well prepared.

'The lady was fantastic. She was so informative and really upbeat about it all and by that point you're quite pregnant and you think 'I'm going to have push this baby out' and I was beginning to get a bit nervous about it and we were

looking round the hospital, like round the department and she was very nice and all the staff were saying hi to her and everything, you know really nice, really friendly.'
(T+D: 1, 31 years old. Received 8 routine visits and 3 extra visits)

Classes that were less successful were viewed as being poorly thought out and women felt that the level and presentation of information was inappropriate for their needs.

'I'm not being horrible or anything but I thought it was boring I was nearly falling asleep because they were showing you this video and I think it was before I was born this video what was on, and I was like, if you want, I watch Baby ER on the telly, I watch that on Sky, I'll tape a bit for you because it's on all the time exactly what was on bit it's up to date. I was thinking you need to get something up to date.'
(C: 8, 21 years old. Received 7 routine visits and 7 extra visits)

It was important for some women to feel that they had something in common with the other couples in the group and the success of the group cohesion sometimes affected the experience of the session as a whole.

'There was a huge variation in age you know there were loads of 16 year olds right up to I was the oldest at 34 and that makes you feel really rubbish when your 34 where as the breast feeding class was much more over 20's and 30's and I wasn't the oldest and that made me feel a lot better because I think, that may well have been why I was embarrassed to ask questions at the antenatal.'
(C: 6, 34 years old. Received 8 routine visits and 2 extra visits).

A positive aspect of a class with strong cohesion was the opportunity for women to chat to others who were at a similar stage of pregnancy.

'At the end they'd have, for the last half an hour, we'd just sit in a big circle and have tea and coffee and cakes and nibbles and there was a midwife came every week. So then we'd go round the room asking what's happened to

people this week and how many weeks pregnant you were and any quirks that you'd had or things that were happening to see if anybody else was having them.'
(T+D: 3, 32 years old. Number of visits not available).

The focus of the antenatal classes was appropriate for most women but for some there was a lack of information on how they would feel after they had given birth and advice on how to care for their new baby. This left women feeling uncertain and anxious when they got home with their baby and some felt they could have been better prepared for the experience.

'They showed me how to bath him and that's been fine, but just things like I didn't know how often he should be feeding, I didn't know how often I should be changing him. You know, how often should he be sleeping, should I wake him to feed him, should I wait until he wakes, I just didn't know. I think there definitely should be some sort of. I'm sure some people wouldn't want it or need it but I think just, I don't know, just basics would be quite good.'
(T: 5, 27 years old. Received 8 routine visits and 0 extra visits)

'If they had told us that it's gonna be like this then you prepare yourself but because, I mean I'm not gonna say anything about the doctors or the health visitor because they looked after me 100% and you know they sort of like said everything's okay and make sure you're eating this make sure you give him this make sure you get your rest but they didn't actually tell us anything about how I was going to feel once I had the baby and you know when people say, you know like, she's got post natal depression and I'm thinking why have you got that I didn't get any of that I just felt really emotional and that why isn't everything falling into place so I just felt like that a lot but I mean I had loads and loads of help and everything so I just think what about those who haven't got any help.'
(C: 14, 33 years old. Number of visits not available)

Two women who felt that they were having particular difficulties once they got home and were lacking in family support suggested that a class after they had given birth would have been valuable for them.

Most women having their first baby viewed antenatal classes as an important factor in the care they receive because they expected the classes to provide an opportunity to gain knowledge about pregnancy, childbirth and caring for a baby. Women whose expectations of classes were not fulfilled were left feeling frustrated by their inability to obtain the information they required to allow them to face the challenges ahead.

4.2.6 Alternative sources of support

Most of the women interviewed seemed to view their community midwife as their main source of informational support during their pregnancy but did utilise other sources to supplement this advice depending on its availability. Additional information and support was provided by friends, relatives or work colleagues and some women accessed various media sources to gain greater information during pregnancy.

'Well me friend she has a 10 month old boy so she'd been through it, it was just finding out that things were normal really even afterwards it was when I was keep crying all the time she said don't worry it'll stop don't worry and it was just finding things are normal I think but probably her and me Mam but I talk to everyone really and me boyfriend was helpful.'
(T+D; 9, 28 years old. Received 7 routine visits and 0 extra visits).

' I've got a book that I read which was exceptionally good and that probably taught me the most out of anything and then if I had any queries I could ask, but to be honest my book was very good.'
(T+D: 7, 32 years old. Received 7 routine visits and 0 extra visits).

All of the women interviewed were aware of literature and internet sources of pregnancy information and utilised them to varying degrees.

4.3 Telephone support intervention

Women in the two intervention groups of the trial were specifically asked their views on the telephone support intervention. The majority of women viewed the intervention as a positive addition to their care.

'What was really nice was I think you and someone else kept ringing all the time and it was really helpful cos you know if I had anything to ask and things and it was just nice to know that you could ask anyone, I liked that.'
(T+D; 9, 28 years old. Received 7 routine visits and 0 extra visits).

There was no negative feedback pertaining to the intervention with only two women feeling that the intervention did not add anything to the care that they were already receiving from their community midwife. Both of these women described their pregnancies as being uncomplicated and as a result they had few concerns or worries.

For women who did not have an optimum relationship with their midwife (T+D: 4 women; T: 5 women) the telephone support intervention offered an alternative opportunity for them to ask questions and elicit information. Of the women who thought the intervention was beneficial (n=28), they did so because of the fact that someone was interested in how they felt and gave them the opportunity to chat about their pregnancy experience.

'It was just nice, it's always nice thing when people ask when you're pregnant, when people ask how are you, is everything alright, just in case there is something, you just think 'oh, well actually…' So it was nice just to get another phone call, like 'do you have any other problems?' Yeah, they were just quite informal chats, 'is everything alright?' So that was nice just to know there was somebody there.'
(T+D: 3, 32 years. Number of visits not available)

Women were not encouraged to make additional calls to the study midwife to ensure that the intervention was delivered consistently. However, three women contacted the study midwife in addition to the planned intervention calls using

the contact number provided for general enquiries. These calls were made because the women felt that they had built up a more positive relationship with the study midwife than their allocated community midwife and the women specifically requested to maintain contact with the study midwife. In these individual cases it was felt that it would be detrimental to the participants to refuse such contact.

'Yeah, she was a big help. especially the day I had to go in for the additional scan, I was quite concerned about the measurements that they'd come up with because they'd said that, well just off the little graph, it looked like the legs were kicking up to the head and the body…for me anyway, and I phoned her up and said I was concerned. And she explained everything and made us feel a lot better about it. And then I just phoned her for everything'.
(T: 13, 27 years old. Received 7 routine visits and 0 extra visits).

The proactive nature of the intervention was also seen as a positive attribute by 22 of the women interviewed. Eleven of the women said that they probably wouldn't have bothered health professionals with what they felt could be viewed as 'stupid' questions' if they hadn't been contacted as a result of taking part in the study. Two women stated that they would have found it helpful to have been able to utilise a dedicated telephone line to contact a midwife easily whenever they had a query in addition to the proactive calls and one woman said that she would have benefitted from telephone calls during the postnatal period.

'Like I say it's down to personality type I'm definitely the kind of person who could do with the odd phone call just to say how are you getting on you know rather than relying on me to phone up and go look, I'm having a problem.'
(T+D: 4, 40 years old. Received 6 routine visits and 1 extra visit)

The feeling of being 'looked after' by health professionals during pregnancy is an important factor for some women and the additional telephone support intervention appeared to offer this opportunity. As mentioned previously, nulliparous women have a great need for relevant, timely information during the

course of their pregnancy and value the opportunity to ask questions as required.

When asked if they would choose to have the telephone support intervention if pregnant again, the majority of women interviewed said that they felt it would be a useful addition to their antenatal care (T+D: 8/15 women; T: 11/15 women). Two women in each group felt that they would not require an additional support intervention in a subsequent pregnancy because they would have their own pregnancy experience to reflect upon and would not have as many concerns or questions.

4.4 Uterine artery Doppler screening

During the course of the interviews women who had received uterine artery Doppler screening were asked their views on the intervention. All but one of the women interviewed had received a low risk result and 11 women found this a reassuring addition to their care. None of the women expressed any concerns about the actual experience of having uterine artery Doppler screening included in the ultrasound examination.

'It was reassuring in a way knowing that the blood supply and all that was getting into the placenta okay. That made you feel a bit better because you know sometimes you think to yourself, because you read up on placentas not being healthy placentas and not having enough and that's how this has happened to the baby and whatever. So it was good to know that everything was working alright.'

(T+D: 10, 26 years old. Received 5 routine visits and 4 extra visits)

Most women felt that they would welcome any test that is designed to check on the normal progression of the pregnancy because it gave them extra peace of mind.

'I think it's quite important to do probably anything, I mean, god, I'll do anything that helps or anything that's going to be better for the baby. I think it's important to do'.

(T+D: 15, 37 years old. Received 5 routine visits and 0 extra visits)

The woman who had received a risk positive result at 20 weeks discussed how she had been anxious until her scan at 24 weeks when the blood flow was found to be normal. Another participant whose uterine artery Doppler screening result was normal expressed how she was surprised when she developed PE in the latter part of her pregnancy but still thought the intervention was worth having.

'I used to have, well when I was on the pill I had high blood pressure so it had crossed my mind that it might happen, but I had one of those extra scans, the Doppler and they said it was unlikely that I would ever get pre-eclampsia, but I did, so I was surprised. I mean it was still worth it because it was to see if the blood was getting to the placenta and everything, so it was still worth having.'
(T+D: 6, 32 years old. Received 6 routine visits and 3 extra visits)

Of the 15 women who were interviewed and who had received uterine artery Doppler screening, 10 women said they would opt for it to be included in their antenatal care if given the option in a subsequent pregnancy. Women's views on uterine artery Doppler screening were only elicited when they were asked directly during the course of the interviews suggesting that although women viewed the intervention as being useful, it did not seem to feature highly in their recall of events relating to their antenatal care.

4.5 Impact of ultrasound scans

The women interviewed described the reassuring value of ultrasound scans in general during pregnancy and how they found the experience of visualising the baby to be immensely positive.

'I think it kind of, because I know your body's changing all the time but you don't, well I didn't feel that I really sort of put a person into that. It was like it was still me getting fat rather than there being somebody growing inside me and when you see the scan you see like somebody moving around, little heartbeats and little spines and, oh wow. I think it was really important actually and I think

it probably makes you look after yourself as well because you think you've got to look after somebody else too.'
(T+D: 1, 31 years old. Received 8 routine visits and 3 extra visits)

Some women felt that the gap between their anomaly scan at around 20 weeks gestation and giving birth was a long time and that they would have very much welcomed the inclusion of an ultrasound scan later in the pregnancy to reassure them that things were progressing normally. When asked if there was anything they felt was lacking in their antenatal care provision, the most frequent suggestion from participants was for an extra ultrasound scan during the third trimester.

'It's an awful long time to go because you go on virtually half your pregnancy without checking that everything's alright. I mean I know I could feel the baby moving but just that extra reassurance.'
(T: 5, 32 years old. Received 8 routine visits and 0 extra visits)

Women generally value ultrasound screening as a method of reassuring them of normality and wellbeing during pregnancy. Uterine artery Doppler screening seems to have little detrimental effect on women's experience of pregnancy but the reassuring effect of this screening method specifically seems to vary between women.

4.6 Conclusion

The analysis of the interview data provided valuable evidence surrounding the issues that were salient to women in their evaluations of antenatal care during their first pregnancy and their perceptions of the interventions tested.

In keeping with the mixed methods design of the study, a parallel mixed data analysis of the quantitative and qualitative data was undertaken and resulted in the generation of inferences, made from both sets of data (Teddlie and Tashakkori 2009), the inferences were then synthesised to produce conclusions which will be discussed in the following chapter.

Chapter 5. Discussion

5.1 Introduction

This is the first study to evaluate interventions designed to provide low risk nulliparous women with additional support and reassurance during pregnancy following the implementation of a reduction in the number of routine antenatal visits (NCCWCH 2003). The study found that the support intervention packages tested did not affect the mean total number of antenatal visits that women required and there was no difference between the trial groups for any of the psychological outcomes measured. The null hypotheses were therefore accepted. The data obtained from the interviews with women provided insight into the determinants of women's views of antenatal care they received and how they perceived the trial interventions.

5.2 Strengths and Limitations

5.2.1 Primary outcome measure

The chosen primary outcome measure was the total number of antenatal visits received by women after 20 weeks gestation, including planned visits and extra visits at midwives clinics, hospitals and GP surgeries. The outcome measure was selected on the basis of the available evidence from previous trials at the time of the trial design. It was clear from this evidence that were are difficulties in effectively implementing and maintaining a reduced antenatal visit schedule, with women in developed countries consistently having more visits than recommended (see Table 3) (McDuffie et al. 1996; Sikorski et al. 1996; Binstock and Wolde-Tsadik 1995). Traditional schedules of antenatal care were organised to incorporate more routine antenatal visits for nulliparous women than multiparous women therefore allowing a greater potential to reduce the number of visits for nulliparous women without affecting clinical outcomes.

In retrospect, the selection of total antenatal visits as the primary outcome was problematic for a number of reasons. When using the total number of visits received, it is necessary to consider carefully the type of visits that have the potential to be replaced by a support intervention and visits that are caused by factors that will always require a face-to-face visit with a midwife or other health

care professional. Prior to this study there was no published evidence to explain the reasons why women make unscheduled antenatal visits (Lauderdale et al. 2010), the location of these visits and whether some visits that could be omitted by the administration of an effective support intervention (Magriples et al. 2008).

