Multi-site implementation of a promising innovation in low income communities: support for childbearing women

Final Version 1.0
21st September 2012

Short title:	Multi-site evaluation of a volunteer doula service
NRES reference:	12/WM/0342
Trial Sponsor:	University of Nottingham
Sponsor reference:	12099
Funding Source:	NIHR Service Delivery and Organisation programme now incorporated into NIHR HS & DR programme

STUDY PERSONNEL AND CONTACT DETAILS

Sponsor:
Contact name

University of Nottingham
Mr Paul Cartledge
Head of Research Grants and Contracts
Research and Graduate Services
King's Meadow Campus
Lenton Lane
Nottingham
NG7 2NR

Chief investigator:

Professor Helen Spiby
Professor in Midwifery
School of Nursing, Midwifery and Physiotherapy
A Floor, Queen's Medical Centre
University of Nottingham
Nottingham, NG7 2RD
Phone: 0115 8230820
Fax:
Email: helen.spiby@nottingham.ac.uk

Co-investigators:

Professor Josephine Green
Professor of Psychosocial Reproductive Health
Mother and Infant Research Unit
Department of Health Sciences
Area 4, Seebohm Rowntree Building
University of York, Heslington
YORK, YO10 5DD
Phone: 01904 321823
Fax:
Email: jo.green@york.ac.uk

Dr Helen Duncan
Programme Director, ChiMat
Health Data Analyst
Yorkshire and Humber Public Health Observatory
Innovation Centre
York Science Park, Heslington
YORK, YO10 5DG
Phone: 01904 567652
Fax:
Email: helen.duncan@york.ac.uk

Ms Julie Scarfe
Head of Midwifery
Midwifery
St James Hospital and Leeds General Infirmary
Leeds Teaching Hospitals NHS Trust

Beckett Street
Leeds, LS9 7TF
Phone: 0113 2064636
Fax:
Email: Julie.Scarfe@leedsth.nhs.uk

Jenny McLeish
Voluntary Sector advocate
Phone: 01904 321832
Fax:
Email: jkmcleish@yahoo.co.uk

Associate Professor Murray Smith
Faculty of Science
Room C02 Pharmacy
University Park
University of Nottingham
Nottingham, NG7 2RD
Phone: 0115 9516236
Fax:
Email: murray.smith@nottingham.ac.uk

Study Coordinating Centre: School of Nursing, Midwifery and Physiotherapy
University of Nottingham

SYNOPSIS

Title	Multi-site implementation of a promising innovation in low income communities: support for childbearing women
Short title	Multi-site evaluation of a volunteer doula service
Chief Investigator	Professor Helen Spiby
Objectives	To answer four broad questions: What are: Q1: the implications for the NHS of a volunteer doula service for disadvantaged childbearing women? Q2: the health and psychosocial impacts for women? Q3: the impacts on doulas? Q4: the processes of implementing and sustaining a volunteer doula service for disadvantaged childbearing women?
Study Configuration	Multi-site study at five sites
Setting	NHS maternity services and Third Sector organisations
Sample size estimate	Sample size estimation is not appropriate. The sample is dictated by the participants available for each constituency.
Number of participants	Based on information from sites, 15-20 service staff (3-4 at each site), 5 local champions, 5 commissioners, 5 Heads of Midwifery, 30-40 midwives (6-8 in each of 5 focus groups), maximum 600 women referred to the service, maximum 160 volunteer doulas.
Eligibility criteria	Involvement with the volunteer doula service (e.g. local champion, staff, doula, referred for support) or professional role (e.g. midwife, Head of Midwifery, commissioner).
Description of interventions	This is an evaluation of an existing service, not an intervention study. Participants will be invited to participate in at least one of the following: questionnaire, focus group, individual interview.
Duration of study	The study will take place over 18 months. Participant's duration of involvement is as follows: service staff (two interviews or focus groups each lasting approx. 1.5 hours, up to one year apart); local champions, commissioners, Heads of Midwifery (one telephone interview, approx. 1 hour); midwives (one focus group, approx. 1 hours); women referred to the service (any combination of the following:

	questionnaire lasting up to 20 minutes, focus group lasting approx. 1.5 hours, telephone interviews lasting up to 0.5 hours); volunteer doulas (questionnaire lasting up to 0.5 hours, with a minority additionally taking part in a focus group (1.5 hours, anticipated n=8) or a follow-up telephone interview (up to 0.5 hours, anticipated n=10).
Outcome measures	Clinical and public health outcomes for women and babies (e.g. mode of delivery, breastfeeding rates) will be collected using the anonymised service database and compared with reference groups. Data collection with women will include experiences of the service and impacts on use of healthcare and other statutory services. Data collection with doulas will include experiences of the service and impacts for the doulas, women and wider community.
Statistical methods	The economic evaluation will take an incremental analysis approach. Questionnaire data will be analysed using SPSS for descriptive statistics (means, frequencies etc), and exploring similarities and differences within the sample as sample size allows.

ABBREVIATIONS

ChiMat	national Public Health Observatory for Children and Maternity
CI	Chief Investigator overall
Doulas	Volunteer doulas
HoM	Head of Midwifery
ICF	Informed Consent Form
KI	Key Informants
NHS	National Health Service
PI	Principal Investigator at a local centre
PIL	Participant Information Leaflet
REC	Research Ethics Committee
R&D	Research and Development department
SAE	Stamped addressed envelope (for return of questionnaires)
Women	Women referred to the service (unless stated otherwise)

TABLE OF CONTENTS

STUDY BACKGROUND INFORMATION AND RATIONALE

Background and contribution of existing research:

The maternal mortality rate for disadvantaged women[1] is higher than for the general population[1]. Similarly, for babies born to disadvantaged women, the chances of dying around birth or within the first month of life are higher than for babies of women who are not in adverse circumstances[2]. Disadvantaged women have higher rates of smoking and formula feeding than other population sub-groups and are less likely to access routine services for themselves and their babies. Barriers include a lack of access to appropriate services (e.g. for very young women and their partners), lack of staff training in culturally-appropriate care, and a lack of knowledge among health professionals about relevant interventions and services that they could refer to. Recently published guidance for service provision for pregnant women with complex social factors recommends that such barriers are addressed; multi-agency working should be supported and the care provided by different agencies integrated[3].

Support and care in pregnancy, labour and postpartum have a positive impact on women's wellbeing and outcomes including reduced operative birth and increased breastfeeding rates. In the UK, the provision of intra-partum support has traditionally been the role of the midwife. However, current midwifery staffing levels are low and it is challenging to provide women with the ongoing support they need in these vulnerable and formative months. There is evidence that a significant proportion of women are worried by feeling unsupported by healthcare professionals during at least part of their labour[4]. This lack of support is often due to high workloads on busy labour wards and is unlikely to improve in the medium term, given the demographic profile of the midwifery workforce with a high number of retirements anticipated in the next ten years. It is also recognised that services can offer care that is somewhat fragmented, with little coordination between midwives, health visitors, GPs, and social services, all of whom are likely to be involved in the care of families during pregnancy, birth and the early postpartum weeks. Such support and coordinated care is likely to be especially important in low income communities and for young women, as women in these circumstances have lower rates of breastfeeding, increased rates of infant mortality, and are more vulnerable to problems with emotional and psychological wellbeing[2].

The proposed research aims to examine an award-winning innovative social enterprise service that has been established in one city, Hull, and that is now rolling out to other sites. Based on principles derived from controlled studies conducted in other countries, the Hull Goodwin Doula Project offers lay support to women in vulnerable circumstances with the aim of enhancing support and improving the uptake of existing health and social services.

The lay support is offered by volunteer 'doulas', a term to denote a woman who supports other women during pregnancy, birth and breastfeeding. The role is not one of a clinical professional, but of a trained lay supporter and does not include the support provided by female members of the woman's own family. Doulas offer emotional and physical support and companionship, and facilitate communications between the woman, her partner and healthcare professionals and services[5]. In some situations, doula support may also include guidance with parenting. There is a substantial evidence base, derived from randomised controlled trials and other studies conducted in a diverse range of settings and systems, in

[1] A wide definition of disadvantage is adopted here to include social deprivation, low income, social isolation, lone parenting, teenage parenting, drug or alcohol use, asylum seekers and refugees, mental illness, domestic abuse and safeguarding.

countries including South America, the US, Sweden, Finland and Belgium, that have demonstrated the benefits of doula support for childbearing women and their families. However there is no contemporary evidence derived from UK settings.

