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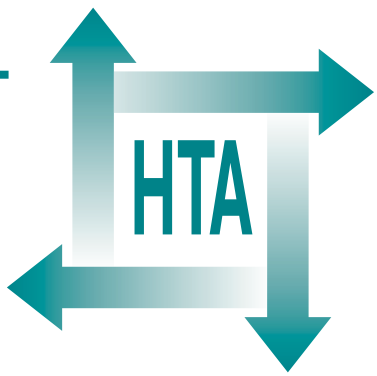

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Costs and benefits of community postnatal support workers: a randomised controlled trial

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The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for the recommendations for policy contained herein. In particular, policy options in the area of screening will be considered by the National Screening Committee. This Committee, chaired by the Chief Medical Officer, will take into account the views expressed here, further available evidence and other relevant considerations.

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Contents

List of abbreviations

ANCOVA	analysis of covariance
A&E	accident and emergency
CI	confidence interval
CMSW	community midwifery support worker (service)
df	degrees of freedom
DUFSS	Duke Functional Social Support
EPDS	Edinburgh Postnatal Depression Scale
GHP	general health perception
GP	general practitioner
NVQ	National Vocational Qualification
PND	postnatal depression
QALY	quality-adjusted life-year
RCT	randomised controlled trial
RLE	role limitation emotional
RLP	role limitation physical
SD	standard deviation
SF-36	Short Form-36 health status questionnaire
SW	support worker
TENS	transcutaneous electrical nerve stimulation

Executive summary

Objectives

This study aimed to measure the effect and the total cost per woman of providing postnatal support at home, based on a Dutch model. The research hypothesis was furnished by some existing evidence that postnatal support could reduce the risk of postnatal depression and encourage breastfeeding.

Design

The randomised controlled trial aimed to measure differences in health status in a group of women who were offered postnatal support from a community midwifery support worker (SW) compared with a control group of women who were not offered this support. Women were followed-up by postal questionnaire at 6 weeks and 6 months postnatally.

Setting and subjects

All women who delivered a baby at the recruiting hospital were eligible to take part in the trial if they lived within the study area, were aged 17 years or over, and could understand English.

Intervention

The intervention consisted of the SW offering practical and emotional support and to help women rest and recover after childbirth. The SW offered ten visits in the first 28 days postnatally, for up to 3 hours per day. The SW's activities included housework, talking with the mother, and care for the baby or other siblings. The service was provided in addition to routine visits by the community midwife.

Main outcome measures

The primary outcome was the general health perception domain of the Short Form-36 at 6 weeks. Secondary outcomes were mean Edinburgh Postnatal Depression Scale (EPDS), Duke Functional Social Support (DUFSS) scores and breastfeeding rates.

Results

The 623 randomised women were well-matched by group with a good response to follow-up. At 6 weeks there was no evidence of a significant difference between the two groups for the primary outcome. There was a non-significant trend for the control group to have better mean DUFSS and EPDS scores at 6 weeks. Breastfeeding rates were not significantly different at follow-up. At 6 months, both groups had similar health status. Satisfaction with the service was higher than for all other services received.

The incremental cost of introducing the service comprised setting up and running the service. There were no differences between the groups in other resource use (general practitioner contacts, hospital services, prescriptions or medicines bought for mothers and babies) to 6-month follow-up. The total mean NHS cost to 6-month follow-up for the intervention group was £180 per woman greater than for the control group (confidence interval, £79.60, £272.40).

Conclusions

Although women valued the service, there was no evidence of any health benefit at the 6-week or 6-month follow-up, no difference in use of NHS services, and the additional cost of the service provision would be around £180 per woman.

Additional studies are required to identify the support-related outcomes of importance to postnatal women, and to compare the effectiveness of different models of antenatal and postnatal support.

Chapter 1
Background

Introduction

Resource use in postnatal services

For most of the 760,000 women each year who have a baby in the UK,[1] childbirth should be a normal life event, requiring few specialist resources. Postnatal care is provided in both primary and secondary care settings by midwives, general practitioners (GPs) and health visitors. In recent years, the length of postnatal inpatient stay has reduced from 11 to 4 days or less, transferring resource use from the hospital to the community. Whilst maternity services use considerable resources annually, there is little evidence of appropriateness, clinical effectiveness or efficiency of care provided.

Postnatal morbidity

Until the late 1980s there was very little rigorous research into postnatal care and morbidity. Research carried out in the early 1990s revealed high levels of enduring physical morbidity in postnatal women.[2] The incidence of depression after childbirth and the potential consequences for infants were also identified.[3] The extent and duration of this physical and psychological morbidity was often unrecognised by healthcare professionals.[4]

Maternity services

Postnatal visits by a midwife have traditionally featured the physical examination of women and whilst the effectiveness of some elements of this care has been questioned,[5] the importance of emotional support for women after childbirth has been emphasised.[6]

In the early 1990s there was a call for changes in maternity services[7] and for the adoption of a more individualised approach that was sensitive to women's needs.[8] It was recommended that new approaches to care should be subject to rigorous evaluation, including women's preferences for and acceptability of services.

In 1994, a call for proposals was issued by the NHS Health Technology Assessment (HTA) Programme for the evaluation of the role of GPs, midwives and other primary care workers in antenatal and postnatal care. Evaluation was needed to inform models of practice and define different roles in postnatal care. Research was also required to provide evidence of the efficiency of services, with a focus on the different levels of risk. This report describes an evaluation by randomised controlled trial (RCT) of the effectiveness and costs of a novel approach to postnatal support.

Women's need for support after childbirth

The transition to parenthood has been described as a stressful major life event, involving changes in demands, responsibilities, routines, work and social life.[9] Women may experience physical morbidity (some of which is associated with common interventions during labour and delivery), and feel psychologically overwhelmed, compounded by fatigue, which can put them at greater risk of postnatal depression (PND). Many symptoms will resolve, but others may become a chronic problem. Problems adapting to motherhood can vary according to women's expectations, knowledge and support received from their partners.[10] New fathers are not always best equipped to provide support for their partners, having little knowledge or experience themselves.