This study provides valuable evidence about the reasons why women have additional antenatal visits; the majority (67%) of all additional antenatal visits were made because of commonly occurring pregnancy complications or suspected complications such as raised blood pressure and reduced fetal movements (shown in Table 15). In 18.4% of additional visits the reason for the visits was not stated in the women's notes; 1.6% of additional visits were made because of raised maternal anxiety or to facilitate extra time to talk through topics such as birth plans and home birth and 12.8% of unscheduled visits occurred as a result of a range of other medical/pregnancy complications such as anaemia, placenta praevia and suprapubic pain. Further, the majority of extra visits occurred in the Maternity Assessment Unit (MAU) and the next most frequent location was the community midwife antenatal clinics. These findings clearly demonstrate that a significant proportion of low risk nulliparous women will experience complications that cannot be predicted by selection criteria such as those set out in the NICE guidelines (NCCWCH 2008).

The design of the present study was based on the previous literature of the impact of reduced visit schedules and the effects of support interventions for pregnant women. There was evidence from the interviews conducted that women had a requirement for more frequent visits if they perceived that they had pregnancy complications irrespective of the health professionals perception of their pregnancy. Additionally, psychosocial difficulties such as relationship problems, housing worries and anxiety and/or depression impacted on women's satisfaction with the number and content of the visits they received. Although the majority of presentations for additional care are cited as being for physical problems, it is likely that a proportion of pregnancy symptoms or complications may be the manifestation of a lack of social support, social difficulties or increased anxiety and worry. It is likely that women would still require reassurance from a midwife or medical practitioner in these

circumstances. As a consequence of the findings of the present study, a review of the wider literature was undertaken in a bid to gain a greater insight into the reasons why women may require additional care during pregnancy.

Previous research with non-pregnant patients has shown that there is a link between patients experiencing physical symptoms of ill health and the incidence of depression (Trivedi 2004). Sleep deprivation, physical symptoms of illness and depression have also been linked during pregnancy (Da Costa et al. 2010; Kamysheva et al. 2010; Jomeen and Martin 2007). Although the direction of causation between depression and physical complaints is not clear, it can be hypothesised that underlying psychological difficulties could result in a greater number of consultations with midwives and medical staff. A study of 476 nulliparous women showed that the prevalence of symptoms experienced during pregnancy could be predicted by increased levels of stress and low pregnancy adjustment (Rodriguez et al. 2001). Research focussing on the determinants of attendance in general practice, has shown that frequent attendance is correlated with psychological distress and social factors such as unemployment and single status (Vedsted and Christensen 2005). Furthermore, there is evidence to show that social support, perceived stress and negative affect account for a significant proportion of variation in the incidence of both medically significant and common pregnancy symptoms and that perceived health, in conjunction with the presence of symptoms predicts health care utilisation during the third trimester (Rodriguez et al. 1999).

It is evident that the relationship between physical ill health and psychological wellbeing is complex. Frequent presentation for additional care may also be as a result of previous or ongoing maternal abuse. There is evidence to suggest that a history of childhood abuse is associated with significantly more common complaints during pregnancy such as heartburn, backache and constipation (Lukasse et al. 2009) and may result in greater worries about baby's health during pregnancy (Eide et al. 2010). A large study of nulliparous women found that intimate partner violence was also associated with poorer physical and psychological health during pregnancy (Brown et al. 2008).

The degree to which an individual is concerned about their health can impact on their utilisation of health care. Health anxiety is a concept that incorporates a range of concerns about illness based on an individual's interpretation of symptoms and perceived symptoms (Alberts et al. 2011; Kowalyk et al. 2009). A study of non-pregnant patients who consulted their general practitioners (GP) concluded that high levels of health anxiety result in an increase in the number of GP visits and a reduced level of reassurance about symptoms from friends and family (Conroy et al. 1999). Although it has been shown that health anxiety is not elevated during pregnancy when compared to levels in non-pregnant women, it is likely that individuals who are generally highly anxious about their health will be more likely to present for additional care when pregnant (Kowalyk et al. 2009). It has also been found that high levels of maternal anxiety during pregnancy may result in mothers having greater utilisation of paediatric health services for their infants although it is unclear whether pregnancy anxiety has a physiological effect on the fetus' immune system or whether high anxiety levels during pregnancy are a predictor of hypervigilent behaviour regarding symptoms of illness (Goldman and Owen 1994).

Although there was no correlation between the STAI scores and the number of additional visits, the evidence from the interview data obtained in this study appears to support the previous work cited. Women who took part in the interviews were more likely to describe feeling that they did not receive a sufficient number of antenatal visits when they felt that their pregnancy was not straightforward because of the occurrence of pregnancy complaints and complications, psychological difficulties such as anxiety, worry and depression or social challenges. Women were more likely to report being content with the visit schedule when they viewed their pregnancy as being uncomplicated and they were able to continue with activities, in the same way as they did when not pregnant, such as going to the gym. Previous studies have also reported a positive association between exercise during pregnancy and psychological wellbeing (Hegaard et al. 2010; Da Costa et al. 2003; Goodwin et al. 2000).

The evidence from this study and related previous work in this area shows that the need for additional support and visits during pregnancy is a complex and

multifaceted phenomenon. This study would have benefitted from putting a greater emphasis on women's own perceptions of pregnancy complications, the possible underlying causes for such complications and the most appropriate way to meet the needs of women that are currently unmet by routine antenatal care (Novick 2009). With hindsight, these factors should have been more of a focus of the research although the findings from this study have contributed valuable information to a previously sparse knowledge and provided useful directions for further research.

It is clear that the study interventions may have increased the number of unscheduled visits that women received. In some cases, the discussions that took place during the TSI calls prompted referral to other health care professionals and may have contributed to an increase in non-scheduled antenatal visits. Similarly, the introduction of UADS resulted in some women receiving additional ultrasound scans and antenatal clinic appointments if the outcome highlighted that the woman was at increased risk of developing PMD. The impact of the interventions on the number of additional antenatal visits further brings into question the choice of total number of antenatal visits as the primary outcome measure.

Clearly, the concerns of nulliparous women can deviate greatly from the concerns of midwives and medical staff. This was demonstrated by women's accounts elicited from the interviews; a proportion of women have a need for the recognition of their pregnancy as a significant event and to be 'looked after' by their midwife. The requirement that women have for additional antenatal care is an issue which is affected by both physical and psychological factors, although it is clear from the findings of this trial that most of the reasons cited for additional visits would probably not be amenable to a telephone support intervention even if the visits occurred because of perceived rather than actual complications of pregnancy. Thus, on reflection there were significant limitations to the primary outcome chosen.

5.2.2 Study design

Overall, the study was well designed and executed resulting in reliable findings. The study recruitment process was effective and achieved the required number of participants within the proposed time frame (February 2004 to January 2007). The randomisation system was easy to use and there were no problems with the process. It was designed and managed by staff based within Newcastle University who had no connection to the trial and the individuals responsible for recruitment and randomisation were not aware of the trial allocation sequence. This ensured that there was minimal selection bias in the allocation of participants to the study groups although it is accepted that it is not possible for bias to be eliminated entirely in any research process (Jadad 1998). It was necessary for the purposes of the study to make an assessment of women's pregnancy risk status and due to the nature of the interventions the participants and researcher could not be blinded to group allocation.

There were limitations identified with the provision of the telephone support intervention. The telephone discussion guide was designed to encourage flexibility in the discourse that took place between the study midwife and participants, allowing them to raise any concerns that they had during their pregnancy. The aim was to provide a proactive intervention that could be tailored to women's individual needs that did not restrict the type of support that was provided. Women were also referred to additional sources of information and support if required. The gestation at which the calls were made was standardised for all of the participants and was scheduled when women were not due to receive a routine antenatal visit. However, it is acknowledged that women's anxieties during pregnancy are not predictable, either in timing or cause and cannot necessarily be accurately anticipated by either the woman or midwife.

All of the women included in the study were able to provide at least one contact telephone number showing that access to the intervention was universal for this population. However the study identified that there are significant barriers to the implementation of the full support intervention, with most women receiving fewer calls than planned. This could have affected the impact of the intervention

and resulted in there being no statistically significant benefit demonstrated. The single centre design could be viewed as a limitation of the study; a multicentre study would have provided a more robust assessment of the implementation of the intervention but it is unlikely that the negative result was influenced by the single centre design.

The exclusion of women who required an interpreter is recognised as having a significant impact on the results. The sample is not representative of the population investigated or generalisable to the wider population. There is evidence to demonstrate that women in non-White minority groups are more likely than White women to perceive that they have poorer health and feel more depressed (Jayaweera and Quigley 2010). Furthermore, women in Black and ethnic minority groups when compared to White British women tend to initiate antenatal care later and report receiving poorer information during pregnancy (Redshaw and Heikkila 2010). Late initiation of antenatal care and insufficient number of visits has been associated with an increased risk of maternal death (Centre for Maternal and Child Enquiries (CMACE) 2011) and it has been suggested that women who do not speak and/or understand English may have increased requirements for support and reassurance during their first pregnancy (National Collaborating Centre for Women‘s and Children‘s Health 2010). It was not possible to utilise interpreters for this study due to practical and financial constraints. The use of a telephone support intervention for non-English speaking women may be an area that warrants further research.

A further limitation of the study was the exclusion of some teenage women. At the time of recruitment, all women living within Newcastle-upon-Tyne who were under the age of 18 were provided with additional support from the teenage pregnancy team. The team is a multidisciplinary collaboration which incorporates additional antenatal care in relation to social and emotional needs, including a designated teenage pregnancy midwife who arranges extra visits with women if required. Because young women were already able to access additional support from this source, it was felt that their inclusion in the study was not appropriate. However, women who booked at the hospital who did not have access to this additional support were included in the study.

There are limitations associated with the testing of two interventions simultaneously. A small proportion of women declined to take part in the study because they felt that having uterine artery Doppler screening may cause them greater anxiety in the case of a screen positive result (2.9% of women approached). It is possible that women who declined to take part in the study because of their concerns about the screening process may have been generally more anxious during their pregnancy, therefore reducing the overall rate of anxiety in the study sample. However, this seems unlikely because the mean STAI Trait scores in this sample (36.2) were similar to the scores of pregnant women in the ARIA trial (38.1) which investigated the effects on anxiety levels of giving rapid amniocentesis results to pregnant women (Hewison et al. 2006) and a study of women's antenatal worries about the baby (38.4) (Statham et al. 1997a). Although no women indicated that they did not take part in the study because of the telephone intervention, there remains the possibility that this component of the trial dissuaded some women from participating which could also bias the results. The study results also provide no data on the psychological effects of uterine artery Doppler screening in isolation although the interview data suggests that the effects would not have been significant.

Women who took part in this study were asked to record in their own handheld notes if they contacted a healthcare professional by telephone after 20 weeks gestation and a request for this information was repeated in the covering letter included with the postal questionnaires. None of the women documented that they had made telephone calls to health professionals, although it is highly unlikely that there was no additional telephone contact between women and their midwives. There was also no system in place for community- based health care professionals to record the details of telephone calls they had with women because women were in possession of their own notes.

The difficulty of obtaining reliable health care utilisation data has been previously reported in the literature and there is evidence to suggest that there may be differences between patient reports and hospital notes (Coyle et al. 1999). It has been shown that hospital notes are generally more accurate than

relying on participant recall but it is accepted that there are limitations with all sources of data (Evans and Crawford 1999).

5.3 Sample

There was no difference in the demographic characteristics of the three trial groups. The mean age of participants at the time of recruitment is comparable with the national average age to have a first baby of 27.5 years and the majority of participants were married or cohabiting (National Statistics: www.statistics.gov.uk). The proportion of women in the trial who described their ethnic group as 'white' was higher than the population of women who booked for maternity care at the hospital during the trial (71.7% of all women irrespective of parity).

The restriction of the sample to low risk nulliparous women utilising the risk criteria provided in current national guidance (NCCWCH 2003) resulted in a rigorous selection criteria for the inclusion of participants in the trial when compared to other studies focussing on reduced antenatal visits (Tables 1 and 2). Two studies undertaken in developing countries did not attempt to select women based on their risk and used cluster randomisation (Villar et al. 2001a) (Majoko et al. 2007). A further study conducted in a developing country recruited from a clinic designed to care for low risk women only (Munjanja et al. 1996). The other studies reviewed (citied in Tables 1 and 2) did apply criteria for their selection of low risk women although it was not determined by pre-existing national guidelines and so the criteria varied between studies (Walker and Koniak - Griffin 1997; McDuffie et al. 1996; Sikorski et al. 1996; Binstock and Wolde-Tsadik 1995). In the study by McDuffie et al (1996), 41.5% of the women considered for inclusion were unsuitable to take part due to existing factors that resulted in them requiring an increase in antenatal care. This is considerably higher than the proportion of women excluded in this study (17.3%) but could be due to the fact that this study sample is exclusively nulliparous women. The study by Binstock et al (1995) excluded 10% of women because they had pre-existing medical conditions. This study recruited both nulliparous and multiparous women so clearly the selection criteria for the trial differed significantly from the trial by McDuffie et al (1996). The figures for

the number of women who were excluded as a result of their risk status are not provided in the other studies discussed.

5.4 Economic analysis

The present study provides only a simple costing of the trial interventions. It would have been useful to undertake a more comprehensive investigation into the economic impact of telephone support +/- uterine artery Doppler screening as well as the cost of additional antenatal visits to provide a greater insight into the overall costs of components of antenatal care provision.

A separate study of a subsample of women taking part in the present trial was undertaken by a health economist. This study, conducted in parallel to the present study utilised discrete choice experiments and recruited a convenience subsample of 100 nulliparous women to illicit the values women place on various component parts of antenatal care: type of provider and location, number of visits, content of visits, telephone support intervention and uterine artery Doppler screening (Deverill et al. 2010) (Appendix S). Accepting the limitations of discrete choice experiments (Lancsar and Donaldson 2005; Bryan and Dolan 2004), the findings of the discrete choice experiments performed in this context provide valuable information that supplements the outcomes and discussion of this trial. The main results of the study are shown in Table 29.