Existing evidence base

In preparation for this grant application, we conducted a rapid review of studies of 'doula support' including systematic searches on the following databases: Medline, Embase, Cochrane and CINAHL. The search was not limited by country, date, methodology or language.

Support during labour from trained doulas is associated with reduced length of labour[6], less pharmacological pain relief and oxytocin augmentation and fewer instrumental or operative births[7]. All of these are important outcomes for women and their babies and reflect the QIPP Quality Metrics. In particular, instrumental and operative births are associated with increases in the risk of morbidity for women or their babies. This morbidity includes postpartum haemorrhage[8], genital tract trauma for the mother[9] and increased risk of intracranial haemorrhage for babies[10].

In addition to positive impacts on labour outcomes, there is also evidence of positive impacts on breastfeeding[11], including increases in the proportion of women initiating breastfeeding and continuing with exclusive breastfeeding[12]. It is particularly noteworthy that these positive impacts have been achieved in groups where rates are frequently lower than national figures, including low income, first time mothers. These findings reflect the wider evidence base of breastfeeding support by peers[13] and resonate with contemporary policies that encourage the implementation of peer support for breastfeeding[14].

Positive benefits on women's psychosocial well-being include more positive feelings about labour and less anxiety[12], increased feelings of control[15] and confidence as a mother and fewer women experiencing postpartum depression and anxiety[16]. Evidence suggests that doula support during labour may also have potential positive effects on parenting behaviours and the relationship between a woman and her child[17]; including increased acceptance of a baby immediately after birth and an increase in behaviours such as stroking, smiling and talking to their babies[18] and more positive parenting when babies are two months old[19].

All of these findings resonate with important aspects of the policy context and many also offer potential benefits to the NHS from reduced resource use, including shorter inpatient stay following normal birth compared to assisted birth and fewer referrals to specialist services, including mental healthcare. Evidence of benefit from doula care is particularly striking for women in situations of social or economic disadvantage, those with lower educational attainment and where supportive contact starts during pregnancy. There are also suggestions that the provision of doula support is associated with increased use of *required* health care services[20].

The UK NHS spent £1.6bn on maternity services during the year 2008. Part of this cost is attributable to the high rate of caesarean sections that increased from 12% in 1990 to 24% of all births in 2008, each costing between £1,197 and £3,194[21]. It was further estimated that the cost to the NHS for maternal care due to smoking in pregnancy is between £8m and £64m per year (depending on the costing approach)[22]; a further £12 to £23.5m per year is spent treating infant conditions attributable to smoking during pregnancy. Another study estimated that the cost of neonatal care for low birth weight babies was between £12,344 and £18,495 per child in English hospitals[23]. These items reflect those in the QIPP Productivity Metrics.

The impacts of doula care described above are derived from quantitative data generated by randomised controlled trials and included in systematic reviews. There is a relative dearth of qualitative evidence to enable understanding of the experience of receiving doula support. The evidence that is available from women who received doula support indicates a greater sense of participation during labour[24]. A recent study of the experience of receiving doula support in Sweden identified continuity; the 'natural' nature of the support provided and of a human dimension to the birth experience as the key characteristics of doula support. Private doulas are available in the UK[25]; these are usually accessed by women from higher income groups who can afford to pay for their services. The potential to perpetuate inequalities in health and social support persists if mechanisms are not identified to allow doula support to be available, at scale and in particular, without cost to disadvantaged women.

Although existing evidence from a range of countries identifies important benefits to the provision of lay support in labour, key questions remain. There is a dearth of UK evidence, and doula support is rare in the UK, especially for disadvantaged women. Existing studies have as their major focus lay support in labour, yet there may be advantage in providing such support throughout the childbearing episode.

The current innovative service: the Hull Goodwin Doula Project

The Goodwin volunteer doula project in Hull, established as a social enterprise initiative, has provided support to over four hundred women in situations of social disadvantage since 2005. The project developed in an area of Hull with high levels of social and economic deprivation, poor education, housing difficulties and with health states lower than the general population. Women are referred to the Goodwin service by health professionals, interpreters, social services workers and the Teenage Pregnancy Support Services. Support can be offered at any stage but commonly starts around the sixth month of pregnancy and continues until six weeks after delivery. Following an initial facilitated meeting, subsequent contact occurs approximately fortnightly during pregnancy until the last month when contact occurs weekly. This project therefore differs from many of the studies of doula support identified, several of which were limited to care in labour and immediate postpartum.

The Goodwin project also differs in what the doulas are trained to do. Women who volunteer to provide the doula service, who are themselves usually women from the local area with children, receive training for the role, accredited by the Open College Network. Topics included in the training are preparation for birth and the birthing process, breastfeeding, child protection, domestic abuse awareness training, cultural diversity and communication skills. The doulas are expected to work closely with existing services, and to optimise women's use of both health and social services; for example, attending smoking cessation clinics, accessing Healthy Start, and attending clinic appointments. Signposting women to other services (e.g. smoking cessation) is another key part of the doula's role. Women referred to the service are matched with doulas according to personality, background, locations and availability. Volunteer doulas receive reimbursement of expenses, for example, travel and childcare during training sessions. There are systems in place to provide ongoing support for the doulas, through, for example, project workers (Locality Development Workers).

Although a full scale evaluation of this service has not been conducted, descriptive data are available. These data indicate a range of positive benefit when compared with the whole population of the city; under normal circumstances, women with the deprivation profile of those cared for would expect substantially worse outcomes. Data collected from the series of 111 women who accepted support in the year 2009-2010 show a caesarean section rate

of 20% (vs. local rates 24.5%) and higher rates of breastfeeding initiation (79%) than that of the local population (55%). 39% of women supported came from black and minority ethnic communities, and 22% were under age 20. Testimonies from women who accepted the service indicate their appreciation; positive features described include companionship and support and practical advice in the postpartum. There are also suggestions that experience as a volunteer doula has enabled subsequent access to employment and higher education, indicating a community development aspect to this work[26]. The scheme has received positive endorsement within the maternity profession with acknowledgement of a 'best practice' award from the previous Health Minister (Johnson). Confirmed funding is available for the Goodwin initiative until 2013 from NHS Hull and Hull City Council, where there is established support for the service and established multi-agency working. Information available to date has been collated by the Goodwin project management team, who welcome a comprehensive, independent evaluation of the impacts of their service, including the identification of factors that contribute to successful implementation in the UK setting.

Descriptive data such as those above, informed the Department of Health's decision in March 2009, to provide 3 years funding (£267,000) to support roll-out and replication in up to eight additional sites. This funding supports the provision of a comprehensive portfolio that informs every aspect of establishing and running a volunteer doula service, including: consultancy expertise for one year, support with issues related to human resources, volunteer recruitment and induction; 'training the trainer'; promotional material and support; training for the first cohort in each roll-out site and access to accredited training materials. Sites have to provide and fund their own staff. Identification of replication sites has been slower than expected. By February 2011, four sites had confirmed service funding for replication (Leeds, South Essex, Bradford and Tower Hamlets), which have substantially different service and demographic contexts from Hull. The initiative has been presented at the W*orkforce challenges facing maternity services* meeting held at the King's Fund (April 2010) and interested sites around England. Several of the latter are seeking to identify funding to enable roll-out into their maternity services. It is timely, therefore, that maximum information is gained from the experiences of the Goodwin initiative and from the first four identified replication sites, where it can be anticipated that new challenges to the adoption of this innovation will emerge[27].

STUDY OBJECTIVES AND PURPOSE

PURPOSE

This research addresses a number of key health policy areas including the need to reduce infant mortality and inequalities in health and care, improving the physical and emotional well-being of childbearing women, promoting normality in childbearing, improving the quality and productivity of maternity services, developing the workforce and examining large scale workforce change, reducing smoking, increasing breastfeeding rates and improving child health and development.