Antenatal preparation usually focuses on the woman's labour and pays less attention to what to expect when their baby arrives. Attachment to a new baby is influenced by the mother's emotional health, social support system, competence in caregiving and how well the baby 'fits' the mother's expectations.[11] Women who may need additional support are first-time mothers, those who have little family or few friends, very young women or those without partners, and older mothers who may also need more rest.[12] Those women who have the additional stress of moving house during their pregnancy or after the baby is born, with the disruption of their social support networks that this might bring may also need more support.[13]

Postnatal physical morbidity

The extent of women's enduring physical morbidity after childbirth has only recently

been established.[2,4,13] Early retrospective studies suggested that the use of epidural analgesia during labour was associated with the problem of backache.[14] A more recent prospective study[15] has suggested that back pain following delivery was most likely to have been a continuation of an antenatal back problem and there was no direct relationship to the use of epidural analgesia.

Approximately 15% of women have an assisted vaginal delivery, using either forceps or a vacuum extractor, both of which are associated with greater maternal morbidity. This includes the use of and consequences of episiotomy, the occurrence of urinary infections and maternal lacerations. Compared with obstetrics forceps, use of the vacuum extractor results in a significant reduction in the incidence of maternal trauma, the need for an episiotomy and the need for regional (epidural or spinal) anaesthesia.[16]

Episiotomy is the commonest intervention carried out in both normal and complicated deliveries. Rates vary widely between units ranging from 26% to 67% of deliveries throughout the UK.[17] This intervention results in increased blood loss at the time of delivery,[18] a higher infection rate and an increase in third- and fourth-degree lacerations.[17] It also produces twice the short-term pain and discomfort experienced by women who have a spontaneous tear and at least ten times more than those who have an intact perineum.[19] More than a quarter may still have perineal complications at 3 months.[13] Other work has suggested a long-term problem of dyspareunia in up to 6% of women who have had an episiotomy.[20]

The regional rate of Caesarean section in 1994 ranged from 13.2% to 17.6% in the UK.[21] The principal morbidity attributable to Caesarean section, after the first 2 days are febrile morbidity associated with infection or haematoma formation and anaemia, requiring blood transfusion. The incidence of febrile morbidity is 5–10%[22] and when the Caesarean section is carried out as an emergency the incidence is greater.[23] A Caesarean delivery and a general anaesthetic may also be associated with a poorer breastfeeding outcome[24] and risk of PND.[25]

A mother's early attachment to her baby can be influenced by high levels of intervention and the use of pethidine in labour, which are associated with problems with breastfeeding.[24]

Mental health after childbirth

Most women will feel exhausted at some time after the birth of their baby as a result of the extreme physical demands of motherhood, but many will also experience other diverse, worrying symptoms. The term postnatal illness has been used for a number of conditions and although possibly a continuum, three need to be distinguished. The 'baby blues' is said to affect up to 80% of women within a few days of the birth of their baby, but lasts no more than a few days and is unlikely to require treatment. Puerperal psychosis is a severe mental illness, with dramatic symptoms affecting one in 1000 women in the first few months after delivery, requiring urgent psychiatric treatment.

PND is a more common condition, which may begin soon after childbirth but even with treatment, can last for up to 1 year after delivery. The reported incidence appears to vary, affecting around 10–17.5% of women,[26,27] depending on the criteria used and the time of assessment postnatally.[28] The wide range of symptoms can include feelings of anxiety, guilt, helplessness, inadequacy, irritation, lack of drive and loss of concentration. Some women may also feel ambivalent about their baby.

There has been growing concern about the effects this long-lasting depression might have on infant development[3] and the emotional and cognitive development of older children.[29,30] Although there is little evidence to date, there is also a belief that depression in some women may affect their partners who also become depressed[31] thereby reducing their ability to cope in supporting the mother or other children.

It has been argued that depression after childbirth is not very different from depression in non-pregnant women and that women experience postnatal distress and less satisfaction in their relationships at this time, particularly with their partner.[32] Depression has been described as an understandable response to the demands of motherhood[28] and it has been suggested that this distress should not be confused with clinical depression.[33] Although there is no consensus about the cause of postnatal distress or depression, there is an association with risk in women who have a number of psychosocial risk factors, including a poor relationship with the baby's father, recent stressful life events, poor social support, previous psychiatric history,[26] a low family income or no confidante.[34] Working class women with children at home have a four-fold greater risk of

developing depression than middle class women.[35] Common treatments include antidepressants and counselling. Many women with depression postnatally may not receive any extra support, in part because their problem has not been fully recognised, or because women are afraid to admit their true feelings.[36]

Postnatal social support

There is increasing epidemiological evidence of a beneficial effect of social support on health and survival[37–41] and an incremental benefit with amounts of social support. The worst situation is no social support at all, which increases the risk of mortality and possibly also morbidity.[40] There may also be an association between low levels of social support and increased use of primary care services.[42]

Social support is a complex multidimensional phenomenon.[10,41] Although there is no consensus on a conceptual definition, social support includes emotional and material support and information-giving, and can be seen as an interactive process with access to naturally helpful actions or behaviours that can have a positive effect on well-being. Although the explanation as to whether ill-health precedes or follows poor social relationships is unclear,[40] the theory suggests that social support can work to promote health in two main ways and both of these actions may operate together in chronic disease processes:[39]

- **main beneficial effect** – promoting health directly and enhancing well-being
- **stress buffering effect** – interacting with the adverse effect of stress and reducing the physiological effect of stress.

The need for social support varies throughout life and people are socialised to provide support for others for what are seen as normal chronological events (such as partnership and parenthood) and to provide extra support for a problem or a crisis. In the 1960s women's own mothers were identified as their greatest source of support, though more recently women's partners have been identified as most supportive[43] followed by their own mother or their partner's mother.[13]

A study of second-time mothers reported that practical support was the most desirable form of support in the early postnatal period, to allow them to be with their infants and to help alleviate fatigue.[44] Women who said they received practical support from a spouse were found to be less angry postnatally and less likely to report fatigue. There are some women, however, who do not receive the social support they need; partners are sometimes unavailable or, for many reasons, do not meet the women's expectations.[45] Some women with high stress and little psychological or social support may have a greater chance of postnatal complications than women who have a equal amount of stress or greater anxiety, anger or fatigue, but more support.[46,47]

The positive effect of social support in pregnancy has been confirmed by systematic review.[48] A number of intervention studies have examined the effect of additional social support, particularly to women at above average risk of a low birthweight baby.[49,50] Most have reported the positive effect on well-being, functional status and perinatal outcomes with no reported negative effects.