Table 29 - Marginal rates of substitution between number of antenatal visits, payment and other antenatal care attributes

Preferred attribute level	Number of visits women prepared to sacrifice for preferred service attribute	Payment women willing to make to get preferred service attribute
Midwife at local clinic	3.91	£322
10 visits	N/A	£85
Usual check-ups and preparation for birth	2.60	£221
Telephone advice line	4.33	£368
Uterine artery Doppler screening	3.55	£302

(Deverill et al. 2010)

The evidence from the 'Support and Reassurance in Antenatal Care Trial' showed that a third of women interviewed expressed a wish for more visits. Similarly, the results of the discrete choice experiments demonstrated that when given the choice, low risk nulliparous women preferred ten visits rather than seven and for their antenatal their care to be provided by a community midwife at a clinic that was local to them (Deverill et al. 2010).

Although women's responses showed that the quantity of antenatal visits was important, they placed greater emphasis on the provision of a telephone support intervention and uterine artery Doppler screening. Specifically, women were willing to both reduce the number of routine visits that they received by four and pay an additional £368 to have access to telephone support by a midwife (Deverill et al. 2010). This finding contrasts somewhat with the responses from women during the interviews although it is important to consider that the responses to questions from Deverill et al (2010) were given antenatally whereas the interviews for the discussed study took place during the postnatal period.

5.5 Implementation of interventions

5.5.1 Telephone support intervention

The main difficulty encountered in delivering the telephone support intervention was an inability to contact women because they had changed telephone numbers or moved house and not informed researchers of their new number, or they were unavailable when the call was made. The telephone intervention was successfully delivered to 59% of women at 29 and 33 weeks gestation, decreasing to 52% of women at 37 weeks. The mean number of telephone calls received by women was 1.6, which is just over half the three calls that were proposed. Prior studies of telephone support interventions during pregnancy and postpartum have experienced similar difficulties in implementing the telephone intervention. A trial providing a telephone support intervention to women at increased risk of preterm birth reported that participants received only half of the proposed intervention calls (Moore et al. 1998). A support intervention for low income pregnant women found that only 71% of participants received more than half of the proposed number of proactive telephone calls

and 25% of women received only a quarter of the proposed number of calls (Bullock et al. 2002). Similarly, a telephone-delivered support intervention for pregnant women who smoked reported that 55% of participants received the full intervention, 13% received half of the calls and 32% were not contacted at all (Stotts et al. 2002).

If participants were not contacted on the first attempt only one further attempt was made because of time constraints within the study and those that exist within a usual care setting. The imposed limit on number of attempted calls is likely to have adversely affected the success rate of the implementation of the intervention. Previous studies have shown that multiple unsuccessful calls have to be made before contact with the woman is achieved. A study of a peer-volunteer telephone intervention to reduce postnatal depression found that for every 5 successful contacts a further 5 unsuccessful calls were necessary (Dennis 2003) and in a support intervention for low income pregnant women, an average of at least three unsuccessful calls had been made before the participant was reached (Bullock et al. 2002). Calls were made at a time that was convenient for women including evenings and weekends (as determined by the participants when recruited). Mobile and landline telephone numbers were used in a bid to optimise the number of successful calls. It became clear that it was difficult to initiate telephone contact with some participants because they were still working and busy with their usual activities. The reduction in the success rate of the calls at the 37 week gestation time point could be accounted for by the fact that more women had moved house or changed telephone numbers and a proportion of women had given birth (6.8%).

The findings of this study and previous research findings demonstrate that the extra resource use associated with unsuccessful calls needs to be considered when designing such interventions. It is possible that the women who were not reached were most in need of support although there was no correlation between the number of calls received, the STAI score and the number of unscheduled antenatal visits that women made. Accepting that there were significant difficulties in providing the proposed intervention in its entirety, during the interviews, some women stated that they did value the opportunity to talk

about their concerns and felt that the proactive design was helpful. Women discussed how they would be unlikely to contact a midwife regarding concerns that could be viewed as trivial, but were happy to ask such questions when contacted by the research midwife.

The interviews also suggested that a telephone support intervention may be most effective if provided by a midwife who did not provide the remainder of a woman's antenatal care. Most women were happy with the interpersonal relationship they had with their community midwife, although for some women the opportunity to receive support from an alternative midwife was valued because of their experience of a suboptimal interpersonal relationship with their own midwife. Women identified a number of deficiencies in the relationship they had with their midwife, namely the personal characteristics of the midwife, the lack of provision of information, absence of an individualised approach, no continuity of care and little acknowledgement of the pregnancy as a significant event. These findings are similar to the views expressed by women in qualitative studies designed to identify key aspects of communication between women and health care professionals during antenatal care (Puthussery et al. 2010; Raine et al. 2010).

There was the opportunity for women to build up a rapport with the midwives delivering the telephone support intervention because the telephone support intervention was provided by only two midwives. The provision of continuity of care was an aspect of the TSI that was viewed positively by the study participants. There is previous evidence to show that in studies of continuity of midwifery care, women who see the same midwife consistently experience a more positive relationship, describing the midwife as being caring, skilled and interested in them as an individual (Waldenstom and Turnbull 1998). In a qualitative study, it was found that caseload midwifery can result in midwives using a less hierarchical style of communication when undertaking antenatal visits, with communication taking a conversational form and facilitating more choice and control for women (McCourt 2006). This suggests that the development of a relationship between the woman and her midwife is reciprocal with both parties gaining from a positive relationship that is developed over

time. This can be applied to both face-to-face and telephone encounters. A recent qualitative study found similar results; women expressed a wish to have proactive informational and emotional support from midwives irrespective of whether they had other sources of support during pregnancy and wanted midwives to show genuine interest in them as individuals (Seefat-van Teeffelen et al. 2011).

The qualitative interview data from the present study showed that the proactive design of the telephone intervention was an aspect that women valued because it allowed them the opportunity to voice their concerns without the burden of having to initiate contact with a midwife or other health care professional. However, a more flexible approach to the timing of the telephone calls may have been more responsive to women's needs and contact could have been led by the women themselves or been a combination of proactive and reactive support. The narrative of women in the postnatal interviews showed that the telephone support intervention was generally well received with no negative responses being elicited and only two women stating that it didn't enhance their care in any way.

Although the results of the study showed that the telephone intervention calls conferred no statistically significant benefit to women in terms of number of antenatal visits required, levels of anxiety, social support or pregnancy worries it remains a possibility that a small proportion of women would have found it a useful addition to their care. Further evidence that the TSI was valued was demonstrated by the choices of women who took part in the DCE of women's views of antenatal care. It was found that women were willing to pay the greatest sum (£368) to be provided with a telephone support intervention in addition to their usual antenatal care (Deverill et al. 2010). Furthermore, most of the interviewed sample of women stated that they would want TSI to be part of their care in a future pregnancy. Those women, who said that they did not feel it would add value, considered that their experience of their first pregnancy would make them feel more confident in a subsequent pregnancy.

5.5.2 Uterine artery Doppler screening

The introduction of UADS into the clinical service was relatively straightforward and well supported by sonographers with measurements obtained in 99.6% of cases; this is consistent with previous studies (Bower et al. 1993). Women who were interviewed described the process as acceptable and only one woman withdrew her consent for UADS at the time of the examination because she felt unwell during the scan.

The screen positive rate at 20 weeks was comparable to previous studies (13.5%) but much lower at 24 weeks (1.8%). Bower al (1993) reported a screen positive rate of 16% at 20 weeks which dropped to 5.1% at 24 weeks although the sample was unselected women. The researchers defined screen positive based on a resistance index (RI) > 95th percentile and both unilateral and bilateral notching. In another study of unselected women using the same parameters to define increased impedance, a screen positive rate of 9.1% at 20 weeks and 3.9% at 24 weeks using continuous wave Doppler was reported (Harrington et al. 1996). Frusca et al (1997) studied a sample of nulliparous women which they stated had no risk factors for developing pre-eclampsia, (although the criteria used for selection were not reported) (Frusca et al. 1997). The sample had a much higher rate of 30% screen positive results at 20 weeks and a persistently high impedance (mean RI > 0.58) rate of 8.6% at 24 weeks gestation using continuous wave Doppler. The differences in methodology in the studies could account for the differences compared to the present results.

The population studied had a relatively low rate of significant PE and FGR with only 1/727 women developing severe PE. However, the prevalence of PE (2.3%) is consistent with a large multicentre prospective study of unselected women at 22-24 weeks, in which the rate of PE was 2.6% in nulliparous women (Yu et al. 2008) and a recent screening study of unselected women at 11-13 weeks gestation where the incidence of PE was 2.2% (Akolekar et al. 2011). Both of the studies used the definition of PE described by the International Society for the Study of Hypertension in Pregnancy, which is the same definition employed in this study (Brown et al. 2001).The rate of FGR (below the 10th

percentile for gestational age) is 8.7% which is similar to the rate of FGR in a previous study (9.3%) (Khaw et al. 2008).

The interview data showed that women generally welcomed any screening intervention that provided them with reassurance about the wellbeing of their baby. The results of the previously discussed DCE study showed that women did place value on the addition of UADS to their care and were willing to reduce the number of routine visits they received and pay £302 to have the screening incorporated into their care (Deverill et al. 2010). It was evident from the interview data however, that concerns specifically about the development of PMD, did not feature highly in this sample of women. This is despite the fact that the detection of PMD is fundamental to the way in which antenatal visits are structured and is the pregnancy complication most likely to affect them during their first pregnancy.

Evidence from the interview data analysis demonstrated that ultrasound visualisation of the fetus in particular was valued highly; women who were interviewed frequently expressed a wish for a greater number of ultrasound scans during their pregnancy, particularly during the third trimester because they found them to be reassuring about the baby's wellbeing . A previous study examining the reasons why women appreciate ultrasound during normal pregnancies found that women value both the clinical and psychological aspects of a normal scan (Gudex et al. 2006).

The possible negative psychological consequences of introducing screening in a low risk population cannot be ignored. Although the findings suggest that UADS screening does not appear to increase anxiety in a low risk population of nulliparous women, the number of screen positive women in the study was relatively small which makes it impossible to draw any definite conclusions about the impact of receiving a screen positive result and the impact of being deemed at increased risk for developing PE and/or FGR in the absence of an effective treatment. It has been shown that women may be more likely to place an emphasis on abnormal results from ultrasound scan because they have a

positive attitude in general to this antenatal investigation (Petersen and Jahn 2008).

There is evidence to show that women do not interpret risk information in the same way as health professionals and are more likely to view themselves as either being at high risk or no risk of developing the condition that is being screened for (Baillie et al. 2000). This was supported by interview data from one woman in our study who expressed surprise at developing PE after having had a normal UAD screen. This further demonstrates the importance of ensuring that risk information is provided in a way that is easy for women to understand (Wildschut et al. 2006; Green et al. 2004) , particularly when the screening test is relatively new or has not been used in the low risk pregnant population.

5.6 Anxiety

The provision of screening risk information to women appears to improve their knowledge levels but can have negative effects on their levels of anxiety. A previous study of women who were at high risk of preterm delivery looked at their experiences of receiving information about these and found that the provision of information resulted in improved understanding but increased anxiety (Yee and Sauve 2007) . There is evidence to show that although the perception of risk during pregnancy can be over-estimated by women as a result of information that they receive, the presentation of individualised risk information in an informative and sensitive manner can actually alleviate worry (Robinson et al. 2011).

It was found that the group of women in the present study demonstrated relatively average levels of anxiety prior to the commencement of the interventions with mean STAI-state scores in the three groups at 20 weeks gestation of 36-37. These results are comparable with other studies of similar samples of women during pregnancy (Hall et al. 2009; Petersen and Jahn 2008; Hewison et al. 2006; Quagliarini et al. 1998; Thornton et al. 1995). The results suggest that the introduction of the TSI and UADS did not result in an increase in low risk nulliparous women's anxiety levels which is reassuring. There was no significant change in women's anxiety levels throughout the duration of

pregnancy, which is a similar finding to a previous study using the STAI (Thornton et al. 1995). It is reassuring to find that low risk nulliparous women are not highly anxious in general although it is relevant to note that anxiety is only one component of a woman's psychological experience of her first pregnancy. Women's responses during the interviews showed that a proportion of them had concerns and worries about issues that were salient to them but this may not have manifested as raised anxiety levels.

5.7 Interview process

The decision to incorporate qualitative interviews into the trial design was made because of the complexity of effectively assessing how women perceive their antenatal care and whether it met their needs. This information is crucial when planning and designing provision of antenatal care. The way women view their care is frequently approached by the measurement of satisfaction with care; the recommendations of a Health Technology Assessment review (HTA) suggested that the optimum method of acquiring insight into 'satisfaction' with healthcare was by using a combination of quantitative scores supplemented by semi-structured interviews (Crow et al. 2002).The interview process also provided the opportunity for further discussion and explanation of the aspects of care that were useful and those that could be improved. Interviews also provided clarification of women's sources of support during pregnancy. Women were also asked their views of the TSI and UADS, if given the choice, whether they would include these interventions in their care during a subsequent pregnancy.

The original aim was to interview women 6 weeks post delivery to optimise their recall of the experience of pregnancy and the care they received but it was found that women were generally reluctant to be interviewed so soon after the birth of their baby and felt more comfortable with doing so at 8-10 weeks post delivery. This change ensured that a more diverse cross-section of participants were willing to take part in the interview process than if the 6 weeks postpartum time point had been enforced. A limitation of undertaking postnatal interviews was that some women found it difficult to focus on their antenatal experience and wanted to take the opportunity to discuss intrapartum and postnatal issues

resulting in a trade off between interviewing women postnatally once they have experienced all of their antenatal care and conducting interviews during the latter stages of pregnancy. Some women stated that the research interview itself provided them with a valuable opportunity to talk through pregnancy events which they had not been able to do otherwise. This finding is similar to a previous qualitative studies focussing on antenatal psychological distress (Furber et al. 2009; Raymond 2009). It is possible that a one-to-one discussion with women in their own homes during the third trimester may offer women the opportunity to express concerns in a way that is not currently achieved by a traditional antenatal visit.