This study will provide systematically-derived evidence that will be carefully analysed and synthesised. The findings will inform the decisions and practices of commissioners, provide answers to commissioners' questions related to providing support for disadvantaged childbearing women, inform maternity service provision and multi-agency working, inform future volunteer doula programmes, and provide evidence for optimal implementation and sustainability of volunteer doula programmes and similar non-professional roles. It will help to address inequalities in health and care. It will augment the evidence base related to the

adoption of innovation in health services, and it will quantify health gain and economic impact of roll-out at scale.

AIMS AND OBJECTIVES

The project aims to answer four broad questions:

What are:
Q1: the implications for the NHS of a volunteer doula service for disadvantaged childbearing women?
Q2: the health and psychosocial impacts for women?
Q3: the impacts on doulas?
Q4: the processes of implementing and sustaining a volunteer doula service for disadvantaged childbearing women?

Specific objectives within these are:

Q1: Implications for the NHS

1. To determine clinical and public health impacts for women and their babies, including type of delivery, low birth weight, admission to Neonatal Unit; method of infant feeding planned during pregnancy; infant feeding initiated at birth and baby's feeding method at 6 weeks of age; impact on mothers' smoking behaviour and to compare these for women who have received the volunteer doula service with data for the general Hull PCT population, a designated statistical neighbour and England averages
2. To identify the impacts on and experiences of NHS maternity care services and providers (midwives and Heads of Midwifery)
3. To identify impacts on other NHS services including referral to and uptake of smoking cessation services
4. To determine the actual and potential impacts on NHS maternity resource use of roll-out of doula support at scale
5. To determine potential savings to the NHS through clinical events averted by the service

Q2: Health and psychosocial impacts on women

6. To identify underlying beliefs and theories about how the service works and the contexts in which it has more or less impact
7. Based on this, to identify key outcomes which will allow the theories to be tested
8. To identify the views, experiences and psychosocial impacts on women who have been recipients of the service
9. To examine the characteristics and reasons of women who disengage from the service

Q3: Impact on volunteer doulas

10. To identify the views and experiences of the volunteer doulas and the impacts on their life course

Q4: Implementing and sustaining the service

11. To provide an independent assessment of the costs of providing a volunteer doula service, including training
12. To identify the challenges, facilitators and barriers experienced by the manager and staff (Locality Development Workers) of the Goodwin volunteer doula initiative in establishing and maintaining the service
13. To identify the process of agreeing funding for service costs and the main factors responsible for the positive decision
14. To examine facilitators and barriers to implementation in the roll out sites and the extent to which these differ between sites and compared to the original service
15. To investigate the experiences of the replication package at the roll out sites

STUDY DESIGN

STUDY CONFIGURATION

Setting

We will be working with five Volunteer Doula Services, run either by NHS or Third Sector organisations, the original Hull Volunteer Doula Project and four roll out sites (South Essex, Leeds, Tower Hamlets and Bradford). All are focused on providing a service for disadvantaged childbearing women. Two are restricted to women from minority ethnic groups and a third serves an area with a very large minority ethnic population.

Design

Conceptual framework: This study takes a Realistic Evaluation perspective[28], in recognition of the complex intervention being investigated in a real-life setting. The focus is therefore not so much on addressing the question 'does it work?' but rather the subtler question of 'what works for whom in what context'. Use of this framework is built upon theorised mechanisms of how and why the intervention is effective which are derived both from the literature and from key informants.

Data collection sources: Data addressing the four main research questions will be collected from the following sources and is described in greater detail in the following pages:

Q1: What are the implications for the NHS of a volunteer doula service for disadvantaged childbearing women?

1. Obstetric and other health outcomes for women and their babies, as well as some process data, have been gathered over the years by the Hull Goodwin Doula Project in a bespoke database. Anonymised data will be compared with selected population reference groups allowing an estimate of the impact for the NHS at scale, including a health economic analysis, using established methods.
2. One-off telephone interviews with Heads of Midwifery in each site.
3. Focus groups with midwives in each site.

Q2: What are the health and psychosocial impacts for disadvantaged childbearing women?

4. Data collection with all women who have been referred to the service (all sites), including a retrospective survey, focus groups and telephone interviews. Women will be identified from service records by local service staff who will forward invitations to participate on behalf of the research team.
5. The anonymised information from service databases of the Hull Goodwin Doula Project and the four roll out sites, as above, in addition to anonymised paper-based service documents (including initial referral forms and service evaluation documents).

Q3: What are the impacts on volunteer doulas?

6. A focus group with 6-10 experienced volunteer doulas in Hull early in the project.
7. A survey of all volunteers who have been trained by the service (all sites, to be accessed via the services records) with possibility of follow up telephone interview.

Q4: What are the processes of implementing and sustaining a volunteer doula service for disadvantaged childbearing women?

8. Focus groups with Locality Development Workers (or equivalent) in each site. These are the employees who facilitate the service, e.g. by matching doulas with referrals. Focus groups will be repeated after one year to assess change.
9. Interviews with project managers in each site. Interviews will be repeated after one year to assess change.
10. Interviews with local champions, i.e. the people who have been instrumental in championing the service in the roll out sites.
11. Interviews with commissioners in each site.

In addition, it is expected that the interviews and focus groups with all other staff and doulas in the roll out sites will also contribute towards addressing this question.

STUDY MANAGEMENT

The CI, Professor Helen Spiby, is based at the University of Nottingham and has overall responsibility for the study. Professor Spiby shall oversee all study management with support from Professor Jo Green, who is the PI for the University of York site. Project management meetings of Professor Spiby and Professor Green and the research fellows will be held fortnightly and other co-applicants will be invited to join these in person or by teleconference at appropriate stages.

An Advisory Group will be established. Membership will include the range of stakeholders for the doula service, public health and academic expertise. Members will be drawn from participating sites, across disciplines and the service user/advocacy community. We anticipate a maximum of two Advisory Group meetings during the course of the research, as additional advice will be available to us between meetings by email and teleconference.

The data custodian will be the CI. Staff at project sites will distribute and follow-up questionnaires with women referred to the service and volunteers. The questionnaires will be returned by post to the University of York. Paper copies of any data (e.g. questionnaires, transcripts, anonymised service documents) will be stored in locked filing cabinets where the majority of the study team is located in the Mother and Infant Research Unit at the University

of York during the course of the study and transferred to the University of Nottingham for storage. Electronic files will be stored on password-protected secure servers. Audio recordings of interviews and focus groups will be stored on password-protected secure server and transferred securely to the transcriber. Anonymised data derived from service databases will be stored by ChiMat using encrypted memory sticks and a password-protected secure remote server. The data will be stored for 7 years in accordance with the University of Nottingham storage of data policy.

DURATION OF THE STUDY AND PARTICIPANT INVOLVEMENT

The study is of 18 months duration.
Duration of study involvement varies across groups of participants, as outlined in Table 1.

Table 1. Summary of participant groups and involvement

Participant group	*Duration of involvement*
Women (questionnaire max. 600; group discussions anticipated n=15-20 groups; telephone interviews anticipated n=20)	A maximum of: one questionnaire (20 minutes), attending group discussion (1.5 hours), telephone interview (0.5 hours). Taking part in multiple data collection streams may occur over several weeks, with separate consent sought on each occasion.
Volunteer doulas in Hull (KI) (1 focus group)	One focus group (1.5 hours) several months before taking part in the questionnaire (below).
Volunteers doulas (all sites) (questionnaire max. 160, and, for a subsample, follow-up telephone interview; anticipated n =10)	One questionnaire (20 minutes) potentially followed by a follow-up telephone interview (0.5 hours) up to three weeks later.
Locality Development Workers (or equivalent) (KI) (all sites)	Two focus groups (each 1.5 hours) several months apart.
Project managers (KI) (all sites)	Two interviews (each 1 hour) several months apart.
Heads of Midwifery (all sites)	One interview (1 hour).
Midwives (1 focus group per site)	One focus group (1 hours).
Local champions (roll out sites)	One interview (1 hour).
Commissioners (all sites)	One interview (1 hour).