An RCT showed that an antenatal intervention where midwives listened, responded and informed women when asked, was associated with a mean birthweight 38 g higher than the control, less intervention during delivery and better reported physical and psychosocial health.[50] The intervention offered one brief visit to the women postnatally. A 1-year follow-up showed health benefits for the mothers and their infants. At a 7-year follow-up representing 47% of the original sample, the intervention appeared to have had a lasting positive effect on the mothers and their children.[51]

Also, a supportive companion during labour has been associated with a positive effect on pregnancy outcomes; reduction in the length of labour and reduced need for augmentation.[52,53]

A systematic review of trials with interventions to support socially disadvantaged women found the trials all had methodological problems and it was concluded that there was still a need for larger, more rigorous trials examining the impact of social support on outcomes for both socially disadvantaged mothers and their babies.[54]

Provision of postnatal care and support

Support after childbirth in the UK was formerly provided by healthcare professionals, the woman's family and in many cases, a home help, provided by the local social services. Changing patterns of

family life have resulted in less help being available to new mothers from the extended family. The home help service is now rarely available to women after childbirth, usually only in the most extreme of circumstances, such as after triplets. Health visitors and community midwives recognise the need for social support among women with young children living with poverty or debt and the complex relationship between their self-esteem, confidence in money management, the constraints on their lives and their actions. Healthcare workers provide listening, befriending support, but they are constrained by time, work pressures and other ideologies, from providing other forms of social support.[55] At least one independent midwifery practice provides a mother's help as part of its package of care.[56]

In the NHS hospital setting throughout the UK, postnatal care is provided mainly by trained and trainee midwives and other non-professional support staff (healthcare assistants, nursing auxiliaries, support workers (SWs)). Whilst there is some variation between maternity units in the tasks they perform, the role of such staff is to provide non-technical support, assistance with hygiene for the woman and help with the new baby,[57] but it is uncommon for them to be involved in community postnatal care. However, in some areas of the NHS in England, SWs have been incorporated into community midwifery teams as a skill mix exercise, such as in Hillingdon Hospital NHS Trust. In such cases, the midwife responsible for the woman's care delegates duties to the SW.

Midwifery home visiting

The aims of postnatal care have traditionally covered three areas:

- promoting the physical recovery of the mother
- establishing sound infant feeding practices, and
- strengthening the mother's confidence in herself and in her ability to care for her baby.[58]

The postnatal period is defined in the Midwives Rules and Code of Practice[59] as:

> "a period of not less than 10 and not more than 28 days after the end of labour, during which the continued attendance of a midwife on the mother and baby is requisite."

In 1997 there were, on average, eight postnatal contacts in the community per mother, totalling over four million midwifery home visits nationally.[60] Since 1988 the number of antenatal contacts has risen by 50% while the number of postnatal contacts has decreased by 18%.[60] Routine postnatal visiting at home by a midwife in the UK formerly comprised daily visiting up to the tenth day after birth, though this has recently been superseded by the permission to provide selective visiting.[61] The Expert Maternity Group suggested that postnatal care should be flexible and meet the needs of individual women.[8]

Little research has been carried out into the content of midwifery postnatal visiting. Four factors that lengthen such visits have been identified as:

- performing a Guthrie test
- complications at delivery
- women previously unknown to the midwife, and
- visits to women who had previously breastfed.[62]

Visits had a mean duration of 24.2 minutes. Several features were not associated with longer visits and these included health and social problems and the absence of family and partner support.

Although midwives carry out a wide variety of tasks during postnatal home visiting, these do not always meet women's needs, such as problems with breastfeeding.[13] In a study of the determinants of quality in maternity care, the aspects of postnatal care important to women were identified, as developing confidence in care of the new baby and coping at home.[63] Midwives and women did not concur on issues of importance with the exception of breastfeeding.[63]

It has been suggested that current service provision is not meeting the health needs of women due to the widespread and persistent morbidity that occurs after childbirth.[2] Bick suggests that routine examinations by midwives should be reduced and more time allowed for women to raise health and other concerns.[64] The opportunities for this may be increased where midwives work in programmes that provide continuity of carer.[64]

Satisfaction with postnatal care

Postnatal care in hospital remains the least satisfactory element of maternity care.[65] In contrast, most women appreciate postnatal home visiting, despite the lack of evidence of clinical effectiveness on outcomes such as breastfeeding.[66] However, women cite difficulties in continuity of care, conflicting advice and the inconvenience of unpredictable visits.[13] Conflicting advice from midwives has been found to be a major source of dissatisfaction with postnatal care and a contributor to emotional distress.[58] There is still a significant level of dissatisfaction, with 20% of

women reporting that the frequency of visits was inappropriate for their needs[66] and continuity remains an issue in some areas of the UK.

Home visiting practice

The Audit Commission highlighted the variation in visiting policies between Trusts and the absence of evaluation of the various patterns of care.[66] There are regional variations in postnatal care and consequently in use of resources.[65] The aims of postnatal care appear uncertain to the Audit Commission:[66] to prevent and treat immediate health problems or to give women time to recover and get to know their babies. They suggest the evaluation of traditional visiting practices and targeting of visits to those in need.

Breastfeeding

Breastfeeding is associated with several health gains, including protection against gastroenteritis for the infant[67] and a reduced risk of premenopausal breast cancer[68] and ovarian cancer[69] for the mother. Social support is one of the important factors in encouraging successful breastfeeding, whether from an informal or professional support network.[70,71] Programmes found to be successful include extra visits from a midwife,[72] extra advice and support for working class women,[73] and the support of both peer counsellors[74] and doulas (a woman helper and companion during childbirth) in RCTs conducted outside the UK.[75] In many areas within the UK women have organised themselves into breast-feeding peer support networks[76,77] with some success, perhaps because of the need for more support from family and friends for breastfeeding women.[78]

It is suggested that women would have better experiences of breastfeeding if they had access to appropriate support and accurate information, particularly continuity of support.[79] However, that may not always be achieved as problems with conflicting advice persist, albeit less frequently in the community than in hospital[65] with 14% women reporting that they did not receive consistent advice, 13% reporting that they did not receive practical help and 10% did not receive active support and encouragement.[65]

In situations where women experienced delays in holding their baby after birth, the likelihood of breastfeeding was diminished.[80] In this survey, 66% of women in Great Britain were found to have commenced breastfeeding, though delays in providing the first breastfeed beyond 1 hour after birth were associated with discontinuing breastfeeding within the first 2 weeks.[80]

Many studies have identified factors associated with the continuation of breastfeeding and higher social class and previous successful experience were associated with a longer duration. Despite this, however long the duration of breastfeeding, women may still like more help.[81] Matich and Sims found differences between women planning to breastfeed and those planning to bottle feed in the information support available to them.[70] They identified the baby's father as an important source of tangible support for those planning to breastfeed. McIntosh identified a lack of support from healthcare professionals in both hospital and community and suggested a particular need for more support in the first 14 days.[82]

Alternative models of support

Models of lay support to families have been introduced in parent to parent projects such as Newpin[83,84] and Home Start, where experienced mothers, as volunteers, either befriend or visit families in situations of stress.[85] Sources of lay support also include user groups, such as local branches of the National Childbirth Trust, who have both breastfeeding counsellors and postnatal support networks. However, such groups are not accessed by all women and tend to have a bias in their membership towards more highly educated and financially secure women.