5.8 Conclusion

The determinants of women's experiences of their first pregnancy are varied, complex and may not be easy to identify. However, the results suggest that women's perceptions of their pregnancy and health, may impact on their requirements for antenatal visits. It is clear that in order to meet nulliparous women's' need s effectively, support interventions and the provision of antenatal care should be responsive to change over the duration of the pregnancy and differences between individuals. These findings provide important implications for the future planning and rationalisation of antenatal care.

Chapter 6. Implications for clinical practice

6.1 Introduction

The nationally recommended antenatal visit strategy for low risk pregnant nulliparous women has been implemented at the Royal Victoria Infirmary, Newcastle upon Tyne (NCCWCH 2008). This is the first study to demonstrate that although a reduction of antenatal visits has been achieved, women are receiving more visits than proposed when scheduled and unscheduled visits are collated.

6.2 Implications

The criteria for selecting women to receive standard antenatal care appears to be appropriate for assessing medical risk although it is possible that rare complications could be missed; an extremely large study would be required to determine whether this is the case. An alternative approach to assessing women's individualised risk of developing complications of pregnancy has been proposed. Antenatal visits could be stratified by undertaking an integrated hospital visit in the first trimester incorporating screening for placental mediated disease, fetal abnormality, preterm delivery and gestational diabetes (Nicolaides 2011). This could facilitate a significant reduction in the number of routine antenatal visits particularly during the second and third trimester but does not address the issues of psychosocial support for women.

Although the assessment of medical risk appears to be effective, it does not effectively incorporate the assessment of women's psychological wellbeing other than to identify women who have a history of mental illness. If we accept that the functions of antenatal care are more far reaching than just to screen for and treat medical conditions, the assessment of a woman's need for extra support has to be approached in an alternative way. If this aim was achieved, antenatal care could be tailored to meet the needs of women who subsequently develop psychological difficulties such as antenatal depression and anxiety (Furber et al. 2009; Jomeen 2004). Both the medical and psychological risk for women evolves over the duration of the pregnancy (Jordan and Murphy 2009) and a more flexible approach to antenatal care provision would allow for changes in women's psychological state, social situation and physical health.

Previous studies have implemented psychosocial risk screening during pregnancy, incorporating measures of psychological, social and emotional wellbeing (Priest et al. 2008; Matthey et al. 2004). The evaluation of psychosocial risk in this way appears to be effective and predictive of positive functioning during pregnancy and up to six weeks postnatally (Karatas et al. 2009). An alternative approach has been to focus on enhancing midwives knowledge of the psychosocial issues that women face during pregnancy with the aim of improving the midwives listening skills and ability to pick up cues and discuss issues further (Hegarty et al. 2007; Gunn et al. 2006). Although these studies have gone some way to highlighting the possibilities available to screen women for psychosocial problems during pregnancy, it is clear that it is only useful to do so if antenatal care is organised in such a way to provide additional help and support to women identified as experiencing difficulties (Austin 2004).

There was evidence to suggest that some women found the proactive telephone support from a midwife to be beneficial, this is a method of providing support that could be relatively easily incorporated into the current provision of antenatal care. An alternative strategy could be the provision of telephone support by peer volunteers, previous studies have shown that peer support can have positive effects on breastfeeding rates (Dennis et al. 2002) and the incidence of postnatal depression (Dennis 2003) .

The most appropriate means of supporting women has yet to be identified but utilisation of new communication technologies is emerging as a possibility. A recent systematic review found that text reminders and prompts were an effective means of encouraging changes in health behaviour in other healthcare settings (Cole-Lewis and Kershaw 2010). In a study of 68 low risk pregnant women, higher levels of satisfaction and confidence and lower levels of anxiety were shown when women received twice weekly support text messages from 28 weeks gestation (Jareethum et al. 2008). Further, a study found that women valued proactive contact by text message during their pregnancy to remind them of forthcoming antenatal appointments (Raine et al. 2010).

Other forms of communication technology have been utilised in the care of women including videoconferencing (Lindberg et al. 2009) and blood pressure monitoring by telemetry (Cartwright et al. 1992). It is evident that there is an increasing need for antenatal care to embrace the use of the internet by women as an additional information resource (Lagan et al. 2010) and the development of new communication technologies including social networking sites such as Facebook, email contact and Skype. The utilisation of such technologies can be adapted to meet women's preferences and to provide more accessible and supportive care, particularly for marginalised groups. The economic impact of utilising different technologies also needs to be evaluated.

6.3 Conclusion

It has been shown that low risk nulliparous women are generally satisfied with a reduced schedule of care and demonstrate low levels of anxiety throughout pregnancy and postnatally although there are some aspects that could be improved. The current provision of antenatal care is inflexible in the location and timing of appointments. Women expressed a desire to have greater choice in when and where their appointments take place, with a need to accommodate work commitments. Most women are happy with the care that their midwife provides; however women who do not develop a positive relationship with their midwife need to be offered access to alternative sources of support.

The role of midwives in the provision of antenatal care needs to be examined to determine whether the current structure of visits optimises their skills and enhances the quality of service that they provide to women. Routine assessments for low risk women such as urinalysis and blood pressure monitoring could be performed by health care assistants (Linay and Rogers 2011; Royal College of Midwives 2003) or women themselves under supervision of midwives (Gaudion and Menka 2010), thereby giving midwives the opportunity to more effectively determine which women would benefit from additional support and to implement support strategies.

Chapter 7. Directions for future research

7.1 Introduction

The results of the study have highlighted that there is a significant lack of knowledge of the determinants of women's use of antenatal services and it is evident that women do not have the same concerns as health professionals about their health and wellbeing during pregnancy.

7.2 Future directions

Future research is needed to identify the reasons why women access additional care and the factors associated with underutilisation of care. This would inform the development of interventions to supplement routine antenatal care schedules and facilitate greater understanding about the needs of women during pregnancy.

Alternative methods of contacting women other than face-to-face visits offers healthcare providers with opportunities to redirect resource use while providing the flexible care that women value. Future studies are needed to investigate whether alternative communication methods are acceptable and valued by women. Future research should focus on studies that investigate innovative provision of care by utilising new technologies, alternative care settings and organisation of care with an aim to provide a service that is responsive, progressive and woman-centred.

Further information is needed to assess how to incorporate women's psychosocial situation into the stratification of risk when planning antenatal care. This would help to more effectively determine which women could benefit from extra support during pregnancy. Research is also required to investigate whether women prefer proactive or reactive support, or a combination of the two.

Appendices

A. Quality assessment form
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Appendix A: Quality assessment form

Quality of study

	YES	NO	Unclear	N/A
Sample				
Adequate sample size	☐	☐	☐	☐
Stratified/random sample	☐	☐	☐	☐
Representative of study population	☐	☐	☐	☐
Low attrition	☐	☐	☐	☐
Intervention studies only				
Clearly defined intervention (reduction of confounds)	☐	☐	☐	☐
Assessors blinded to treatment allocation	☐	☐	☐	☐
Randomisation low risk of bias (i.e. 3rd party)	☐	☐	☐	☐
Different groups similar at baseline	☐	☐	☐	☐
Analysis intention to treat	☐	☐	☐	☐
Interpreting results				
Mostly validated measures	☐	☐	☐	☐
Mostly appropriate timing of measures (length)	☐	☐	☐	☐
Measures consistent with aims	☐	☐	☐	☐
Conclusions consistent with results	☐	☐	☐	☐

Yes = 1
No = –1
Unclear = 0

Total quality score ☐/

(Collins et al 2004)

Appendix B: Patient information sheet

Patient Information Sheet

Support and Reassurance in Antenatal Care

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this information

- ***What is the purpose of the study?***

One of main aims of antenatal care in the second half of pregnancy is to ensure the placenta (afterbirth) continues to function normally. When this doesn't happen, women can develop high blood pressure or their babies may be small. Recently medical evidence has found that the number of antenatal visits can be safely reduced without increasing the risk of these problems. This of course means women have less contact with midwives and other professionals. The purpose of the study is to see if providing women with extra support from a midwife and/or extra information at the time of their 20 week scan about the development of the placenta is beneficial. The study will take 3 years to complete.

- ***Why have I been chosen?***

You have been chosen because you are having your first baby and you are booked to deliver at the Royal Victoria Infirmary.

- ***Do I have to take part?***

It is up to you to decide if you would like to take part or not. If you do take part you will be free to withdraw at any time and without giving a reason. A decision to withdraw or a decision not to take part, will not affect the standard of care you receive. You will be given a copy of this information sheet to keep.

- ***What will happen to me if I take part?***

At the time of your routine 20 week scan, a midwife will discuss the study with you and give you time to ask any questions you may have. In the study the women who take part will be allocated to one of three groups:

1. Normal (routine) care (with visits at 25, 28, 31, 34, 36, 38 & 40 weeks of pregnancy)
2. Normal care with additional telephone contact with a midwife at **29**, **33** and **37** weeks.
3. Normal care with additional telephone contact and extra information about placental blood flow collected at the time of the routine scan.

Normal placental blood flow reduces the risk of high blood pressure or a small baby later in pregnancy. If blood flow is reduced, the scan will be repeated at 24 weeks of pregnancy. If the blood flow remains reduced, the risk of developing these problems is increased approximately 5 fold. These women will be offered an extra scan later in pregnancy. However the **majority** of women with reduced blood flow do not develop problems.

If you agree to join the study the type of antenatal care you get will be determined by chance: in other words there is a 1 in 3 chance you will receive routine care, a 1 in 3 chance you receive the extra telephone contact and a 1 in 3 chance you will have the extra telephone contact and the extra part of the scan.

During your pregnancy at **20, 28** and **36** weeks gestation and at **6** weeks after the birth we will ask you to complete and return a questionnaire (in a stamped addressed envelope provided). The questionnaire asks about any worries you have and also your views on the care you have received. A small number of women will be asked if they would mind being interviewed by a midwife after they have had their baby. The aim of the interview is to get more information about their antenatal care.

- ***What are the possible disadvantages and risks of taking part?***

Taking part in the study may result in a change to your care. The extra contact and information may be helpful but it could lead to additional anxiety. A midwife counsellor will be available to see any women who feel anxious as a result of taking part in the study. Measurement of placental blood flow takes 2-3 minutes and involves no risk or discomfort to you or your baby.

- **What are the possible benefits of taking part?**

We hope that any changes to your antenatal care will be of benefit but this cannot be guaranteed. The information that we get from the study should help us to improve antenatal care in the future.

- **Will my taking part in this study be kept confidential?**
- **What will happen to the results of the research study?**

All information that is collected about you during the course of the research will be kept strictly confidential and your name will never appear in print. When the study is finished (in 2006) the findings will be published in medical journals and, if requested, summaries will be sent to those who have helped in the study.

- **Contact for further information**

Vikki Snaith
Research Midwife
4th Floor,
Leazes Wing
Royal Victoria Infirmary
Newcastle upon Tyne
Tel: 0191 2820540

Thank you very much for taking the time to read this information

Appendix C: Consent form

Consent form

Support and Reassurance in Antenatal Care

STUDY NUMBER

Addressograph or:

Name: _____

Hospital number: _____

Date of birth: _____

Address: _____

☐ Control

☐ Intervention

☐ Intervention + Doppler

1. I confirm that I have read and understood the information sheet for the above study and have had an opportunity to ask questions ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected ☐

3. I am aware that I will be sent questionnaires as part of the study and agree to return them ☐

4. I agree to take part in the above study ☐

Name _____ **Date:** ☐☐ ☐☐ ☐☐

★ **Signature:** _____

Name of person taking consent _____

Date: ☐☐ ☐☐ ☐☐ **Signature:** _____

SRAC study consent, version 2

Appendix D: Out of area midwife information sheet

Dear Colleague

We are currently undertaking the above research study at the Royal Victoria Infirmary. The study has been designed in light of the recent NICE (2003) recommendations, which reduced the number of visits that low risk nulliparous women should have during their pregnancy.

The proposed visit schedule for these women is:

25, 28, 31, 34, 36, 38 and 40

_____ has very kindly agreed to take part in the study and has been randomised to:

Control group ☐

Intervention group ☐

Intervention + Doppler group ☐

Control group:
Women in this group will have usual antenatal care

Intervention group:
Women in this group will have usual antenatal care + telephone contact from a study midwife at 29, 33 and 37 weeks gestation. The aim of the telephone contact is to provide the opportunity to discuss any concerns and/or ask questions. We will refer the woman to an appropriate health professional such as yourself if there is a clinical indication.

Intervention + Doppler group:

The telephone intervention will be carried out in the same way as described above. In addition to this the women in this group will have uterine artery Doppler screening performed at the time of their routine anomaly scan. The aim of this part of the scan is to categorise women as being at low or increased risk of developing pre-eclampsia or a having a small baby later in pregnancy. It is hoped that the majority of women who receive a low risk result will find this information reassuring.

Women who have a reduced uterine artery blood flow at **20 weeks** will have the scan repeated at 24 weeks gestation, it is likely that **the blood flow pattern may be normal** at this stage. This would mean that these women are **not at an increased risk** for developing pre-eclampsia or having a small baby.

If the blood flow pattern is still reduced we will offer an ultrasound scan at **30 weeks gestation** to check fetal growth and placental function. We would be grateful if you could check blood pressure and urinalysis in the usual way.

We would be grateful if you could document any visits that are **additional** to those recommended by NICE on pages 17 – 18 of the handheld notes. The reason for this is to allow easier data collection after the study has ended.

Please do not hesitate to contact me if you have any queries about the study. Thank you very much for taking the time to read this letter.

Yours sincerely

Vikki Snaith

Research Midwife
Royal Victoria Infirmary
Newcastle upon Tyne

Tel: 0191 2820362
Email: vikki.snaith@ncl.ac.uk

Appendix E: Telephone discussion guide

Telephone Intervention

1st : 2nd: Time: AM PM Evening Any	Name: Telephone:	Study no: Gestation: 29 33 37

Introduction ❑ Name and purpose of study ❑ Qualified midwife ❑ Reminder of reason for telephone call	**Additional Comments**
Maternal Physical Health ❑ Do you feel generally physically well? ❑ Have you experienced any illness or symptoms that you are worried about? ❑ Are you able to work and or continue your usual pastimes? ❑ Do you have any questions about your physical health? ❑ If you encounter any practical problems do have someone to help you with them?	
Emotional Wellbeing ❑ Would you say that you feel happy or unhappy most of the time? ❑ Do you feel worried or anxious? If so, what are you particularly worried or anxious about? ❑ Do you have someone to turn to if you if you need to talk about concerns	
Fetal Wellbeing ❑ Do you have any worries about your baby? ❑ Do you have any questions about your baby's health?	