Note: KI = Key Informant

End of the Study

The end of the study will be data collection from the last participant.

SELECTION AND WITHDRAWAL OF PARTICIPANTS

We will be working with five Volunteer Doula Services, run either by NHS or Third Sector organisations, the original Hull Volunteer Doula Project and four roll out sites (South Essex, Leeds, Tower Hamlets and Bradford). All are focused on providing a service for disadvantaged childbearing women.

Strategies for selection and withdrawal of participants are described by group (as described in Table 1 above).

Recruitment

Women who have been offered the doula service: the retrospective questionnaire survey

This project will involve disadvantaged women including teenage mothers, and women who are separated from their families and speak no English (e.g. asylum seekers). They may well be suspicious of strangers asking them questions and worry about the possible unseen implications of their answers, for example with regard to benefit entitlements or their applications to stay in the UK. Some topics may be particularly sensitive to some of these sub-groups, such as obstetric details and depression. It is, however, vital to try to include these women as they have been the target recipients of the doula services. It will be important that women are approached to take part by someone that they trust, and that they are reassured of anonymity and confidentiality. The initial information and request to take part will come from the Doula service itself, on behalf of the research team, although no-one from the service will be directly involved in data collection. Questionnaires will be returned directly to the research team. It will be emphasised that the researchers are independent of the service and that nothing that women tell us will be shared with anyone outside the research team in a way that allows them to be recognised.

We recognise that response rates are likely to be low for a variety of reasons: this is a mobile population so we will have difficulty locating some women; some women will be non-English speaking since at least two of the roll out sites are focusing on women from Black and Minority Ethnic (BME) communities; some women may not be able to read and write either in English or in their own language. Nonetheless, we will do whatever we can to encourage women to take part since their views and experiences are central to evaluation of the service. Specific steps are described below.

Service staff will attempt to contact all women who have ever been referred to the service (including women who subsequently failed to engage with the service but not those still in receipt of the service) in each of the five sites.

The records of the doula service will indicate a particular woman's needs and circumstances. The service will make the first approach using their standard practice (e.g. for a woman needing to be approached in a non-English language, approach by bilingual staff, or use of an interpreter).

Where women are known to have had poor outcomes including perinatal death or where their baby has been removed into the care of social services, we will still attempt to include such women as their experiences are also important. We will acknowledge their situation sensitively and invite their participation.

At the first approach, women will be told about the independent evaluation and asked if they would be happy to be sent a research pack containing further information about the research, together with the questionnaire and information about the focus groups. Where the service does not have a current telephone number, the service will send the information and questionnaire using the last known address. Women will be sent a paper copy of the questionnaire (including a pre-paid return envelope addressed to the research team). In recognition of potential literacy issues, irrespective of preferred language, women will also be offered the option of having a researcher (or interpreter appointed by the research team) telephone them to talk them through the questionnaire. Questionnaires will not therefore be translated.

The covering letter (Appendix 1) to accompany the women's questionnaire (Appendix 2a+b) will contain all aspects pertaining to participation in the study and contact details for the research team will be provided to enable the potential participant to ask any questions.

Women who have been offered the doula service: group discussions

We plan to conduct a maximum of 2-3 focus groups at each roll-out site and a maximum of 4-5 at the original Hull site, including one non-English language focus group (conducted in a single language) at each site; however this will depend on uptake and languages spoken.

At the time of contacting women about the research, service staff will ask women to consent to being contacted by the research team to discuss the focus groups further.

The PIL about the focus groups (Appendix 3) will be enclosed with the questionnaire, or the information will be provided verbally by the researcher when contacting women who have consented to being contacted by the research team to discuss the focus groups further. Where women are contacted by an interpreter, the interpreter will provide the information about the focus groups.

Women who have been offered the doula service: telephone interviews

We recognise the diversity of circumstances and outcomes for women referred to the service and that women may wish to share their views and experiences on an individual basis. Particular groups of women will be offered the opportunity of a telephone interview. Priority will be given to those women who have experienced poor outcomes to their pregnancy or those who have taken part in a group discussion and feel that they have additional experiences that could not be shared in a group setting. We anticipate a maximum of 20 telephone interviews with women.

The option of a telephone interview will be discussed at the time of contacting the woman in relation to the questionnaire. Those women that would prefer to take part in a telephone interview will be provided with the PIL relating to the telephone interview (Appendix 4).

Volunteer doulas

Focus Group at the original site (Key Informants)
The volunteer focus group aims to represent a range of views and experiences by inviting, with the assistance of the Hull project staff, volunteers from different training cohorts and with different sociodemographic backgrounds. The Hull project staff will contact volunteers to explain about the research and invite them to take part. Interested volunteers will be sent a PIL and ICF (informed consent form) by the service staff and be given the opportunity to raise any questions via the staff. The staff will liaise between the participants and research team to arrange details of the focus group.

Postal questionnaire survey and follow-up discussion
All volunteers (past and present) will be identified by service staff using records and contacted by post with a covering letter (Appendix 5), questionnaire (Appendices 6a and b), and stamped address envelopes. The covering letter will contain all aspects pertaining to participation in the study, including the voluntary nature of participation, and contact details for the research team will be provided to enable the potential participant to ask any questions.

Information about the follow-up telephone discussions will be provided with the questionnaires. Volunteers will be invited to identify on the questionnaire if they would be willing to take part in a telephone interview to explore any topics in more detail. A member of the research team will contact these participants directly using the details provided by the participants.

Staff
All staff will identified by virtue of their professional role and will be invited to take part by a member of the research team. Potential participants will be provided with a PIL and ICF (Appendices 7-11) and offered the opportunity to discuss any questions pertaining to participation. It will be explained to all potential participants that participation is entirely voluntary.

Staff: Doula service staff
All of the sites are aware of the evaluation and some staff have been involved in developing the research proposal. All doula service staff will be asked to participate at up to two time-points.

Staff: Heads of Midwifery
Heads of Midwifery will be approached directly by a member of the research team.

Staff: Midwives
The midwife focus groups will use convenience sampling. We plan to ask each HoM to forward an email from us (Appendix 9a) to midwives asking them if they have had experience of caring for a woman who has had support from the doula scheme and, if so, whether they would be willing attend a focus group, with the HoM's permission, during working hours and at their place of work to discuss their views and experiences.

Staff: Local champions
Local champions (i.e. the people who have been instrumental in championing the service) will be identified by service staff and approached by a member of the research team.

Staff: Commissioners

Commissioners will be identified by service staff and approached by a member of the research team.

It will be explained to all potential participants that entry into the study is entirely voluntary and that their employment (where appropriate) will not be affected by their decision. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Eligibility criteria

Participants will be identified by virtue of the following:

- referral to the service (women)
- having volunteered for the service (volunteer doulas)
- their professional role or involvement with the service (staff)

The volunteer focus group aims to elicit a range of views and experiences by inviting, with the assistance of the Hull project staff, volunteers from different training cohorts and with different sociodemographic backgrounds.

Midwives will be eligible for focus groups based on working in a unit that provides care to women who may be supported by a volunteer doula.

Inclusion criteria

Individuals aged 16 or over.

- The age limit for midwives, service staff, commissioners, local champions, commissioners and doulas is likely to reflect working age (respectively 21-65 for midwives and 18-65 for the other groups); however, any participants of retirement age will also be eligible to participate.

Exclusion criteria

All women who have ever been referred to the service (including women who subsequently did not engage with the service) will be eligible with the exception of those who are still being supported by the service will not be invited to participate. Additionally, service staff may identify that it is not appropriate to approach some women due to the women's personal circumstances.

Expected duration of participant participation

Table 1 provides details on the duration of involvement for the different participant groups.

Participant Withdrawal

The majority of participation involves taking part at one time-point. Participants may be withdrawn from the study either at their own request or at the discretion of the CI. Participants will be made aware (via the PIL and ICF) that should they withdraw the data collected to date cannot be erased (e.g. if participating in a focus group) and may still be used in the final analysis. We will seek consent to use the data in the final analyses where appropriate.