Spencer[86] described a model of antenatal family support based on the French *travailleuse familiale*, which was subsequently evaluated in a trial in Manchester. Lay workers offered emotional and practical support to women at high risk of having a low birthweight baby. No differences were found in maternal outcomes but there was a perception that women found the support valuable, as it improved their subjective well-being.[49]

In The Netherlands there is one well established model of support for new mothers, which is a key component of the maternity service provision. The Kraamzorg or Maternity Aide provides a range of care packages in the woman's home for 3–8 hours per day, usually during the first 8 days after the birth. This worker takes over the running of the household, does housework and cares for young children in the family. The Maternity Aide provides help and advice with infant feeding, carries out clinical observations on the mother and baby, and reports any problems to the midwife, who retains responsibility for the care of the woman and her baby for the first 8 days after the birth.[87]

The role of Maternity Aide supports the autonomy of the midwife and allows her to concentrate on midwifery duties.[88] The role also supports a home birth rate of approximately 40%[89] and offers support in the early days of breastfeeding, though the long-term effectiveness of this support has been questioned.[90] The quality of care provided by the Maternity Aides is highly rated by families, though availability is perceived as inadequate.[91] It is used by approximately 75% of women[90] and the costs of the service are reimbursed through a health insurance scheme.[92]

Costs of maternity care

There has always been pressure on the NHS to make best use of maternity care resources.[93,94] While the total annual cost of maternity care in England and Wales is around £1.1 billion, each delivery can cost £1700 on average.[66] A number of efforts have focused on cost-containment in maternity care, for example, a drive for day-care management of hypertension in pregnancy aiming to reduce inpatient workload and costs[95] and reduced postnatal length of stay. The Audit Commission concluded recently that cost and effectiveness issues need to be considered alongside women's views.[66] The costs of maternity care are spread between the provider units and GPs for antenatal, intrapartum and postnatal care and vary according to whether the delivery is a low- or high-risk birth, and the location of monitoring and the location of the birth. There may be 18 decision points throughout the progress of the pregnancy and delivery that have resource implications.[96]

Antenatal care costs

The Audit Commission[66] estimated that £10 million could be saved by reducing antenatal contacts. There is evidence that low-risk women make on average 14 antenatal visits, exceeding the recommended number.[97] A detailed cost analysis of antenatal care in Glasgow for 1667 women found the total societal costs for antenatal care were £417–450 per woman.[98]

Intrapartum care costs

Deliveries involving an intervention cost more than those without. A normal delivery might cost on average £363, ranging from £189 to £773 and a Caesarean section might cost on average £1123, ranging from £837 to £1560.[99]

Postnatal care costs

This area of care is not over-funded compared with antenatal and intrapartum care. Only 2% of postnatal care and 8% of antenatal care was provided in primary care in the 1970s and almost 85% of all the monies went to the hospitals.[94] As the mean length of stay was 7 days, postnatal care accounted for 52% of the total spent on maternity care, while antenatal care accounted for 31% and intrapartum care accounted for only 17%. The cost then ranged from £393 to £484 for a woman's delivery.[94] The mean duration of postnatal stay in both England[100] and Scotland has been reducing over several years to less than 4 days. The cost per inpatient day is around £75[95] and for a singleton birth, the average cost for postnatal stay, including intrapartum care might be £451 (at 1989 prices).[99] This pattern of reducing the length of postdelivery stay is not necessarily cheaper for the NHS as a whole, not only because the main costs for length of stay are associated with early postnatal care, but also because this has resulted in more home visits by midwives.[101] Women who have had a Caesarean section are likely to stay in hospital on average for 7 days, compared with less than 3 days for a normal delivery.[66]

Most of the costs for midwifery services (88%) are likely to comprise salaries.[101] The cost for a community midwife visit (in 1990 prices) was estimated as £6.53,[95] of which 77% comprised midwifery care (£5.03) and 23% comprised travel (£1.50). Travel costs now comprise a larger proportion of total costs than in 1977, when women might expect 13 visits from a community midwife for a home confinement and eight visits for hospital admission; a single visit cost £2.77 for midwifery care with 9% of the cost (27p) for travel.[102]

NHS costs for maternity care in Scotland have recently been calculated in an RCT of 1299 women.[103] The mean postnatal stay was found to be 3.3 days and the mean number of community postnatal visits was 4.9 before the women were transferred to the health visitor on day 11.[104] In some health authorities in England, midwifery visiting continues only until the tenth postnatal day, but elsewhere, midwives continue to visit throughout the first postnatal month. Mean costs for antenatal care ranged from £288 to £296, mean intrapartum care costs were £241, whereas mean postnatal care costs ranged from £352 to £471.[103] Sensitivity analysis examining the effects of increased caseload reduced the cost of postnatal care to £404 per woman.

NHS resource use is often calculated without taking into account costs to a family because they

are difficult to quantify. The median time taken for a home visit in the Glasgow trial was 45 minutes (range, 20–105 minutes) with no out-of-pocket expenses for the women, but an opportunity cost (median) was estimated as £2.82 per woman.[103]

This historical review of costs has examined only the NHS perspective up to the point of transfer to the health visitor. We are aware of no work that has prospectively examined the effect of additional social support on costs for all aspects of NHS resource use to 6 weeks or 6 months postnatally.

Summary

There is some evidence that social support provided antenatally and during labour and delivery is good for women and their babies. In the UK, there is no model that offers women **additional practical and emotional support** at home during the postnatal period. Research is required to establish the effectiveness of the provision of postnatal social support, and in particular the efficiency of **additional** support provided by workers trained specifically for this new role. The potential benefits of such an intervention might include:

- reduction of tiredness and improvement in physical morbidity
- reduction of PND and the use of anti-depressants
- extended duration of breastfeeding
- reduction in use of NHS resources, or
- improved levels of satisfaction with postnatal care.