Have you contacted a health professional by telephone since your last antenatal visit? If so, how many times?
Referred to: (if applicable)
Reason for referral: (if applicable)

Call length:				

☐ 29 weeks ☐ 33 weeks ☐ 37 weeks

Extra notes
Please remember to ask about AN classes!

Appendix F: Uterine artery Doppler information sheet – low risk

Support and Reassurance in Antenatal Care study

What was the purpose of the additional part of the scan? (uterine artery Doppler screening)

The aim of the scan was to look at the flow of blood through the arteries leading to your uterus. By looking at the pattern of the blood flow we are able to predict the chance that you will develop problems such as pre-eclampsia or delivering a small baby.

Pre-eclampsia is a condition that affects 1 in 20 pregnancies and can lead to problems for both the mother and the baby. The most common symptoms of this are raised blood pressure, protein in the mother's urine and swelling.

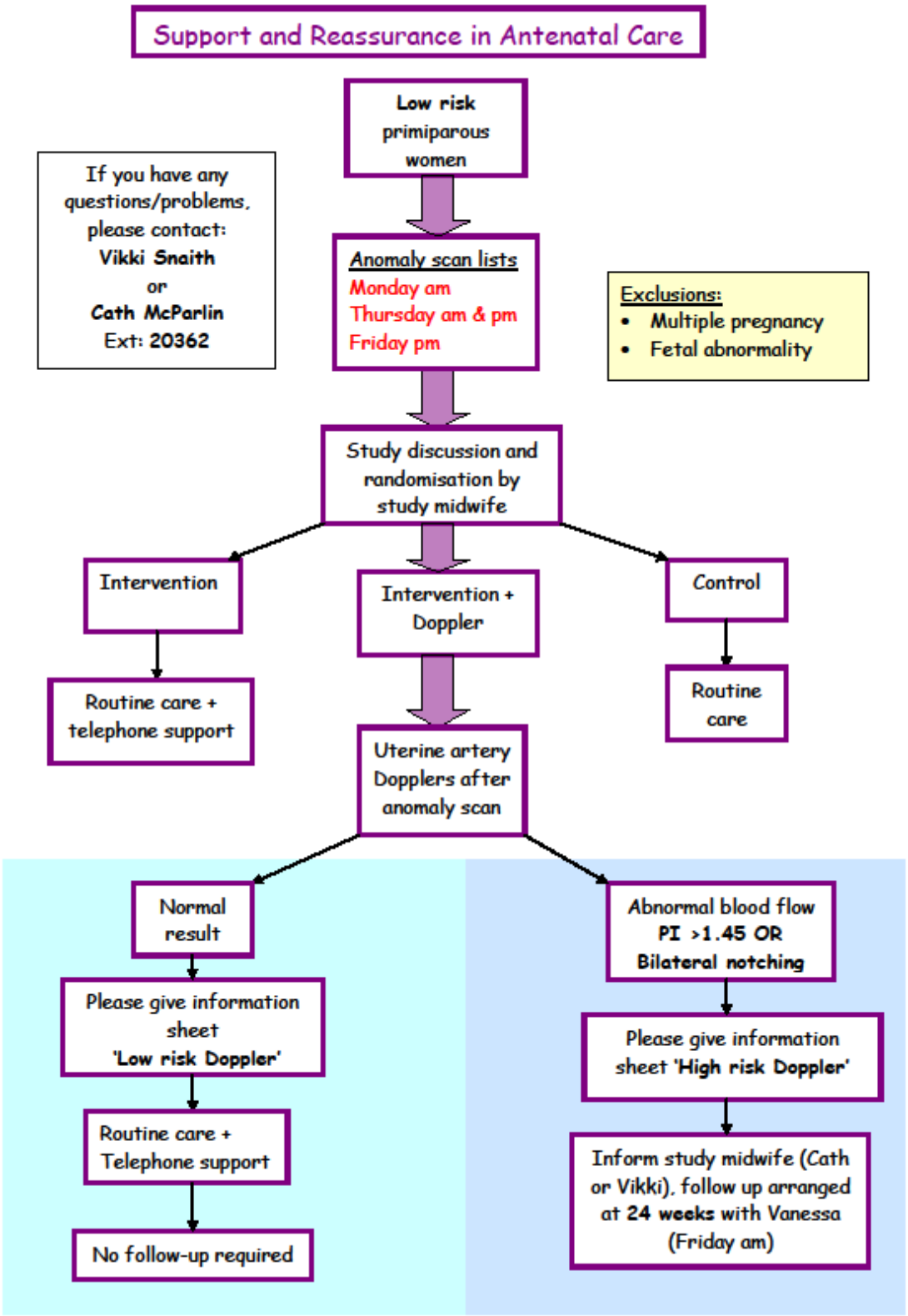
Approximately 1 in 10 women have a baby that is classed as being 'small', most small babies are healthy but a few babies will require extra care monitoring during pregnancy and after delivery.

How will the scan help?

By finding out that the blood flow to your uterus appears normal it is believed that you have a **low** chance of developing problems such as pre-eclampsia or having a 'small' baby.

This knowledge will hopefully reassure you. It is still essential that you still attend all of your planned antenatal appointments with your community midwife so that she can monitor you blood pressure and the growth of your baby as planned.

Appendix G: Sonographers study flow chart



Appendix H: Uterine artery Doppler information sheet – increased risk

Support and Reassurance in Antenatal Care

What was the purpose of the scan?

The aim of the scan was to look at the flow of blood through the arteries leading to your uterus. By looking at the pattern of the blood flow we are able to predict the chance that you will develop problems such as pre-eclampsia or delivering a small baby.

Pre-eclampsia is a condition that affects 1 in 20 pregnancies and can lead to problems for both the mother and the baby. The most common symptoms of this are raised blood pressure, protein in the mother's urine and swelling.

Approximately 1 in 10 women have a baby that is classed as being 'small', most small babies are healthy but a few babies will require extra care monitoring during pregnancy and after delivery.

Pre-eclampsia and having a small baby are most serious when they are present before 34 weeks gestation.

What will happen if the blood flow is reduced?

If the blood flow appears to be reduced we will ask you to come for a second scan when you are 24 weeks pregnant.

It is **most likely** that the second scan will show a normal blood flow to your uterus, which will mean that your risk of developing pre-eclampsia or having a small baby is not increased.

If the blood flow is still reduced at the time of the scan at 24 weeks gestation the risk of you developing pre-eclampsia and/or a small baby are increased by 5 times.

It is important for you to continue to visit your community midwife as planned and we will offer you a scan when you are 30 weeks pregnant to check the growth of the baby and the function of your placenta.

A reduced blood flow pattern does not mean that you will definitely have pre-eclampsia or a small baby but gives us the opportunity to monitor your pregnancy in the best way to ensure that these problems are detected early if they do occur.

Appendix I: 20 week questionnaire

Questionnaire 1

Initials: | | |

Study number: | | | | |

Date completed: | | | | | | |

Support and Reassurance in Antenatal Care (SRAC)

Thank you for agreeing to take part in this study.

Please complete this questionnaire following the instructions given.

All the answers you give are confidential and will not be shared with the hospital

When the questionnaire is complete please return it to the study midwife in clinic

Thank you very much,

Vikki Snaith and Cath McParlin
Research Midwives

Directions

A number of statements which people have used to describe themselves are given below.

Read each statement and then tick the appropriate box ☑ to the right of the statement to indicate how you feel **right now**, that is, **at this moment**. 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 present feelings best.

		Not at All 1	Somewhat 2	Moderately 3	Very Much 4
1.1	I feel calm	☐	☐	☐	☐
1.2	I feel secure	☐	☐	☐	☐
1.3	I am tense	☐	☐	☐	☐
1.4	I feel strained	☐	☐	☐	☐
1.5	I feel at ease	☐	☐	☐	☐
1.6	I feel upset	☐	☐	☐	☐
1.7	I am presently worrying over possible misfortune	☐	☐	☐	☐
1.8	I feel satisfied	☐	☐	☐	☐
1.9	I feel frightened	☐	☐	☐	☐
1.10	I feel comfortable	☐	☐	☐	☐
1.11	I feel self-confident	☐	☐	☐	☐
1.12	I feel nervous	☐	☐	☐	☐
1.13	I am jittery	☐	☐	☐	☐
1.14	I feel indecisive	☐	☐	☐	☐
1.15	I am relaxed	☐	☐	☐	☐
1.16	I feel content	☐	☐	☐	☐
1.17	I am worried	☐	☐	☐	☐
1.18	I feel confused	☐	☐	☐	☐
1.19	I feel steady	☐	☐	☐	☐
1.20	I feel pleasant	☐	☐	☐	☐

		Almost Never 1	Some Times 2	Often 3	Almost Always 4
2.1	I feel pleasant	☐	☐	☐	☐
2.2	I feel nervous and restless	☐	☐	☐	☐
2.3	I feel satisfied with myself	☐	☐	☐	☐
2.4	I wish I could be as happy as others seem to be	☐	☐	☐	☐
2.5	I feel like a failure	☐	☐	☐	☐
2.6	I feel rested	☐	☐	☐	☐
2.7	I am 'calm, cool and collected'	☐	☐	☐	☐
2.8	I feel that difficulties are piling up so that I cannot overcome them	☐	☐	☐	☐
2.9	I worry too much over something that doesn't really matter	☐	☐	☐	☐
2.10	I am happy	☐	☐	☐	☐
2.11	I have disturbing thoughts	☐	☐	☐	☐
2.12	I lack self-confidence	☐	☐	☐	☐
2.13	I feel secure	☐	☐	☐	☐
2.14	I make decisions easily	☐	☐	☐	☐
2.15	I feel inadequate	☐	☐	☐	☐
2.16	I am content	☐	☐	☐	☐
2.17	Some unimportant thought runs through my mind and bothers me	☐	☐	☐	☐
2.18	I take some disappointments so keenly I can't put them out of my mind	☐	☐	☐	☐
2.19	I am a steady person	☐	☐	☐	☐
2.20	I get in a state of tension or turmoil as I think over my recent concerns and interests	☐	☐	☐	☐

Here is a list of some things that other people do for us or give us that may be helpful or supportive. Please read each statement carefully and place a tick (✓) in the blank that is closest to your situation.

Here is an example:

	As much as I would like				Much less than I would like
I get enough holiday time		✓			

	As much as I would like				Much less than I would like
1. I have people who care what happens to me					
2. I get love and affection					
3. I get chances to talk to someone about my problems at work or with my housework					
4. I get chances to talk to someone I trust about my personal and family problems					
5. I get chances to talk about money matters					
6. I get invitations to go out and do things with other people					
7. I get useful advice about Important things in life					
8. I get help when I'm sick in bed					

a) What is your age? | | |

b) At what age did you leave full time education? | | |

c) What is the highest educational level you have reached?
(Please tick (✓) as appropriate)

- ☐ I have no formal qualifications
- ☐ GCSE level (CSE or 'O' level or equivalent)
- ☐ 'A' level or equivalent
- ☐ First degree (e.g. BA, BSc) or equivalent
- ☐ Higher Degree (e.g. MSc, PhD)
- ☐ Other (please state) _____

d) What is your home postcode?

a) Are you?

- ☐ Single
- ☐ Married/Living with partner
- ☐ Widowed, divorced and separated
- ☐ Other – please write

e) How many children do you already have?

f) Your date of birth?

Appendix J: 28 week questionnaire

Questionnaire 2

Initials: | | |

Study number: | | | | |

Date completed: | | | | | | |

Support and Reassurance in Antenatal Care (SRAC)

Thank you for agreeing to take part in this study.

Please complete this questionnaire following the instructions given.

All the answers you give are confidential and will not be shared with the hospital

When the questionnaire is complete please return it in the **FREEPOST** envelope provided

Thank you very much,

Vikki Snaith and Cath McParlin
Research Midwives

Directions

A number of statements which people have used to describe themselves are given below.
Read each statement and then tick the appropriate box ☑ to the right of the statement to indicate how you feel **right now**, that is, **at this moment**. 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 present feelings best.

		Not at All 1	Somewhat 2	Moderately 3	Very Much 4
1.1	I feel calm	☐	☐	☐	☐
1.2	I feel secure	☐	☐	☐	☐
1.3	I am tense	☐	☐	☐	☐
1.4	I feel strained	☐	☐	☐	☐
1.5	I feel at ease	☐	☐	☐	☐
1.6	I feel upset	☐	☐	☐	☐
1.7	I am presently worrying over possible misfortune	☐	☐	☐	☐
1.8	I feel satisfied	☐	☐	☐	☐
1.9	I feel frightened	☐	☐	☐	☐
1.10	I feel comfortable	☐	☐	☐	☐
1.11	I feel self-confident	☐	☐	☐	☐
1.12	I feel nervous	☐	☐	☐	☐
1.13	I am jittery	☐	☐	☐	☐
1.14	I feel indecisive	☐	☐	☐	☐
1.15	I am relaxed	☐	☐	☐	☐
1.16	I feel content	☐	☐	☐	☐
1.17	I am worried	☐	☐	☐	☐
1.18	I feel confused	☐	☐	☐	☐
1.19	I feel steady	☐	☐	☐	☐
1.20	I feel pleasant	☐	☐	☐	☐

Here is a list of some things that other people do for us or give us that may be helpful or supportive. Please read each statement carefully and place a tick (✓) in the blank that is closest to your situation.