Informed consent

The ICF will be signed and dated by the participant before they enter the study. The research team will explain the details of the study either in person or in a covering letter and the participant will be able to ask any questions concerning study participation, ensuring that the participant has sufficient time and information to consider participating or not. One copy of the ICF will be kept by the participant and one copy will be kept by the research team.

Continuing consent is not relevant to the current study. Should there be any subsequent amendment to the final protocol, which might affect a participant's participation in the study, continuing consent will be obtained using an amended ICF which will be signed by the participant.

Women who have been offered the doula service: the questionnaire survey

Completion and subsequent return of questionnaires (by whichever method) will be deemed implied consent therefore completion of a separate ICF is not appropriate for women referred to the service.

Women who have been offered the doula service: group discussions
Written informed consent will be provided by all women taking part in group discussions (Appendix 12).

Women who have been offered the doula service: telephone interviews
Women taking part in telephone interviews will be asked to provide verbal informed consent before commencing the interview, acknowledging each point on the ICF (Appendix 13), with the interviewer signing to confirm verbal consent has been given by the woman before the participant enters the study. This approach will be utilised to maximise engagement with potential participants who are disadvantaged and therefore a particularly vulnerable group of women.

Volunteer doulas

Focus Group at the original site (Key Informants)
Written informed consent will be provided by all volunteer doulas taking part in group discussions.

Postal questionnaire survey and follow-up discussion
Completion and subsequent return of questionnaires (by whichever method) will be deemed implied consent therefore completion of a separate ICF is not appropriate. The sub-sample of

volunteers providing further clarification or detail on questionnaire responses will complete a reply slip when returning the questionnaire (Appendix 6a+b), ticking each statement and providing their contact details, together with a signed and dated ICF (Appendix 10). The cover letter will explain the details of the study and the participant will be able to contact the research team to ask any questions concerning study participation, ensuring that the participant has sufficient time and information to consider participating or not. Verbal consent will be confirmed before commencing the interview.

Staff: Doula service staff

Written informed consent will be provided by all service staff taking part in group discussions and individual interviews.

Staff: Heads of Midwifery

Heads of Midwifery will be asked to return a signed and dated ICF by post (Appendix 10). Verbal consent will be confirmed before commencing the interview, acknowledging each point on the ICF.

Staff: Midwives

Written informed consent will be provided by all midwives taking part in group discussions (Appendix 11).

Staff: local champions

The same process will be used as described under Heads of Midwifery.

Staff: Commissioners

The same process will be used as described under Heads of Midwifery.

STUDY REGIMEN

Table 2. Summary of planned primary data collection

Data source	Interviews	Questionnaires	Focus groups
Women referred to the service	20 max. (by telephone)	600 max. (retrospective survey)	10-15 (2-3 at each site)
Volunteer doulas (Key Informants)			1 (Hull site)
Volunteer doulas	10 max. to follow up questionnaire responses (by telephone)	160 with possibility of follow up telephone interview	
Doula service managers	11, incl. 6 initial (all sites incl. 2 in Hull because of change of manager) and 5 at 1-year follow-up (all sites)		
Locality Development workers or equivalent			10, incl. 5 initial and 5 at 1-year follow-up (all sites)
Heads of Midwifery (HoM)	5 (all sites)		
Midwives			5 (all sites)
Local champions	4 (roll out sites)		
Commissioners	5 (all sites)		
TOTAL	**55**	**760**	**25-30**

Data collection from women who have been offered the doula service
This is an important part of our study in order that service users are given a voice. This is particularly important in this situation where the users are, by definition, disadvantaged and are least likely to have their voices heard through other means.

The relatively small number of women involved (circa 100 per year in Hull, fewer in the roll out sites), had led us to plan a mixed methods study in order to maximise what can be learnt. However, due to budgetary constraints prohibiting a longitudinal qualitative analysis, we are obliged to limit data collection from women to a retrospective study which will incorporate all five sites; this will be predominately quantitative but will also involve some qualitative data collection involving focus groups and telephone interviews.

We will take a Realistic Evaluation perspective[28] to address the question of 'what works for whom in what context' based on theorised mechanisms of how and why the intervention is

effective. At this level the analysis is therefore within the sample, rather than comparison with a control group. However, a number of data sources are available to us which will allow us to contextualise our quantitative findings against relevant reference groups as well (see below).

Women's outcomes

The use of a Realistic Evaluation Framework[28] means that the choice of outcome measures is critical and that they will be chosen to test underlying beliefs and theories about how the intervention works.

The following domains of outcomes are likely to be included in data collection from women:

- health behaviours
- emotional wellbeing
- social support
- health status
- attitudes and practices (including breastfeeding)
- relationship with doula
- overall retrospective assessment of the benefits and disbenefits of the service.

In addition some demographic data will be gathered, e.g. education undertaken, employment status, partnership status and support network.

Women who have been offered the doula service: the retrospective questionnaire survey

It is expected that circa 600 questionnaires will be distributed assuming 400 from Hull (from 2007-12) and 50 from each roll out site (2011-12). Responses will be anonymous unless women wish to identify themselves. For some women contact will have been quite recent, for others it could be as much as 5 years previously. This could potentially allow us to look for trends in the data by taking this time lapse into account, although it should be noted that there will be inevitable confounding with the age of the child and number of subsequent children. It will also allow us some insights into how the service has developed. Given our concerns about a low response rate, we plan to include all women on the services' databases, rather than limiting to, say, the last 3 years, in order to maximise the data, even though we recognise that those whose contact was some years previously are likely to be harder to reach. All data collection instruments will be piloted to ensure relevance and clarity. Because our pool of potential participants is small and unique, piloting will be undertaken with the help of project advisors, including the reference panels of women previously supported by the service.

At the first approach, women will be told about the independent evaluation and asked if they would be happy to be sent a research pack containing further information about the research, together with the questionnaire and information about the focus groups. Where the service does not have a current telephone number, the service will send the information and questionnaire using the last known address. Women will be sent a paper copy of the questionnaire (including a pre-paid return envelope addressed to the research team). In recognition of potential literacy issues, irrespective of preferred language, women will also be offered the option of having a researcher (or interpreter appointed by the research team) telephone them to talk them through the questionnaire. Questionnaires will therefore not be

translated into other languages. Women will also be able to complete their questionnaires at the time of the group discussions if they wish to.

Reminder postcards will be sent to women after 3 weeks (Appendix 14). Because questionnaires will be anonymous, the postcard will be designed to thank those who have already returned questionnaires and state that there is still time to return questionnaires, for those who have not yet done so, although it will be emphasised that participation is entirely voluntary.

The covering letter (Appendix 1) to accompany the women's questionnaire will contain all aspects pertaining to participation in the study and contact details for the research team will be provided to enable the potential participant to ask any questions. Two versions of the questionnaire will be used, according to whether the woman accessed the support service (Appendix 2a-Appendix 2b).

Sites will complete monitoring logs, detailing the number of women approached, number of times approached, dates of contact, reasons for non-approach and reasons for not sending out research packs (e.g. where the woman declines).

Data collection from women: Qualitative methods

In addition to the questionnaires, women will be invited to take part in telephone interviews, or group discussions. Service staff will make the invitation at the time of contact about the questionnaire, as described in Selection and Withdrawal of Participants.

Women who have been offered the doula service: group discussions

Focus groups will enable us to explore in more depth key topics that have been identified through the initial data collection with the Key Informants and discussions with the reference panels.

We plan to conduct a maximum of 2-3 focus groups at each roll-out site and a maximum of 4-5 at the original Hull site (due to larger numbers at Hull), including one non-English language focus group (conducted in a single language) at each site; however this will depend on uptake and languages spoken.

Women's focus groups will follow a topic guide (Appendix 15) and will be audio-recorded, allowing transcription. Pseudonyms will be used to ensure anonymity.