Aim and objectives of the trial

The aim of the trial therefore was to test the effect and to calculate the total cost per woman of providing women with additional postnatal support at home, based on a modification of the Dutch Maternity Aide model, in relation to conventional postnatal midwifery care. The research hypothesis was that there would be a positive effect on women's general health and well-being and that there could be long-term cost savings to the NHS for use of services.

The research objectives were to:

- recruit women who met the trial criteria and consented to take part
- allocate women at random to an experimental or control group
- provide the community midwifery support worker (CMSW) service for women in the intervention group
- monitor all women to 6 months postnatally
- measure costs of all services used
- analyse clinical and cost outcomes by group
- analyse by differences in risk, as far as possible.

Chapter 2
Methods

Design

The study was a prospective RCT, which aimed to measure any difference in self-perceived health status in women who were offered additional postnatal support from an SW compared with a control group. The primary outcome was the change in the general health perception (GHP) domain of the Short Form-36 (SF-36) health status measure.[105]

The trial followed women to 6 weeks and 6 months after their baby was born, to monitor change in self-perceived health status over time. It was not possible to blind the trial as the intervention was obvious both to recipients of the service and to midwives, GPs and health visitors who were in contact with the women in the intervention group. The researchers were blinded to allocation for the purpose of the data handling as there was no group code on the questionnaires received.

The trial population

The trial population consisted of all women who delivered a live baby during the recruitment phase at the recruiting hospital in Sheffield, and met the recruitment criteria, which were as broad as possible (see *Recruitment and consent*, page 12). All women were eligible to take part in the trial if they lived within the area visited by the recruiting hospital's community midwives and were aged 17 years or over.

The exclusion criteria were women who:

- were unable to give informed consent
- were unable to understand and speak the English language
- had a baby requiring care in the special care baby unit for more than 48 hours.

Young women aged 16 years or below were regarded as minors for the purposes of the Ethics Committee, and specific, sustained follow-up support already existed for women who had a baby in the special care baby unit in the form of family care sisters to support the family at home.

It would have been very difficult for the SWs to communicate with women who were unable to speak English and the women themselves may not have been able to indicate their needs. Some women would not have been able to read the research information leaflets, give informed consent or complete the postal follow-up questionnaires privately. The cultural appropriateness of the intervention was not known. Additional funding would have been required to cover the provision of the number of bilingual linkworkers to work alongside the SW for the range of languages spoken in Sheffield.

Where the midwives on the postnatal wards were aware of a potential threat to the health and safety of the SWs within a woman's home, the woman was not invited to participate in the trial.

Intervention

The aim of the intervention was to help women to rest and recover after childbirth, by offering mainly practical and emotional support. Women in both the intervention and control groups were offered conventional postnatal care in the home by a community midwife. The intervention group were offered up to ten additional visits from a new worker, the SW, during the first 28 days after birth, for up to 3 hours per day. The intervention was on weekdays only because of the greater availability of family and other people to offer social support over the weekends. In addition, providing a service at weekends would have increased the cost of the intervention.

The intervention was individualised to each woman's self-defined needs. The SWs worked with the new mothers to help them develop confidence in caring for their new baby or caring for other siblings, reinforcing midwifery advice on infant care and feeding, promoting the provision of a safe environment, providing emotional support and helping with housework. The SWs also provided access to a range of information in a resource folder.

Primary outcome

The primary outcome was a five-point difference at 6 weeks in the mean health status scores between intervention and control group on the GHP domain of the SF-36.[105] This five-point difference is the smallest score change achievable by an individual and is considered as 'clinically and socially relevant'.[106] The normal recovery from delivering a baby has not been documented and there are no established benchmarks for good health at 6 weeks postnatally when women have a clinical examination, mainly to assess morbidity. There is a complex relationship between the health of a mother, her infant and family, which the SF-36 was not designed to measure. Self-perceived health status was measured in both groups at 6 weeks and 6 months postnatally. All outcome measurements were administered by post in the same questionnaire booklet.

The secondary outcomes were Edinburgh Postnatal Depression Scale (EPDS) scores used to assess risk of PND,[107] mean scores on Duke Functional Social Support Scale (DUFSS) used to measure functional aspects of supportive relationships[108] and breastfeeding duration. The EuroQol (EQ-5D) utility measure was used at 6 months.[109]

Women were also asked about other social support available to them at home and their views on the services they had received. They were asked about breastfeeding at 6 weeks and 6 months postnatally and their health visitors were asked for information about breastfeeding and immunisation status at 3 months. A number of questions were used as proxies to assess adaptation to life with a new baby.

Sample size

The primary outcome was used to determine the sample size. The conventional levels of statistical significance and power are 5% two-sided and 80% power. To have an 85% chance of detecting as significant (at the two-sided 5% level) a five-point difference between the control and intervention groups in the mean SF-36 GHP scores at 6 weeks follow-up, assuming a standard deviation (SD) of 20.00 would require approximately 288 women in each group[110] (*Figure 1*). With a loss to follow-up of 20%, approximately 360 (720 in total) women in each group would be required.

With 256 women per group (512 in total) there would have been an 80% chance of detecting as significant (at the two-sided 5% level) a five-point difference between the groups in the mean SF-36 GHP scores at 6 weeks follow-up. With a loss to follow-up of 20%, approximately 640 women in total would have been required. In the protocol it was proposed to recruit 720 women, but because of a slower than anticipated recruitment rate, this was revised during the course of the trial to 640 women to achieve 80% power. A number of strategies were employed to boost recruitment.