Here is an example:

	As much as I would like				Much less than I would like
I get enough holiday time		✓			

	As much as I would like				Much less than I would like
1. I have people who care what happens to me					
2. I get love and affection					
3. I get chances to talk to someone about my problems at work or with my housework					
4. I get chances to talk to someone I trust about my personal and family problems					
5. I get chances to talk about money matters					
6. I get invitations to go out and do things with other people					
7. I get useful advice about Important things in life					
8. I get help when I'm sick in bed					

Directions
Again, please read the statements below then tick the box ☑ which best explains how you feel

		Not at all 1	Hardly at all 2	Slightly 3	Fairly 4	Very 5	Extremely 6
3.1	Worried whether the baby will be strong and healthy	☐	☐	☐	☐	☐	☐
3.2	Worried whether the baby will have a physical disability of any kind	☐	☐	☐	☐	☐	☐
3.3	Worried whether the baby will have a mental handicap	☐	☐	☐	☐	☐	☐
3.4	Worried whether the baby will need treatment in hospital before going home	☐	☐	☐	☐	☐	☐
3.5	Worried whether the birth will be difficult	☐	☐	☐	☐	☐	☐
3.6	Worried whether the birth will be painful	☐	☐	☐	☐	☐	☐
3.7	Worried whether the baby will be alright during the birth	☐	☐	☐	☐	☐	☐
3.8	Worried whether I will get to hospital in time for the baby to be born	☐	☐	☐	☐	☐	☐
3.9	Worried whether I will feel attached to the baby after it is born	☐	☐	☐	☐	☐	☐
3.10	Worried whether I will get my figure back after the baby is born	☐	☐	☐	☐	☐	☐
3.11	Worried whether I will be a good mother to my baby	☐	☐	☐	☐	☐	☐
3.12	Worried whether it will be easy to look after my baby when I go home	☐	☐	☐	☐	☐	☐
3.13	Worried whether the amniocentesis/CVB damaged the baby (if applicable)	☐	☐	☐	☐	☐	☐
3.14	Worried whether the ultrasound scans damaged the baby	☐	☐	☐	☐	☐	☐
3.15	Worried whether the blood test at 16 weeks gestation damaged the baby (if applicable)	☐	☐	☐	☐	☐	☐

a) What is your age? | | |

b) At what age did you leave full time education? | | |

c) What is the highest educational level you have reached?
(Please tick (✓) as appropriate)

- ☐ I have no formal qualifications
- ☐ GCSE level (CSE or 'O' level or equivalent)
- ☐ 'A' level or equivalent
- ☐ First degree (e.g. BA, BSc) or equivalent
- ☐ Higher Degree (e.g. MSc, PhD)
- ☐ Other (please state) _____

d) What is your home postcode?

a) Are you?

- ☐ Single
- ☐ Married/Living with partner
- ☐ Widowed, divorced and separated
- ☐ Other – please write

e) How many children do you already have?

f) Your date of birth?

Appendix K: 36 week questionnaire

Questionnaire 3

Initials: | | |

Study number: | | | | |

Date completed: | | | | | | |

Support and Reassurance in Antenatal Care (SRAC)

Thank you for agreeing to take part in this study.

Please complete this questionnaire following the instructions given.

All the answers you give are confidential and will not be shared with the hospital

When the questionnaire is complete please return it in the **FREEPOST** envelope provided

Thank you very much,

Vikki Snaith and Cath McParlin
Research Midwives

Directions

A number of statements which people have used to describe themselves are given below.
Read each statement and then tick the appropriate box ☑ to the right of the statement to indicate how you feel **right now**, that is, **at this moment**. 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 present feelings best.

		Not at All 1	Somewhat 2	Moderately 3	Very Much 4
1.1	I feel calm	☐	☐	☐	☐
1.2	I feel secure	☐	☐	☐	☐
1.3	I am tense	☐	☐	☐	☐
1.4	I feel strained	☐	☐	☐	☐
1.5	I feel at ease	☐	☐	☐	☐
1.6	I feel upset	☐	☐	☐	☐
1.7	I am presently worrying over possible misfortune	☐	☐	☐	☐
1.8	I feel satisfied	☐	☐	☐	☐
1.9	I feel frightened	☐	☐	☐	☐
1.10	I feel comfortable	☐	☐	☐	☐
1.11	I feel self-confident	☐	☐	☐	☐
1.12	I feel nervous	☐	☐	☐	☐
1.13	I am jittery	☐	☐	☐	☐
1.14	I feel indecisive	☐	☐	☐	☐
1.15	I am relaxed	☐	☐	☐	☐
1.16	I feel content	☐	☐	☐	☐
1.17	I am worried	☐	☐	☐	☐
1.18	I feel confused	☐	☐	☐	☐
1.19	I feel steady	☐	☐	☐	☐
1.20	I feel pleasant	☐	☐	☐	☐

Here is a list of some things that other people do for us or give us that may be helpful or supportive. Please read each statement carefully and place a tick (✓) in the blank that is closest to your situation.

Here is an example:	As much as I would like				Much less than I would like
I get enough holiday time		✓			

	As much as I would like				Much less than I would like
1. I have people who care what happens to me					
2. I get love and affection					
3. I get chances to talk to someone about my problems at work or with my housework					
4. I get chances to talk to someone I trust about my personal and family problems					
5. I get chances to talk about money matters					
6. I get invitations to go out and do things with other people					
7. I get useful advice about Important things in life					
8. I get help when I'm sick in bed					

Directions
Again, please read the statements below then tick the box ☑ which best explains how you feel

		Not at all 1	Hardly at all 2	Slightly 3	Fairly 4	Very 5	Extremely 6
3.1	Worried whether the baby will be strong and healthy	☐	☐	☐	☐	☐	☐
3.2	Worried whether the baby will have a physical disability of any kind	☐	☐	☐	☐	☐	☐
3.3	Worried whether the baby will have a mental handicap	☐	☐	☐	☐	☐	☐
3.4	Worried whether the baby will need treatment in hospital before going home	☐	☐	☐	☐	☐	☐
3.5	Worried whether the birth will be difficult	☐	☐	☐	☐	☐	☐
3.6	Worried whether the birth will be painful	☐	☐	☐	☐	☐	☐
3.7	Worried whether the baby will be alright during the birth	☐	☐	☐	☐	☐	☐
3.8	Worried whether I will get to hospital in time for the baby to be born	☐	☐	☐	☐	☐	☐
3.9	Worried whether I will feel attached to the baby after it is born	☐	☐	☐	☐	☐	☐
3.10	Worried whether I will get my figure back after the baby is born	☐	☐	☐	☐	☐	☐
3.11	Worried whether I will be a good mother to my baby	☐	☐	☐	☐	☐	☐
3.12	Worried whether it will be easy to look after my baby when I go home	☐	☐	☐	☐	☐	☐
3.13	Worried whether the amniocentesis/CVB damaged the baby (if applicable)	☐	☐	☐	☐	☐	☐
3.14	Worried whether the ultrasound scans damaged the baby	☐	☐	☐	☐	☐	☐
3.15	Worried whether the blood test at 16 weeks gestation damaged the baby (if applicable)	☐	☐	☐	☐	☐	☐

Please think about the care you have received during you pregnancy and circle the number which best indicates your agreement or disagreement with each of the following statements.

1. **Experience has shown that I can have appropriate and adequate control over my care.**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

2. **The person(s) responsible for my care are/were caring and compassionate**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

3. **Problems that have arisen up to now have been dealt with effectively**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

4. **My needs have been addressed with appropriate consideration for my time**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

5. **The overall organisation of my care has been appropriate**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

6. **I would choose the same type of care for my next pregnancy**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

a) What is your age? | | |

b) At what age did you leave full time education? | | |

c) What is the highest educational level you have reached?
(Please tick (✓) as appropriate)

- ☐ I have no formal qualifications
- ☐ GCSE level (CSE or 'O' level or equivalent)
- ☐ 'A' level or equivalent
- ☐ First degree (e.g. BA, BSc) or equivalent
- ☐ Higher Degree (e.g. MSc, PhD)
- ☐ Other (please state) _____

d) What is your home postcode?

a) Are you?

- ☐ Single
- ☐ Married/Living with partner
- ☐ Widowed, divorced and separated
- ☐ Other – please write

e) How many children do you already have?

f) Your date of birth?

Appendix L: Postnatal questionnaire

Postnatal Questionnaire

Initials: | | |

Study number: | | | | |

Date completed: | | | | | | |

Support and Reassurance in Antenatal Care (SRAC)

Thank you for agreeing to take part in this study.

Please complete this questionnaire following the instructions given.

All the answers you give are confidential and will not be shared with the hospital

When the questionnaire is complete please return it in the **FREEPOST** envelope provided

Thank you very much,

Vikki Snaith and Cath McParlin
Research Midwives

Directions

A number of statements which people have used to describe themselves are given below.

Read each statement and then tick the appropriate box ☑ to the right of the statement to indicate how you feel **right now**, that is, **at this moment**. 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 present feelings best.

		Not at All 1	Somewhat 2	Moderately 3	Very Much 4
1.1	I feel calm	☐	☐	☐	☐
1.2	I feel secure	☐	☐	☐	☐
1.3	I am tense	☐	☐	☐	☐
1.4	I feel strained	☐	☐	☐	☐
1.5	I feel at ease	☐	☐	☐	☐
1.6	I feel upset	☐	☐	☐	☐
1.7	I am presently worrying over possible misfortune	☐	☐	☐	☐
1.8	I feel satisfied	☐	☐	☐	☐
1.9	I feel frightened	☐	☐	☐	☐
1.10	I feel comfortable	☐	☐	☐	☐
1.11	I feel self-confident	☐	☐	☐	☐
1.12	I feel nervous	☐	☐	☐	☐
1.13	I am jittery	☐	☐	☐	☐
1.14	I feel indecisive	☐	☐	☐	☐
1.15	I am relaxed	☐	☐	☐	☐
1.16	I feel content	☐	☐	☐	☐
1.17	I am worried	☐	☐	☐	☐
1.18	I feel confused	☐	☐	☐	☐
1.19	I feel steady	☐	☐	☐	☐
1.20	I feel pleasant	☐	☐	☐	☐

Here is a list of some things that other people do for us or give us that may be helpful or supportive. Please read each statement carefully and place a tick (✓) in the blank that is closest to your situation.

Here is an example:

	As much as I would like				Much less than I would like
I get enough holiday time		✓			

	As much as I would like				Much less than I would like
1. I have people who care what happens to me					
2. I get love and affection					
3. I get chances to talk to someone about my problems at work or with my housework					
4. I get chances to talk to someone I trust about my personal and family problems					
5. I get chances to talk about money matters					
6. I get invitations to go out and do things with other people					
7. I get useful advice about Important things in life					
8. I get help when I'm sick in bed					

Please think about the care you have received during you pregnancy and circle the number which best indicates your agreement or disagreement with each of the following statements.

1. **Experience has shown that I can have appropriate and adequate control over my care.**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

2. **The person(s) responsible for my care are/were caring and compassionate**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

3. **Problems that have arisen up to now have been dealt with effectively**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

4. **My needs have been addressed with appropriate consideration for my time**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

5. **The overall organisation of my care has been appropriate**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

6. **I would choose the same type of care for my next pregnancy**

Strongly disagree						Strongly agree
1	2	3	4	5	6	7

Appendix M: Questionnaire covering letter

Dear

Thank you very much for agreeing to take part in the **Support and Reassurance in Antenatal Care** study when you attended the Royal Victoria Infirmary for the scan of your baby.

We have enclosed the second questionnaire together with a **FREEPOST** envelope. I would be very grateful if you could complete the questionnaire as soon as you are able and return it in the envelope provided.

If you make any extra telephone calls to your midwife, doctor or the hospital, please make a note of them in your maternity notes (pages 17 – 18).

Please do not hesitate to contact either Cath or Vikki if you have any questions or concerns.

Yours faithfully,

Vikki Snaith & Cath McParlin

Vikki Snaith and Cath McParlin
Research Midwives
Tel: (0191) 2820362

Appendix N: Ethical approval letter

Newcastle and North Tyneside Local Research Ethics Committees
Room G14
The Dental School
Framlington Place
Newcastle upon Tyne
NE2 4HH

Tel: 0191 222 3581
Fax: 0191 222 3582
Email: anne.taylor2@ncl.ac.uk

Our ref: JL//AT/2003/208
Your ref:

23 January 2004

Ms V Snaith
Research Midwife
Newcastle Hospitals NHS Trust
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
NE1 4LP

Dear Ms Snaith

Women's Adherence to Antenatal Visits
Ref 2003/208

Thank you for your letter of 12 January 2004 which addresses the issues identified by the Ethics Committee when it considered your application in respect of this study.

In the light of your response I can now confirm the grant of ethical approval in respect of your research study application.

You should not, however, undertake this research in an NHS organisation until the relevant NHS management approval has been gained as set out in the Framework for Research Governance in Health and Social Care.

Yours sincerely

pp **Dr Jane Lothian**
Chair
Local Research Ethics Committee

2003-208-040123

An advisory committee to Northumberland, Tyne and Wear Strategic Health Authority

Appendix O: Interview Schedule

Schedule for Semi Structured Interview

- Introduction of researcher and recap the purpose of the study.
- Acknowledge that the interview will be confidential

Focus of Questions

1. Do you feel satisfied overall with the antenatal care that you received?

Which aspects were you particularly satisfied/dissatisfied with?

2. Was your antenatal care the same as you expected it to be?

Number of visits ☐
Caregiver ☐
Purpose ☐
Content/Information ☐
Opportunity to talk ☐
Timing ☐

3. Is there anything you would like to change about the care you received?

What would you change?