Women who have been offered the doula service: telephone interviews

We recognise the diversity of circumstances and outcomes for women referred to the service and that women may wish to share their views and experiences on an individual basis. Women will therefore be offered the opportunity of a telephone interview, either in addition to or instead of, completing a questionnaire or taking part in group discussions.

Women's telephone interviews will be audio-recorded, allowing transcription. Pseudonyms will be used to ensure anonymity.

Data collection from volunteer doulas

A number of studies have indicated that volunteers often gain substantial personal benefit from volunteer involvement[26] and the data collected by the Hull Goodwin Doula Project support this. We will therefore be asking the doulas about the impact on themselves as well as their perceptions of the impact on the women that they have supported and the community more broadly. We will also address issues of process and doulas' suggestions for how the service could be improved.

Focus Group at the original site (Key Informants)

A focus group with volunteers at the original site will be included early on in the project (approx. month 3) in the initial data collection with Key Informants and will inform the design of the doula questionnaire. The discussion will be audio-recorded and transcribed using pseudonyms.

Postal questionnaire survey and follow-up discussion

The development of the questionnaire will be underpinned by the interviews with Key Informants (doula service staff) and the volunteer doula focus group. Two versions of the questionnaire will be used, according to whether the volunteer actively supported women following training (Appendix 6a-Appendix 6b). As with the women's questionnaires, data collection instruments will be piloted with the help of project advisors, including the reference panels of volunteer doulas and responses will be anonymous to encourage openness.

Reminder postcards will be sent to volunteers after 3 weeks, adopting the same approach as used with the women.

Respondents will be asked if they would be willing to be telephoned for further information, if required, and a maximum of 10 follow up interviews with doulas will be carried out if issues are raised beyond the scope of the questionnaires.

Data collection from doula service staff (Key Informants) in the Hull Goodwin Doula Project

Fundamental to all subsequent data collection are interviews with the current and former manager of the Hull Goodwin Doula Project and with the Locality Development Workers whose role is key in matching each woman referred with a suitable doula. Not only will these individuals give us valuable information about how the service works in practice and what the enablers, barriers and impacts have been, they will also be KI in allowing us to map the theories and underlying beliefs about "how the intervention works, and for who in which circumstances" [28]. This is an essential underpinning to other data collection tools and thus needs to be conducted early in the project. Similarly, it will be important to hear the views of at least some of the doulas at an early stage, since they are the individuals who actually deliver the intervention and develop relationships with the women. The second interview and focus group at the original site will enable us to explore any developments to the service. All interviews and focus groups will be audio-recorded and fully transcribed.

Data collection from doula service staff (Key Informants) in the roll out sites (project staff and managers)

Other important informants will be the manager and project workers in each of the roll out services. As with their counterparts in the Hull Goodwin Doula Project, these individuals give us valuable information about how the service works in practice and what the enablers, barriers and impacts have been. Of particular interest will be a comparison of their underlying beliefs and attitudes about how the intervention works, with those in other sites. We will be seeking to understand more about how these beliefs and attitudes vary across the sites and how they relate to the reported experiences of doulas and women and their outcomes. Because the roll out sites will be at an early stage of their development, our study also affords the opportunity to study this development over time, by carrying out interviews with these key individuals early in the study and again approximately one year later. The initial interviews and focus groups will ask not only about what has happened so far but also about aspirations for the coming year. The return data collection will be able to revisit these and discover if these hopes were met. All interviews and focus groups will be audio-recorded and fully transcribed.

Data collection from Heads of Midwifery and midwives

The data collection described above will tell us about the immediate impacts of those involved but also of importance are the perceptions of those involved in the delivery of maternity care. Telephone interviews will be carried out with Heads of Midwifery (HoMs) in each of the five sites. Focus groups with midwives will be carried out on hospital premises during working hours and at their place of work to discuss their views and experiences. The telephone interview and focus group will each follow topic guides (Appendices 16-17) and will be audio-recorded.

Data collection from local champions and commissioners

Each roll out site will have had a local champion: an individual who championed the adoption of the project and saw it through to successful commissioning. Their perspectives will be an essential part of developing an understanding of this vital part of the process. To date only four sites have found funding to initiate the service. Others have expressed interest but have been unable to persuade commissioners to make the project a funding priority. This raises the question of what it is that has led these four sites to proceed with implementation of the roll out in an economic climate that has proved a barrier elsewhere. We will therefore also conduct audio-recorded telephone interviews with the key commissioner in each site.

Data from the service database

Data from the bespoke database collected by the service will give descriptive information on outcomes for the service since 2007. It will be possible to examine trends over time, for example of the numbers of women being referred and their characteristics as well as their outcomes. Although the study design precludes any direct comparison group (as explained above) we will be collecting data in a form that will allow multiple comparison reference groups. These will allow us to compare the results for women in our study with comparable data for certain clinical and psychosocial outcomes including health behaviours such as smoking and breastfeeding.

Reference Groups

Reference Group 1: Hospital Episode Statistics and PCT data
1) Detailed analysis of Hospital Episode Statistics and PCT data will be undertaken by analysts at the national Public Health Observatory for Children and Maternity (ChiMat , http://www.chimat.org.uk/) . These data sources will allow us to look at mode of birth, breastfeeding initiation, breastfeeding at 6-8weeks and smoking by a number of demographic factors, e.g. age of mother, ethnic group of mother, economic hardship of mother based on index of multiple deprivation. We will then be able to look at outcomes for demographically comparable subsamples within (i) the general Hull PCT population, (ii) the designated statistical neighbours for Hull and (iii) England averages. ('Designated statistical neighbours' are areas that have been identified as having similar key characteristics based on census data). These data, and Payment by Results tariffs, also hold utility for investigation of improved productivity and potential for cost savings.

Reference Group 2: Picker Institute Survey
The Picker Institute conducts a mandatory survey of women's experiences of maternity services. Questions from the survey will be included in the women's questionnaire to enable comparison between experiences of women referred to the service and experiences of women completing the survey at each site (i.e. at the Trust level) in 2010.

Health Economic analysis

The objective of the economic analysis is to compare the costs and consequences of the doula service with a reference group. The economic evaluation will take an incremental analysis approach and will compare the incremental costs and incremental effects of providing the doula service to pregnant women. The doula service will be assumed to be additional to the currently available services through the NHS.

Whilst it is common practice in the health economics literature to take the cost-effectiveness or cost-utility approach based on short or long-term outcomes[29, 30], these approaches rely on translating the process or intermediate outcomes into a common outcome denominator, which in most cases is the quality-adjusted life years (QALYs). However, for interventions that have diverse range of short-term outcomes, a cost-consequence analysis is also appropriate. This approach is defined as an analysis '... in which costs and effects are calculated but not aggregated into quality-adjusted life-years or cost-effectiveness ratios'[31]. This method is used to display all the key costs and consequences associated with the intervention for the purpose of comparison; the consequences are expressed in the most appropriate natural units for each outcome measure. This approach is particularly relevant when a wide range of multidimensional process outcomes are of interest for a particular intervention[32]. The information presented in this format is understandable and usable for non-health economists[33], and it also overcomes the need for complex economic modelling to estimate the long-term effects expressed in terms of a single common outcome. This approach has been used in many studies in the recent years[34-37].

The main outcomes to be evaluated in this economic analysis will be the clinical events that have been hypothesised to be influenced by the doula intervention, including mode of birth, use of epidural during labour, incidence of low birth weight, rates of breastfeeding initiation and smoking cessation. The anonymised data on these outcomes for the doula service recipients will come from the Hull Goodwin Doula project database, while the estimates for the reference group will be based on the data derived by Chimat (as discussed above). Resource use and unit costs associated with the clinical outcomes will be estimated based on the NHS reference costs database[21] and the Personal and Social Services Research database[38]. The cost of providing the doula service will be estimated based on information from the Hull Goodwin Doula project and the roll out sites. The economic analysis will identify

any cost-savings associated with the doula service along with the benefits of the programme in terms of the outcomes outlined above. The analysis will also estimate uncertainty around cost savings.

Compliance
Compliance is not applicable in this research.

Criteria for terminating the study
The study does not involve any interventional procedures and has minimal time involvement for participants, therefore there are no set criteria for terminating the study.