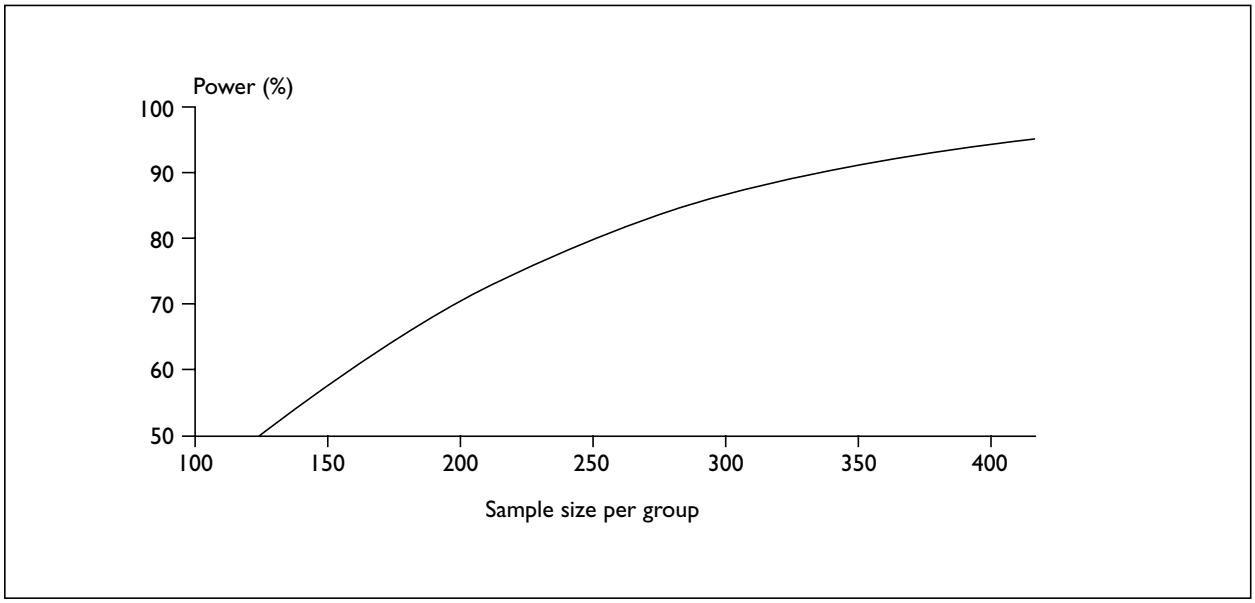

FIGURE 1 *Sample size and power. Two-group t-test of equal means (equal n-values)*

Statistical methods

As a pragmatic trial, as few women as possible were excluded from the trial and all analysis was by intention to treat, irrespective of whether women in the intervention group received visits from an SW. Women who moved out of the trial area were still included in the analysis up to the last point of data collection. All data to be analysed were entered and maintained in a relational database (Microsoft ACCESS) and converted to Statistical Package for the Social Sciences datasets for statistical analysis. At both 6 weeks and 6 months, reminder questionnaires were issued and telephone calls were made to remind those who had not replied or to complete missing responses.

Demographic and clinical data were assessed for comparability between the intervention and control groups. For the continuous measurements (e.g. age and birth weight) the two groups were compared by *t*-tests or Mann–Whitney *U*-test, depending on distributions. For categorical data (e.g. spontaneous onset of labour or Caesarean section) chi-squared tests (χ^2) were used. For dichotomous data with rare events, Fisher's exact test was used to compare groups. For ordinal variables, the Mantel–Haenszel chi-squared test was used.

Summary statistics (mean, SD, median and quartiles) were provided for all clinical measurements and for all patient demographics. For dichotomous variables, only percentages were reported.

The self-perceived health status domain scores (SF-36, EPDS, DUFSS, EQ-5D) were assumed to be continuous measurements. Mann–Whitney tests were used to compare the distributions of responses in the two groups. Non-parametric bootstrap percentile confidence intervals (CIs) were estimated for the difference in mean scores between the groups.[111] The Mann–Whitney test compares the distributions of two groups, whereas the bootstrap CIs are calculated for a characteristic of the distributions (e.g. mean, medium). It is possible that groups can have differences in distributions, but similar characteristics.

At 6 months follow-up, the outcome of interest was the change in health status scores from the 6-week assessment. For each woman, the change in health status from 6 weeks was calculated and the mean changes in the two groups were then compared by parametric and non-parametric tests, depending on distributions. Parametric analysis of covariance (ANCOVA), which assumes the differences are normally distributed continuous measurements with constant variance, was used to adjust for the 6-week health status score.[112]

Outcome measures

SF-36

This was designed to measure health status in the Medical Outcomes Study.[105] It is a brief and comprehensive tool that consists of a 36-item scale measuring eight domains:

- physical functioning
- role limitation physical (RLP)
- social functioning
- vitality
- pain
- mental health
- role limitation emotional (RLE), and
- GHP.

Measurement of these domains generates a 0–100 score, where 100 indicates 'best health'. It also includes one question on change in general health over a set time. The development of the instrument was based on a number of full-length scaled items and the aim was to measure a comprehensive range of health concepts and detect clinically and socially relevant differences in health status and changes over time. It was designed for self-administration or for administration by an interviewer. There are 36 items to complete and the time for completion is about 5 minutes.[110] An anglicised version has been used in the UK and found to be acceptable and easy to use in a general population[110] and suitable for use in groups with varying degrees of ill-health. However, no reports of the use of the SF-36 among women in the first 6 months after childbirth have been identified.

EPDS

The EPDS was developed because of the limitations in the number of available tools for screening for depression, many of which appeared to lack face validity for postnatal women.[107] The tool satisfied the conditions for a screening tool for PND as an acceptable, simple, self-report scale, with satisfactory reliability and validity to minimise the chance of false-positive or false-negative results and it was sensitive to change over time. In addition the tool was validated by Cox and co-workers[107] in a postnatal population in a community setting. From 21 items originally selected, 13 were selected, including seven

newly-constructed items and six adapted from other scales. The validity of this 13-item scale was established on 63 women and three items were removed to improve the specificity. The remaining ten items were validated on 84 women at a mean 12 weeks postnatally. A score of 13 identified all women with a definite major depressive illness, but missed one probable major illness. There were 11 false-positives at this threshold and four women with definite minor depression were missed, that is they were false-negatives. Using a threshold of 12 correctly included all women with probable and major definite depression and reduced the false-negatives to three women, but increased the false-positives to 14 women. At this threshold, the sensitivity for detecting true-positives (n = 35) was 86% and the specificity for detecting true-negatives (n = 35) was 78%. The positive predictive value was 73%. Sensitivity to change was calculated for women who repeated the score and were interviewed for a second time and mean scores were found to be reduced.

The authors emphasised that the EPDS is not a substitute for a clinical assessment and a score of 11 does not indicate the absence of depression. The EPDS was later re-evaluated[113] on a larger population and a lower sensitivity of 67.7% was found at the threshold score of 12. There are problems of validity of the EPDS in a cross-cultural setting. Translated versions are available with the intention of preserving the denotative and connotative meaning, but there may be cultural differences in interpretation and the score may not accurately reflect the mother's mood. Unless the EPDS has been validated for use in that particular language, the score cannot be assumed to have the same meaning across all cultures.[114] Work is at an early stage covering a number of issues relating to psychopathology in a cross-cultural context, cross-cultural expression and measurement of PND.[115] Only the English version of the EPDS was used in the trial.