Appendix P: Example of indexing framework

Participant	Views of antenatal classes	Preparedness for motherhood	Other support	UADS	Views of ultrasound scans	TSI
581 D	The lady was fantastic. She was so informative and really upbeat about it all and by that point you're quite pregnant and you think 'shit, I'm going to have push this baby out' and I was beginning to get a bit nervous about it and we were looking round the hospital, like round the department and she was very nice and all the staff were saying hi to her and everything, you know really nice, really friendly oh this will be a really good experience and I was quite looking forward to it, and then we went to the second one and it was a different lady she was just a little bit negative about the department and saying how she'd seen people come in and sort of have to have their baby in the bit where you go, the assessment bit	Like I don't think you're really prepared for looking after a baby either. That would be really useful I think for somebody to tell you about it was a bit of a shock I think and another thing I was going to say, I don't think people really prepare you for how poorly you'll feel Like I don't think you're really prepared for looking after a baby either. That would be really useful I think for somebody to tell you about.	a friend of mine had just had her baby, it's seven months old, so she's been my sort of link.	when I was having my scan it was all positive as well at the time, and she said "oh no its really good, the baby was really good" and then I had chance to see the little person again which was quite nice and have the blood flow and hear it all swooshing around and its quite reassuring I think. And I think it was quite positive, you know? I wouldn't think you'd feel…I wouldn't feel the need to have one separately, but if you were having it done…its quit nice to know that they're getting fed properly and…isn't it? That reassurance	I think it kind of, because I know your body's changing all the time but you don't, well I didn't feel that I really sort of put a person into that. It was like it was still me getting fat rather than there being somebody growing inside me and when you see the scan you see like somebody moving around, little heartbeats and little spines and, oh wow. I think it was really important actually and I think it probably makes you look after yourself as well because you think you've got to look after somebody else too.	It was quite interesting because the lady again, that I spoke to, I'm not sure whether she was a doctor or a midwife, maybe she was a midwife actually, and she was really informative It was really nice actually. It was nice to speak to somebody and I can't even remember what the questions she asked me were. So I probably whinged on to her about how miserable I was feeling at the end of my pregnancy. I think it's probably better ringing you. Because I think people, you don't want to admit that you feel rubbish do you? You know, you think, 'I'm having a baby. It's meant to be the most wonderful, splendid thing of my life. I'm meant to be joyous' but yeah, I really don't think people come forward with that information very much do you?

Appendix Q: Charting matrix – Relationship with midwife

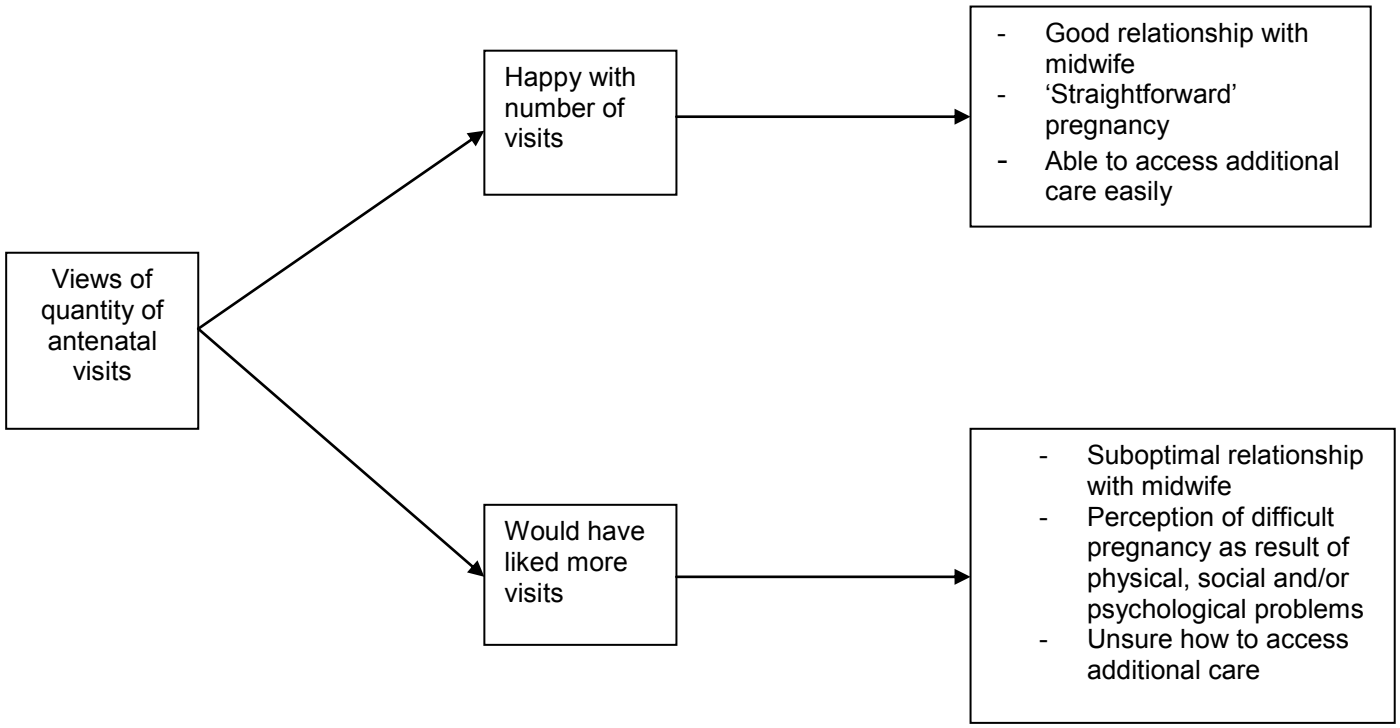
Particp	Age	Educ level	Personality of midwife	Information provision	Individualised approach	Continuity	Normalising of experience	Acknowledgement of event
581D	31	A level	All midwives were pleasant	Good provision of information	Would be nice to have someone to talk to, to say I'm not feeling great today	Lack of continuity but not a problem	Good to be told nothing to worry about	
671D	26	GCSE	Didn't help me sort out classes	Lack of timely information about classes	Not enough time for questions			Didn't feel like I was given the support required for my first baby
689D	37	GCSE	Easy to talk to	Knowledgeable			Put mind at rest	
646D	26	A level	Unhelpful, forgetful	Kept forgetting things that she should have told me	No time to chat, too rushed. Didn't remember things from previous visits		Made to feel stupid when asking if things were normal	Not helpful, I didn't know what to expect as a first time mum
602D	32	Degree	Quite matter of fact	Not sure how to get hold of midwife out of hours				First pregnancy is 'massive deal', visits were shorter than imagined
653D	27	A level	Approachable, lovely			Shame I didn't see her after birth		
613D	32	A level	Nice		Remembered what I did for a living, me as a person	Got to know her as time progressed		
603D	32	Higher degree			Able to contact midwife easily	Saw same midwife throughout		Dismissive of illness
614D	21	GCSE				Same midwife AN and PN		
610D	32	A level	Straight forward	Excellent information provision	Able to contact midwife	Number of different midwives		
612D	40	Degree	Fantastic, very supportive	Provided me with all the information I needed		Saw same midwife		

621D	34	GCSE	Lovely, experienced	Preparation for outcome	Came to see me with student after birth	Saw her all the way through and PN		
625D	32	GCSE	Very helpful					
633D	19	GCSE	Really good to talk to. I didn't feel uncomfortable		Talked about 'normal' stuff – non pregnancy issues			
703I	24	GCSE	Blunt	Lack of information				
695I	35	GCSE				Important for building up good relationship		
727I	20	GCSE	Getting on, would prefer younger midwife		Wasn't treated as individual	Lack of continuity resulted in being sent up to hospital		
743I	24	GCSE	Older midwife like 'mother hen' – looked after me					
631I	27	A level		Performed role appropriately				
622 I	30	Degree	Really good	Answered questions, reassuring				
637I	28	Degree			Only discussion of physical health			
635I	32	A level				Had to keep repeating myself	Insufficient time to ask if 'normal'	I'd never had baby before
604I	25	A level	Easy to get on with	Comfortable asking questions				

617I	27	Degree	Brilliant, lovely	Reassuring		Lack of continuity not a problem		
630I	23	Degree	Everyone was calm and friendly	Reassuring	Felt as though they had lots of time for me, could talk to them about anything	Different midwives but all really nice so didn't matter		
615I	27	A level	She was like me – personality. Approachable	Didn't use medical terminology so that I understood	Recognised me in street and waved			
586I	19	GCSE		Didn't discuss all relevant issues	Didn't do my birth plan			
651I	23	GCSE	Quite nice		Booked out of area so midwives weren't familiar with hospital - irritating			
605C	23	A level	Didn't feel comfortable discussing personal issues	Able to contact midwives if needed to	Midwives had to keep reading through notes	Someone different every week, didn't feel comfortable		
606C	34	A level	Lovely		Did read notes before seeing			
628C	28	GCSE	Very nice and helpful					
509C	32	Degree	Supportive and personable	Felt I could go to her, imperative			Didn't make me feel stupid for asking questions	
530C	31	GCSE	Made to feel at ease	Happy to answer 'daft' questions			First pregnancy don't know what to expect	
523C	35	Degree	Didn't feel listened to, felt vulnerable and didn't want to annoy her		Didn't get to know midwife, different one every time	Lack of continuity – no-one actually knew me		

593C	31	Degree	Knew what they were doing			Should have told me she was going to be on holiday		
555C	34	Higher degree	Great	Midwife made issue out of fact that I wasn't booked at local hospital	Care wasn't individualised in relation to content	Didn't feel continuity was necessary but did get to know midwife better during pregnancy		Got taken more seriously as pregnancy progressed
539C	32	GCSE	Happy, smiley		difficult to ask questions	Didn't know midwife very well,		
562C	32	Degree	Brilliant, caring		Developed bond	Same midwife throughout		
649C	33	GCSE			Discussed anything I wanted	Remembered you without looking at notes		
588C	22	GCSE	Old lady, nice to talk to	Felt down I would have liked to talk to someone sometimes			Could have done with more support, was worried	
608C	32	Degree	Common ground, similar stage in lives		Presence of students prevented disclosure of feelings	Important to have continuity to build up relationship with midwife		Would be nice if importance of pregnancy was identified – excited and scared
643C	33	GCSE	Really good, nice			Saw more than 1 midwife – all good		

Appendix R: Example of mapping and interpretation diagram for quantity of antenatal visits



Appendix S: Deverill et al 2010 publication

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Antenatal care for first time mothers: a discrete choice experiment of women's views on alternative packages of care

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ABSTRACT

Objective: To investigate the views of women in relation to the provision of antenatal care.
Methods: A discrete choice experiment using a sample of 100 women who were nulliparous (pregnant for the first time) and attending for routine ultrasound scan in the 20th week of their pregnancy.
Results: Women preferred antenatal care visits to be provided by a community midwife at a local clinic and to have 10 visits rather than 7. In addition they favoured the provision of education/preparation for birth, the use of uterine artery Doppler screening, and the provision of a telephone advice line. The results show that women were prepared to trade-off fewer antenatal care visits to ensure access to their packages of antenatal care that reflected their preferences.
Conclusions: Whilst the number of antenatal care visits is important to women they may accept fewer visits if antenatal care is provided by midwives and they receive enhanced service provision such as a telephone advice line and uterine artery Doppler screening.

1. Introduction

In 2003 the UK National Collaborating Centre For Women's Health (NCCWCH) issued guidance on routine care for healthy pregnant women. Both midwife-led and GP-led models of care were recommended and it was stated that the place of care used should be 'sensitive to the needs of individual women and the local community' [1]. More recently the key role of choice in determining the type of antenatal care was strongly endorsed in the Department of Health policy document, 'Maternity Matters' [2]. Based on two systematic reviews of the effectiveness of a reduced number of antenatal care appointments [3,4], the NCCWCH guidance recommended that nulliparous women receive a total of 10 appointments. Eight of these visits were after 24 weeks gestation with a focus on screening for pre-eclampsia and fetal growth restriction (FGR). Fewer visits (7 in total, 5 after 24 weeks) were recommended for healthy parous women, recognising their lower risk of complications, particularly pre-eclampsia [5]. In making these recommendations the NCCWCH acknowledged that the strategy of reduced appointments may reduce women's satisfaction with care and lead to poorer psychosocial outcomes.

'Maternity Matters' [2] promised women the choice of type of antenatal care. Key to implementing this national choice guarantee is to understand women's preferences about antenatal care. NCCWCH [1] highlighted the lack of economic studies estimating women's valuation of antenatal care. Using a willingness-to-pay (WTP) survey for different types of care, Ryan et al. [6] found women in Aberdeen were prepared to pay the same for GP/midwife-led care as consultant-led care.

Another method increasingly used to investigate preferences for health care treatments and services is discrete choice experiments (DCEs) [7,8]. DCEs use the notion that an individual's preferences for care depend on the nature and level of the attributes that describe that care [9]. DCEs present hypothetical scenarios describing programmes in terms of their attributes and asking respondents to choose between scenarios. The choices are modelled using econometric theory to investigate respondents' preferences for the health programme of interest. This methodology has been previously used within obstetrics [10–12]. In the context of antenatal care DCEs assess the relative importance of different care attributes and the way in which women are willing to make trade-offs amongst these attributes.

In response to the NCCWCH call for further research into alternative methods of providing antenatal information and support this we conducted a randomised trial (Support and Reassurance in Antenatal Care (SRAC) Trial) addressing the clinical impact of introducing telephone support (at 29, 33 and 37 weeks

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gestation) with or without uterine artery Doppler screening (at 20 weeks gestation) in healthy nulliparous women. A telephone support line provides a convenient form of contact that allows women to receive support and advice whilst in their own surroundings [13,14]. Compared to clinical risk factors, uterine artery Doppler improves prediction of pre-eclampsia and fetal growth retardation and may better inform women and their caregivers about the optimal frequency and timing of antenatal appointments [15,16]. In the study reported here we conducted a DCE in a cohort of women participating in the trial to investigate preferences and values for six attributes of antenatal care.

Attribute	Package A	Package B
Type of care provider and place	Consultant at hospital	Community midwife at a local clinic
Payment towards the total costs of antenatal care	£0	£500
Number of antenatal visits	Ten	Seven
Content of visits	Check up on mother's and baby's health and preparation for birth	Check up on mother's and baby's health
Telephone advice line	Yes	Yes
Doppler screening	No	Yes

Fig. 1. Example of DCE choice set.