STATISTICS/ ANALYSES

Methods

Quantitative analyses: Clinical and public health outcomes
Analyses comparing data from the service records with reference group data will be undertaken by ChiMat (Yorkshire & Humber Public Health Observatory) and members of the Department of Health Sciences at the University of York.

The economic evaluation will take an incremental analysis approach and will compare the incremental costs and incremental effects of providing the doula service to pregnant women. The doula service will be assumed to be additional to the currently available services through the NHS.

Resource use and unit costs associated with the clinical outcomes will be estimated based on the NHS reference costs database[21] and the Personal and Social Services Research database[38].

Quantitative analyses: questionnaires completed by women and volunteer doulas
Data from the questionnaires with the women referred to the service and volunteer doulas will be analysed using SPSS (Statistical Package for the Social Sciences) using both descriptive statistics (means, frequencies etc), and exploring similarities and differences within the sample as sample size allows (e.g. for women's questionnaires, older and younger mothers, site, time since service use, and for doulas' questionnaires, site, amount of experience as a doula).

Qualitative analyses: interviews and focus groups
All focus groups and interviews will be digitally recorded and fully transcribed with pseudonyms used to ensure anonymity. Data collected using interviews and focus groups will be analysed using content analysis to identify themes within the data, underpinned by the framework of Realistic Evaluation.

Sample size and justification

Clinical and public health outcomes

There is no power analysis or sample size calculation per se. The analysis of clinical and public health outcomes and comparison with reference group data will utilise all available data collected at the Hull site, as the original site with highest level of service use.

Experiences of volunteer doula support and psychosocial outcomes
Sample size is based on the use of all available data from the Hull service and four roll-out sites. Low response rates are anticipated and thus sampling is inappropriate. Rather than sampling, the questionnaires will be sent to all volunteers (past and present) and all women referred to the service, with estimates of these numbers having been provided by the services.

ADVERSE EVENTS

The occurrence of clinical adverse events as a result of participation within this study is not expected and no adverse event data will be collected.

We think that it is unlikely that participants would be at any risk by taking part, although occasionally people may feel distressed if the research prompts memories of difficult situations. Involvement of the reference panels and Advisory Group will help to inform the acceptability of topics.

Women referred to the service will be encouraged to contact appropriate professionals, such as their GP or their Health Visitor with any concerns about their health, their child's health or parenting. Contact details of local organisations will be available, for reference, including counselling services. Additionally, a key contact will be identified at each local maternity services who women will be able to contact if they are distressed about their birth experience.

ETHICAL AND REGULATORY ASPECTS

Group discussions will involve ground rules, including mutual respect and the need for confidentiality.

As discussed above, appropriate contact details will be available to women.

In the event that a woman discloses information in group discussion or individual interview suggesting risk of harm to herself or her child, the research team will work with the local service to identify the appropriate agency or contact.

With this exception, all information will be confidential. Participants will not be identified in study reports. The steps taken to ensure confidentiality and anonymity are described elsewhere in this protocol.

ETHICS COMMITTEE AND REGULATORY APPROVALS

The study will not be initiated before the protocol, consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), and the respective National Health Service (NHS) Research & Development (R&D) departments.

Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and any revised forms (e.g. ICF, PIL) have been reviewed and received approval / favourable opinion from the REC and R&D departments. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.

The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the Department of Health Research Governance Framework for Health and Social care, 2005.

INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. For all focus groups and face-to-face interviews, the investigator or their nominee and the participant or other legally authorised representative shall both sign and date the ICF before the person can participate in the study. The participant will receive and retain a copy of the signed and dated ICF and the original will be retained in the study records.

Women taking part in telephone discussions will be asked to provide verbal informed consent before commencing the interview, acknowledging each point on the ICF, with the interviewer signing to confirm verbal consent has been given by the woman before the participant enters the study. Heads of Midwifery, local champions, commissioners and volunteer doulas taking part in telephone interviews will provide written informed consent. Verbal consent will be confirmed before commencing the telephone interviews.

Completion and subsequent return of questionnaires (by whichever method) will be deemed implied consent therefore a separate ICF will not be used.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to participants that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future care, employment, or relationship with the service, in accordance with the relevant participant group. No study specific procedures will be done before informed consent has been obtained.

If the ICF is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended ICF by the REC and use of the amended form (including for ongoing participants).

RECORDS

Study Forms

Centre codes (denoting the five sites) will be allocated to questionnaires. Each participant will be assigned a unique study identity code number, for use on study documents and any electronic database (e.g. SPSS database for women's questionnaires or SPSS database for doulas' questionnaires). The identifiers used will be robust and able to prevent misassignment of data in databases. The database will have in-built checks to ensure that the identifiers used all match with the allocated study number.

The electronic database containing data from the service documents will not require unique study identity code numbers because the data will be fully anonymised and not linked to any other data collection (e.g. questionnaires).

Study forms will be treated as confidential documents and held securely in accordance with regulations. A participant key will be stored separately from the study forms and will include identifying information (e.g. a key will be developed for the service staff, containing participant name, matched to the associated study identity code number). We will not be recording details such as local hospital numbers or NHS numbers.

All paper forms shall be filled in using black ballpoint pen. Errors shall be lined out but not obliterated by using correction fluid and the correction inserted, initialled and dated. The CI or PI shall sign a declaration ensuring accuracy of data recorded in the study forms.

The anonymised information from service databases and anonymised paper-based service documents (including initial referral forms and service evaluation documents) will not be linked with other sources of data (i.e. women's questionnaires).

Source documents

Source documents shall be filed at the Universities of Nottingham and York and may include but are not limited to, ICFs, study forms, field notes, interview transcriptions and audio records. Only study staff shall have access to study documentation other than the regulatory requirements listed below.

Direct access to source data / documents

All source and study documents shall made be available at all times for review by the CI, PI, Sponsor's designee and inspection by relevant regulatory authorities.

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. We will only collect the minimum required information for the purposes of the research. Source and study documents will be held securely, in a locked room, or locked cupboard or cabinet. Access to the information will be limited to the immediate research team and any relevant regulatory authorities (see above). Computer held data including the study databases will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method). Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

QUALITY ASSURANCE & AUDIT

INSURANCE AND INDEMNITY

Insurance and indemnity for clinical study participants and study staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but study participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials

insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

STUDY CONDUCT

Study conduct will be subject to systems audit for inclusion of essential documents; permissions to conduct the study; CVs of study staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. eligibility criteria) and accountability of study materials.

STUDY DATA

Monitoring of study data shall include confirmation of ICFs; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Study Coordinator, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

The subsequent capture of the data on the study database will be checked. Where corrections are required these will carry a full audit trail and justification.

Study data and evidence of monitoring and systems audits will be made available for inspection by the REC as required.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Code of Research Conduct and Research Ethics, the CI or local PI will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The study documents held by the CI on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all anonymised audio recordings, study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE RESEARCH BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice as appropriate in making this decision.

STATEMENT OF CONFIDENTIALITY

Individual participant medical or personal information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this study will be available for inspection on request by the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

PUBLICATION AND DISSEMINATION POLICY

Participants will not be identified in any publications.

Interim reports will be provided to the funder, the National Institute of Health Research (NIHR), at approximately 6 and 12 months. The complete study results will be disseminated to the NIHR and published online via the NIHR electronic journal.

Feedback will be provided to participants and presented to the doula project sites and clinical service leads. Papers will be submitted to peer-reviewed journals and we plan for all members of the research team to present at appropriate conferences. Findings will also be disseminated via professional networks e.g. Royal College of Midwives.

USER AND PUBLIC INVOLVEMENT

We have a co-applicant who is an experienced advocate for disadvantaged childbearing women and who will ensure that all possible steps are taken to access and respect women's voices. We also have the user Vice Chair of the Hull Maternity Services Liaison committee as an Adviser. A user of the Hull Goodwin Doula Service has also given helpful advice through telephone discussion which informed this proposal and is willing to continue to advise on this basis. We hope to engage additional users of the doula service similarly by convening a reference panel at the Hull site. We also hope to establish a reference panel of doulas at the Hull site. The NCT (formerly National Childbirth Trust) are also supporting this proposal. We have convened an Advisory Group to the research that includes both service users and doulas in its membership.