DUFSS

The measurement of social support is known to be problematic and there are few well-validated tools that are useful for practice or research.[39] The DUFSS was developed at the University of North Carolina in 1982, as a brief self-administered questionnaire to measure the functional aspects of social support in primary care.[108] Originally there were 14 items in a five-point Likert scale, with three questions on quantity of support, four questions on confidant support, three questions on affective support and four questions on instrumental support. The instrument was tested on 401 subjects, most of whom were white, female and aged 18–44 years (mean, 35.7 years). It was reduced to eight items after reliability testing. However, no reports of its use among postnatal women have been identified. Although it contains no detail about distribution of scores or responsiveness to change, it covers the domains of affective support (appreciation, respect, love) and confidante support well[108] and is easy and quick to complete.

EQ-5D

This self-rating questionnaire was developed by the EuroQol Group in 1990 to provide a standardised, non-disease-specific instrument to describe and value health-related quality of life and to generate a single index value for each health state or Derived Single Index.[109] It was designed to be self-completed, used in postal surveys and sufficiently short to be used as an addition to other instruments.[116] It originally had six items: mobility, self-care, main activity, social relationships, pain and mood. No reports of the use of the EQ-5D among postnatal women have been identified. The version used had five items, which took less than 5 minutes to complete.

Ethical approval

Ethical approval was obtained from the local Research Ethics Committee. The Local Medical Committee, the Department of General Practice and the local health authority also offered their support for the trial. Prior to the commencement of the trial, an advisory group representing all stakeholders was established and an A4 information sheet was distributed to all GPs, health visitors and community midwives in the health authority.

The consent form for the women to sign prior to recruitment included questions that asked whether the women understood that if a problem with their health was indicated on their questionnaire, the researchers may contact the appropriate support and that the researchers would be requesting access to their hospital and GP records.

Recruitment and consent

Recruitment took place from October 1996 (pilot phase) to November 1997 on the postnatal wards at the recruiting hospital in Sheffield.

As recommended by the Association for Improvements in the Maternity Services[117] it was planned that a research information leaflet would be provided by community midwives to women who were attending for their 32-week antenatal appointment and who were expected to have their baby during the recruitment interval. Additional information, which defined the role of the SWs and informed the women about the range of support, was available for women on up to three occasions: first, during pregnancy via the midwife at the antenatal clinic; second, at the point of recruitment; and third, at the time of the SWs first visit to the woman's home.

Women who delivered a live baby and were eligible for inclusion in the trial, were approached by one of the three researchers. The women were given the chance to discuss the trial further with their partner. All the researchers gave consistent information to the women, who were aware that they had a 50:50 chance of allocation to either group. All women who agreed to participate signed a consent form, were asked about problems in reading or writing English and educational attainment, and completed a questionnaire to provide socioeconomic details.

Assignment to group

The unit of randomisation was the individual woman. The random allocation schedule was prepared in advance in the research office by the statistician, using random digit tables. Using this schedule, sequentially numbered, sealed, opaque envelopes containing information for the women about their assignment to group, were prepared by a clerk. This process achieved a balanced randomisation and concealed the group of allocation from the women, researchers and the midwives on the wards, who were all unaware of the next assignment in the sequence.

To protect her confidentiality no names were used and each woman was given a unique identifying number in order of the recruitment sequence and all documentation used only this number. When a woman was assigned to the intervention group, the relevant SW arranged a first visit by contacting her on the postnatal ward, by phoning or by calling at the woman's home. The management of each woman's care remained entirely with the community midwife and GPs.

Preparation for the trial

SW recruitment and selection

In light of the Clothier report[118] (The Allitt Inquiry), there was an awareness of the need to carefully select and prepare workers to work unsupervised with access to children, safely and competently in women's home. The posts were advertised in the local Job Centre and two maternity units in the city. Only women (21) applied, 16 were interviewed and eight SWs were recruited under the Trust's equal opportunities policy. The essential attributes for the post were:

- the ability to work with people
- a caring, non-judgmental approach
- good verbal, writing and basic numeric skills, and
- willingness to undertake the National Vocational Qualification (NVQ) in postnatal care (Level 2).

Desirable qualities were:

- a supportive attitude
- experience working in care or with infants
- a positive attitude to breastfeeding
- the ability to work flexibly (8 a.m. to 6 p.m. Monday to Friday), and
- the use of a car.

The SWs had pre-employment screening, including physical and mental health and police clearance. The posts were graded at Whitley Scale Grade B (£9115) reflecting the absence of direct supervision whilst working alone in the community. Three SWs used a car for work and their travel expenses were reimbursed as per Whitley Scale. Five used public transport and they were provided with bus passes.

Preparation of the SWs

A training programme was developed in consultation with the recruiting hospital Education and Training Department and the midwifery service. Midwives were involved at an early stage in planning and formulating the postnatal intervention. They contributed to the definition of the SWs' role and to the theoretical and practical elements of the SWs' teaching programme. Outside agencies including Homestart and Home Help services were also contacted. The 8-week training programme aimed to develop the knowledge, skills and attitudes to enable the SWs to provide women with effective practical and emotional support during the early postnatal weeks. Central to the training was the need to prepare the SWs to work

safely, alone in women's homes to the required standard and to standardise the intervention. The course included three modules structured as follows:

- introduction to the role of SW
- postnatal care of mother and baby
- ongoing postnatal care and support in the community.

The training programme included both classroom and clinically-based sessions and practical work experience. Health visitors, midwives and a member of a user organisation contributed to the delivery of the training programme. Two SWs were employed for the pilot phase and in light of their evaluation, minor changes were made to the programme and the other SWs were offered more time to consolidate learning in the clinical setting. The SWs were each allocated a midwife to provide mentorship and assessment. Further training needs were identified as the SWs became established in their role (listening skills, the social worker's role, caring for children in the absence of parents, car safety, first aid and domestic violence) and were addressed during continuing education sessions. The SWs achieved their NVQ (Level 2) Postnatal Care Award, and completed endorsement units accredited to the Domiciliary Care Award and competence in the care of young children. The SWs resource folder contained addresses and telephone numbers of local agencies: toddler groups, citizens advice bureau, health promotion literature (e.g. sudden infant death syndrome), women's groups, financial advice, local advice centres, marriage and family issues, child care and support, and breastfeeding advice.