2. Materials and methods

2.1. Study sample

One hundred healthy nulliparous women with a singleton fetus were recruited from the obstetric ultrasound department at the Royal Victoria Infirmary, Newcastle upon Tyne, UK. The study group was a convenience subsample of women enrolled in the Newcastle SRAC Trial who were attending for their routine 20-week fetal anomaly scan. All the women in the trial were low risk according to NCCWCH criteria [1]. We excluded women who did not speak English. The DCE was administered after the 20-week scan during a 20–30 min interview in the antenatal clinic room. All women gave informed written consent and the study was approved by the Joint Ethics Committee of Newcastle upon Tyne Health Authority and the University of Newcastle.

2.2. DCE design and attributes

Table 1 shows six attributes and levels describing the antenatal care packages after the 20th week of pregnancy. The chosen attributes were based on the literature review and with regard to current antenatal care programmes. They address the number of visits, the place, provider and content of the visits as well as additional telephone support and uterine artery Doppler screening at 20–24 weeks. The attributes were discussed with a sample of pregnant women to gauge whether they covered the main aspects of antenatal care and if any other key factors important in provision of care were missing; no attributes were added after the pilot survey. Payment was included to calculate women's marginal willingness-to-pay for the inclusion of aspects of care such as the provision of a telephone advice line [17].

As described in Table 1, the experiment included two attributes with four levels and four attributes with two levels, a total of 256 ($2^4 \times 4^2$) possible combinations of attributes, or 'antenatal care scenarios'. As this number is too many to be considered by any one individual an orthogonal fractional factorial design was used [18] to reduce the statistically required number of scenarios to 32.

In order to present respondents with a set of choices between scenarios (A and B) the 32 scenarios were used as option A. These 32 scenarios were 'rolled over', meaning the attribute levels in the original 32 combinations were shifted up one level (level 0 became level 1, 1 became 2, 2 became 3 and 3 became 0) to produce 32 additional scenarios (option B) which were randomly allocated to each of the original 32 scenarios (option A) to produce 32 choice

Table 1
Antenatal care attributes and levels.

Attribute	Description	Levels
Type of care provider and place	Describes who will provide the antenatal care	Consultant at hospital GP at local surgery Community midwife at local clinic Community midwife at your home
Payment towards the total costs of care	An indication of a cost you would face if you chose that package.	£0 £500 £1000 £1500
Number of appointments	The number of times that you would attend for antenatal care	7 visits 10 visits
Content of carer visits	A description of what care you will be given over the course of the time that you attend	Usual check ups on your health and your baby's health Usual check ups plus preparation for birth (consisting of education for expectant mothers to learn about pregnancy and labour) and opportunity to ask questions and raise concerns about the birth of your baby
Telephone advice line provided	A telephone call service that allows you the opportunity to ask questions and raise concerns about your pregnancy to a qualified midwife	Yes No
Doppler screening provided	A scan of blood flow to the womb to check the development of the afterbirth. This shows if certain problems in later pregnancy, such as high blood pressure or having a small baby at birth, are more likely to occur. If the scan is NORMAL it indicates that your risk of getting these problems is very low.	Yes No

sets. The 32 choice sets were further divided into two bundles of 16 with respondents randomly allocated to one of the two bundles so that each respondent was presented with 16 choice sets. Fig. 1 shows an example of a choice set, in which respondents were asked to indicate a choice of A, B, or neither.

2.3. Econometric analysis of the data

DCEs draw upon Lancaster's economic theory of demand, which suggests people consume health programmes such as antenatal care because of the characteristics that make up the product/programme [19], and random utility theory, which suggests that the utility (or value) received from a programme comprises of an explainable component and a random component [20,21]. Eq. (i) shows that the utility U_{iq} for the ith alternative (antenatal care package) for the individual q is made up of two components

$$U_{iq} = V_{iq} + \varepsilon_{iq} \quad \text{(i)}$$

where V_{iq} is the explainable, or observable, part of utility, and where ε_{iq} is the random component that represents the unobservable influences that affect utility and are assumed not to be related in any systematic way to the observable part.

In undertaking a DCE, the objective is to model the scenario choices made by the sample of respondents to determine which attributes are important in the choice of antenatal care packages. This is done by estimating V_{iq} from Eq. (i) as a function of the attribute levels characterizing antenatal care which we label X_1–X_6

$$V_{iq} = \beta_1 X_1 + \beta_2 X_2 + \beta_3 X_3 + \beta_4 X_4 + \beta_5 X_5 + \beta_6 X_6 \quad \text{(ii)}$$

where the coefficients β_1–β_6 are estimated in the model and represent the influence each attribute has on the choice of antenatal care package. In order to estimate the choice model we need to assume a distribution for the random term ε_{iq}. By making assumptions about the distribution of the data we estimate Eq. (i) as a multinomial logit (MNL) model [9]. In the results below we examine the trade-offs that women would make between care attributes when choosing an antenatal care package by calculating the marginal rate of substitution (MRS) which quantifies how much of one attribute women in our sample were prepared to give up to obtain more of another attribute. For the model described in Eqs. (i) and (ii), the MRS between two attributes is calculated as the ratio of the coefficients on those two attributes [9].

All analysis was carried out using Stata 8.0 software [22].

3. Results

3.1. Sample demographics

The mean age of the sample was 27.8 (SD 5.3 years) years compared with a mean age of 27 years for the full trial sample. Other demographic details of the DCE sample are shown in Table 2 along with available demographics for the full trial sample. This data shows that whilst we did not record specific data on the women who declined to take part in the DCE study there was little difference between the DCE sample and the whole trial sample.

3.2. Regression results

Table 3 shows the results of the main effects analysis [9] and thus indicates which of the attributes had a significant impact on the choice of care package.

For the analysis the data were coded using effects codes except for payment which was mean centred [9]. This coding system has clear advantages over the alternative system of using dummy coding [23].

Table 2
Demographic details of study sample (n = 100).

Maximum Education Level	% of DCE respondents (% for whole trial sample)
GCSE	22 (27)
A levels or BTEC, GNVQ	32 (26)
Degree	28 (31)
Post-graduate	18 (10)
Missing	0 (6)
Marital status	
Single	10 (6.5)
Married or cohabiting	90 (83.5)
Missing	0 (10)
Income level[a]	
<£15K	39
£15,001–£20,000	23
£20,001–£30,000	23
£30,001–£40,000	9
>£40,001	6

Family Expenditure Survey was £20,534. The mean income level in the North-east region is lower than the UK mean and is reflected in the reported income levels in our sample. NB: details of income were not collected routinely for whole trial sample.

[a] The mean income level in the UK for 2005 according to the UK.

All coefficients are significant at the 5% level except where care is provided by a GP at a local surgery. For provision of care the positive sign and size of the coefficient for 'community midwife at local clinic' suggests that this is the preferred type and place of care provider. The significant negative coefficient on the payment attribute is in suggests that women prefer to pay lower rather than higher amounts for antenatal care (which has face validity). The

Table 3
Regression results.

Variables	Regression coefficient (95% CI)	P value
Care provider/place		0.000
Consultant at hospital	−0.3111(−0.4652 to 0.1570)	0.693
GP at local surgery	−0.0267 (−0.1594 0.1060)	0.000
Community midwife at local clinic	0.3329 (0.18147 0.4844)	
Community midwife at your home[a]	0.0049	
Payment (mean centred)	−0.0015 (−0.0017 to 0.0013)	0.000
Number of visits		
Seven	−0.0852 (−0.1688–−0.0014)	0.046
Ten	0.0852	
Content of visits		
Usual care	−0.2219 (−0.3102 to 0.1337)	0.000
Usual care and preparation for birth	0.2219	
Telephone advice line		
Provided	0.3689 (0.2866 to 0.4513)	0.000
Not provided	−0.3689	
Uterine artery Doppler screening		
Not provided	−0.3022 (−0.3858 to 0.2186)	0.000
Provided	0.3022	
No. of observations	4770	
LR statistic	552.17	
Pseudo-R^2	0.1581	

NB respondents preferred attribute options are those that are underscored.

[a] It should be noted that when using effects codes the coefficient for the 4th level of the care provider attribute is found by calculating the negative sum of the 3 coefficients shown, hence the coefficient for care provided by a community midwife at a patient's home is 0.05.

Table 4
Marginal rates of substitution between the number of antenatal care visits and other attributes.

Preferred attribute level	Number of visits women prepared to sacrifice to get preferred service attribute
Midwife at local clinic	3.91 (0.332/−0.085)
Usual check ups *and* preparation for birth	2.60 (−0.221/−0.085)
Telephone advice line provided	4.33 (0.368/−0.085)
Doppler screening provided	3.55 (−0.302/−0.085)

NB: the absolute values of the calculated ratios are shown; the figures in parentheses show the calculation of the MRS whereby the regression coefficient for each attribute shown in Table 3 is divided by the regression coefficient for the number of visits.

negative coefficient signs on the remaining four attributes show that women prefer the following options; 10 rather than 7 antenatal visits, the provision of education/preparation for birth over no such provision, the provision of uterine artery Doppler screening, and a telephone advice line over no such provision.

3.3. *Marginal rates of substitution (MRS)—trade-offs between service attributes and willingness-to-pay*

We were interested in the number of antenatal care appointments that women would be prepared to give up to obtain their preferred level of four service attributes and these trade-offs are shown in Table 4. The second column shows the number of antenatal care appointments that women would be prepared to give up in exchange for moving to the preferred level of the attributes as shown in column one. For example, women would be prepared to give up 4.33 visits to gain access to a telephone advice service. The fact that they would be prepared to give up marginally fewer visits to access Doppler screening etc. reflects the relative size of the main effects coefficients for the attributes shown.

Table 5 shows the MRS between antenatal care attributes and payment, thus showing the sample's marginal WTP for attribute changes indicated in the last column. Women were prepared to make the largest payment (£368) to gain access to a telephone advice line. Of the five attributes in Table 5 the one considered the least important in terms of the MRS with payment is for the number of visits to be increased from 7 to 10 (£85).

4. Comments

This study adds to the existing literature on healthy women's preferences with regard to the provision of antenatal care. The findings suggest that low risk nulliparous women prefer their antenatal care to be provided by a community midwife in a local clinic with 10 rather than 7 appointments. We also show the trade-offs women would make in the number of appointments to gain access to other preferred aspects of antenatal care. These results are important in the light of the recent policy changes to antenatal care [1,2].

Table 5
Marginal rates of substitution between the payment and other attributes.

Preferred attribute level	Payment women willing to make to get preferred service attribute
Midwife at local clinic	£332 (0.332/−0.001)
10 visits	£85 (−0.085/−0.001)
Usual check ups *and* preparation for birth	£221 (−0.221/−0.001)
Telephone advice line provided	£368 (0.368/−0.001)
Uterine artery Doppler screening provided	£302 (−0.302/−0.001)

NB: the figures in parentheses show the calculation of the MRS whereby the regression coefficient for each attribute shown in Table 3 is divided by the regression coefficient for payment.

The finding that women prefer antenatal appointments locally with midwives contrasts with the previous study by Ryan et al. [6] which reported that women were prepared to pay £2500 for antenatal care with no significant difference between GP/midwife-led care and obstetrician-led care. However, Ryan et al. [6] included nulliparous *and* multiparous women, possibly accounting for the difference in findings; nulliparous women are known to have differing informational needs compared with parous women [24]. Midwife/GP and obstetrician-led care have been shown to result in similar clinical outcomes [1], although there are possible differences in the detection rate of specific complications. Khan-Neelofur et al. [25] reported that detection rates of hypertension, pre-eclampsia and fetal malpresentation were lower with midwife/GP-led care than hospital based care. Although women are satisfied with care packages led by midwives/GPs or hospital consultants, they state greater satisfaction with midwife-managed care [26], as it provides them continuity [27,28].

The NCCWCH guidance recommended the scheduled number of antenatal appointments for low risk nulliparous women should be reduced to ten. The present findings, that 10 appointments were preferred to a more reduced programme, is consistent with a previous trial that found women's psychological needs were not met as effectively with a reduced visit programme (7 visits versus 13 visits) and they were less satisfied with the care they received [29]. Although Clement et al. [30] suggested that parity was not a predictor of satisfaction with standard and reduced programmes of care, it is interesting that nulliparous women were more likely to decline participation in the trial reported by Sikorski et al. [29] As highlighted by the authors, this may reflect nulliparous women's reluctance to consider a reduced pattern of care because of their need for greater support, information and reassurance. While our results indicate that women judge the number of visits to be an important factor in their care, this is less important than other attributes included in our model such as the provision of a telephone advice service. Consistent with this they were willing to pay relatively little to increase the number of visits from 7 to 10 compared with the amounts they were prepared to pay for the provision of a telephone advice service or uterine artery Doppler screening. Thus a further reduction in the number of care visits (from 10 to 7) may be viewed as tolerable if additional support and reassurance are made available.

Telephone contact, as a means of delivering health care, has been shown to be useful for the proactive contact of those with limited access to services (e.g. because of transport or geographical difficulties) and to reduce the number of face to face encounters with women [13,14]. Telephone contact is one means by which pregnant women can be provided with information, support and reassurance in their own surroundings without increasing the number of scheduled visits [31]. Sikorski et al. [29] reported that 86% of pregnant women stated that they would welcome telephone contact with a midwife. In the SRAC trial an experienced midwife contacts healthy primiparous women at 29, 33 and 37 weeks' gestation. This provides an opportunity for women to ask questions and raise concerns about their pregnancy. It is noteworthy that women in our sample were prepared to reduce the number of appointments by more than 4 and pay a sum of £368 to have a telephone support service provided.

Uterine artery Doppler screening at 20–24 weeks provides women and their caregivers with information about the risk of subsequent pre-eclampsia, fetal growth retardation and fetal death due to poor placentation. The 2003 NCCWCH guidance, based on a systematic review [32], concluded that uterine artery Doppler should not be offered routinely in healthy women. An updated systematic review [16] suggested that uterine artery Doppler is a

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