STUDY FINANCES

Funding source

This study is funded by the NIHR Service Delivery and Organisation programme now incorporated into NIHR HS & DR programme.

Participant stipends and payments

Participants will not be paid to participate in the study. Transport will be provided or costs will be fully reimbursed to participants upon presentation of receipts. Women who complete questionnaires will be offered a £5 high street voucher in acknowledgement of their time and contribution. Women who attend group discussions will be offered a £10 high street voucher in acknowledgement of their time and contribution. Refreshments (including lunch) will be provided at the group discussions together with a crèche facility.

SIGNATURE PAGES

Signatories to Protocol:

Chief Investigator: (name)_____Professor Helen Spiby_____

Signature:_____

Date: _____

REFERENCES

1. CEMACH, *Confidential Enquiry into Maternal and Child Health (2007). Saving Mothers' Lives*, 2007, CMACH: London.
2. CEMACH, *Confidential Enquiry into Maternal and Child Health (CEMACH) Perinatal Mortality 2007: United Kingdom*, 2009, CEMACH: London.
3. National Collaborating Centre for Women's and Children's Health, *Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors*, 2010, Royal College of Obstetricians and Gynaecologists: London.
4. Redshaw, M., et al., *Recorded Delivery: a national survey of women's experience of maternity care 2006*2007, Oxford: NPEU.
5. Hodnett, E.D., et al., *Continuous support for women during childbirth*, 2007: Cochrane Database of Systematic Reviews 2007, Issue 3. Art. No.: CD003766. DOI: 10.1002/14651858.CD003766.pub2.
6. Campbell, D.A., et al., *A randomized control trial of continuous support in labor by a lay doula.* JOGNN, 2006. **35**(4): p. 456-464.
7. Kennell, J., et al., *Continuous emotional support during labor in a US hospital: a randomized controlled trial.* Jama, 1991. **265**(17): p. 2197-2201.
8. Stones, R.W., C.M. Paterson, and N.J. StG Saunders, *Risk factors for major obstetric haemorrhage.* European Journal of Obstetrics & Gynecology and Reproductive Biology, 1993. **48**(1): p. 15-18.
9. Lydon-Rochelle, M., et al., *Association between method of delivery and maternal rehospitalization.* Jama, 2000. **283**(18): p. 2411-6.
10. Towner, D., et al., *Effect of mode of delivery in nulliparous women on neonatal intracranial injury.* The New England journal of medicine, 1999. **341**(23): p. 1709-14.
11. Nommsen-Rivers, L.A., et al., *Doula care, early breastfeeding outcomes, and breastfeeding status at 6 weeks postpartum among low-income primiparae.* Journal of Obstetric, Gynecologic, & Neonatal Nursing, 2009. **38**(2): p. 157-173.
12. G Justus Hofmeyr, et al., *Companionship to modify the clinical birth environment: effects on progress and perceptions of labour, and breastfeeding.* British Journal of Obstetrics and Gynaecology, 1991. **98**: p. 756-754.
13. Britton C, M.F., Renfrew MJ, Wade A, King SE., *Support for breastfeeding mothers*, 2007: Cochrane Database of Systematic Reviews 2007, Issue 1. Art. No.: CD001141. DOI: 10.1002/14651858.CD001141.pub3.
14. National Institute for Health and Clinical Excellence, *A peer-support programme for women who breastfeed. Commissioning Guide: Implementing NICE guidance*, 2008, NICE: London.
15. Langer, A., et al., *Effects of psychosocial support during labour and childbirth on breastfeeding, medical interventions, and mothers' wellbeing in a Mexican public hospital: a randomised clinical trial.* British Journal of obstetrics and Gynaecology, 1998. **105**: p. 1056-1063.
16. Wolman, W.L., et al., *Postpartum depression and companionship in the clinical birth environment: a randomized, controlled study.* American journal of obstetrics and gynecology, 1993. **168**(5): p. 1388-1393.
17. Gordon, N.P., et al., *Effects of providing hospital-based doulas in health maintenance organization hospitals.* Obstetrics & Gynecology, 1999. **93**(3): p. 422-6.

18. Sosa, R., et al., *The effect of a supportive companion on perinatal problems, length of labor, and mother-infant interaction.* New England Journal of Medicine, 1980. **303**(11): p. 597-600.
19. Gilbert, S., *Benefits of assistant for childhood go far beyond the birthing room. Report of conference study*, in *New York Times*1998: NY.
20. Mottl-Santiago, J., et al., *A hospital-based doula program and childbirth outcomes in an urban, multicultural setting.* Maternal and Child Health Journal, 2008. **12**(3): p. 372-377.
21. Health, D.o., *NHS reference costs 2009/10*, 2010: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_112590.
22. Public Health Research Consortium, *Estimating the costs to the NHS of smoking in pregnancy for pregnant women and infants. PHRC Short Report 11*, in *http://www.york.ac.uk/phrc/PHRC%20A3-06%20Short%20Report%2011.pdf* 2010.
23. Mistry, H., et al., *Costs of neonatal care for low-birthweight babies in English hospitals.* Acta Pædiatrica, 2009. **98**(7): p. 1123-1129.
24. Campero, L., et al., *"Alone, I wouldn't have known what to do": A qualitative study on social supportduring labor and delivery in Mexico.* Social Science & Medicine, 1998. **47**(3): p. 395-403.
25. Goedkoop, V., *Side by side - a survey of doula care in the UK in 2008.* MIDIRS, 2009. **19**(2): p. 217-218.
26. Byrom, S. and A. Gaudion, *Empowering mothers: strengthening the future*, in *Essential Midwifery Practice: postnatal care*, G.E. S Byrom, D Bick, Editor 2010, Wiley Blackwell: Chichester.
27. NHS Service Delivery and Organisation Programme, *Spreading and sustaining innovations in health serice delivery and organisation*, in *http://www.sdo.nihr.ac.uk/projdetails.php?ref=08-1201-0382004*, NHS SDO: London.
28. Pawson, R. and N. Tilley, *Realistic Evaluation*1997, London: Sage.
29. Briggs, A.H., M.J. Sculpher, and K. Claxton, *Decision modelling for health economic evaluation*2006, Oxford: Oxford University Press.
30. Drummond, M.F., et al., *Methods for economic evaluation of health care programmes*. 3rd ed2005, Oxford: Oxford University Press.
31. Russell, L.B., et al., *The role of cost-effectiveness analysis in health and medicine.* Jama, 1996. **276**(14): p. 1172.
32. Godber, E., R. Robinson, and A. Steiner, *Economic evaluation and the shifting balance towards primary care: definitions, evidence and methodological issues.* Health Economics, 1998. **6**(3): p. 275-294.
33. Mauskopf, J.A., et al., *The role of cost-consequence analysis in healthcare decision-making.* Pharmacoeconomics, 1998. **13**(3): p. 277-288.
34. Burger, S.A., *Cost consequence analysis of outreach strategies for hight risk pregnant women.* Journal of Community Health Nursing, 2010. **27**(3): p. 137-145.
35. Ritchie, K., et al., *Economic modelling of antenatal screening and ultrasound scanning programmes for identification of fetal abnormalities.* BJOG: An International Journal of Obstetrics & Gynaecology, 2005. **112**(7): p. 866-874.
36. Bergmo, T.S., *Can economic evaluation in telemedicine be trusted? A systematic review of the literature.* Cost Effectiveness and Resource Allocation, 2009. **7**(1): p. 18.

37. Barnett, A.H., et al., *UK cost-consequence analysis of aripiprazole in schizophrenia: diabetes and coronary heart disease risk projections (STAR study).* European archives of psychiatry and clinical neuroscience, 2009. **259**(4): p. 239-247.
38. Curtis, L., *Unit Costs of Health and Social Care*, in *Personal Social Services Research Unit*2009, University of Kent at Canterbury: Canterbury.