The SWs worked in one of four geographical areas served by existing community midwifery teams to both encourage liaison with the team and reduce the time travelling between visits. The SWs were required to undertake a full risk assessment of their working environment on the first visit to each client's home to identify all hazards. All SWs were supplied with a mobile phone, circuit breakers (to isolate electric current), rubber gloves, plastic aprons, and tabards to protect their own clothes.

Initially the SWs were managed by a community midwifery manager, but to avoid duplication, this responsibility was assumed by the research midwife. Guidelines were developed to ensure that the SWs worked within their skill base. For their own safety, the SWs' role excluded pet care, outside work, and cleaning windows or stairs.

The SWs completed a detailed activity log after each visit to calculate the time spent on each task and travel time. All the SWs had regular, supervised visits by the research midwife to provide support in their new role, perform assessments, ensure standards of work were maintained and to monitor completion of documentation. Other weekly support mechanisms were also provided.

Validation of use of services

Records from a sample of GP practices, representing 44% of recruited women were examined to assess the frequency of GP contacts at home, by phone and in the GP surgery for the mother and her baby in the first 6 months and to identify any differences in women's reports of GP and hospital consultations. For efficiency, notes were examined from the practices with the largest number of women recruited. The women's consent forms were made available to the GPs before the records were retrieved. The hospital computer and case notes of the same sample of women were examined to record the frequency of use of hospital services for the mother and her baby in the first 6 months.

Economic evaluation

Background and aims

The aim of the economic evaluation was to determine whether providing a CMSW service was a cost-effective use of NHS resources. The technique for performing the economic analysis can only be chosen once costs and health outcomes for both the intervention and control group are known.[119] The intervention would be considered better than usual practice if it was cheaper and more effective, if it was similar in cost and more effective, or if it was cheaper and equally effective. When an intervention is both more effective and more costly, results can be presented in a variety of ways depending on the health outcome measured.

Where effectiveness is measured as a single domain, results can be presented as the cost per unit of effect. For example, in this trial the primary health outcome was the score for the GHP domain of the SF-36 at 6 weeks. If the intervention had generated improvements in health, trial findings could be presented as

the cost per five-point improvement in the intervention group. However, the use of GHP instruments (which do not produce a single quality of life score) in cost-effectiveness analysis is contentious.[120] Moreover, it would not be possible to compare the CMSW service intervention with other NHS programmes that use different outcome measures. This would require a generic outcome measure such as quality-adjusted life-year (QALY). Where a new programme improves health, results can be presented as cost per QALY gained.

In this trial however, the main purpose of the economic analysis was to compare total costs and benefits for the intervention and control groups at 6 weeks and report any differences. Secondary analysis compared total costs and benefits for both groups at 6 months.

Methods

Where possible, all costs were identified, measured and valued from the perspective of the NHS. In addition, resource-use data were also collected to provide service commissioners with information about costs from the perspectives of the women in the trial and external agencies, such as social services. For the purposes of this trial the three main cost categories were:

- costs to the NHS
- costs incurred outside the health service, and
- personal costs incurred by women in the trial.

Use of resources by both groups was tracked for 6 months after delivery. The main sources of data were self-completed questionnaires issued to the women at 6 weeks and 6 months postdelivery. Women were asked about use of health and social services, subsequent to the birth of their baby and also about personal costs, such as purchases of medication for themselves or their baby. They were also asked whether partners and family or friends had taken time off work to help them after their baby was born. *Table 1* shows the important costs identified for each group.

Data collection and costing methods

Intervention group costs only

The CMSW service set-up costs mainly comprised staff time, costs to develop the SW role and training package, and costs to provide initial and ongoing training. Costs were therefore calculated as number of hours spent in training and development multiplied by the individual staff member's salary. Salaries for most trainers included 11.5% employer on-costs (national insurance and superannuation contributions) and 28% overheads (19% direct overheads and 9% indirect). For the remaining staff, employer on-costs and overheads are unknown because they were already included in the salary figures.

Additional expenditure included fees for registration of SWs for their NVQ and for purchase of certificates. Training costs were spread over the expected working lifetime of the SWs, (assumed to be 10 years), using a discount rate of 5% and assuming an average of 25 visits per fortnight for a whole time equivalent SW. The trial assumed working for 37.5 hours per week, 45 weeks per year and assumed 10 days' sick leave.

These data allowed calculation of the training cost element per SW visit. However, given that the training programme was expected to last around 10 years before major revisions would be required, and that the full costs of developing the programme were spread over only six remaining SWs, the final cost per SW visit would **overestimate** the true cost of a visit if a full

TABLE 1 *Important costs identified for each group*

Important costs	Intervention group	Control group
NHS		
Postnatal care	CMSW programme set-up costs	
	SW visit costs	
	Midwife visit costs	Midwife visit costs
Other NHS costs	GP services (including prescriptions)	GP services (including prescriptions)
	Health visitor services	Health visitor services
	Hospital services	Hospital services
	Secondary mental health services	Secondary mental health services
External agencies	Social services	Social services
Personal costs	Over-the-counter medications	Over-the-counter medications
	Formula baby milk	Formula baby milk

programme, employing more than six SWs, were introduced within the next 10 years. The cost of an SW visit mainly comprised staff time costs. This included length of home visit, travel and administration time. Times for each activity (visit, travel and administration) were recorded and annual salaries (£9115 per whole time equivalent) were used to calculate cost per visit. Employer on-costs and overheads were estimated at 9% and 19% respectively, while capital overheads were estimated at £1900.[121] Additional costs included travel reimbursements, circuit breakers, tabards, maps and mobile phones. Only those women who had at least one visit from an SW were included in the calculation of a cost per SW visit.

Intervention and control group costs

For the 6-week cost analysis, only women who returned a 6-week questionnaire that is, women for whom all resource-use data were available, were included: 282 (90.7%) for the intervention and 269 (86.2%) for the control group.

To calculate total costs at 6 months postnatally, only those women for whom all resource-use data were available at 6 weeks **and** 6 months were included in the analysis. For the intervention and control group the numbers were 252 (81.0%) and 219 (70.2%), respectively.

Whenever possible, local sources were used to estimate costs of resources. Otherwise nationally published estimates were applied. All relevant identified resources are listed in *Table 2* with details of how they were measured and their respective sources of cost data for valuation purposes. All costs were estimated in 1996 values.

Where occasional data items were missing from questionnaires, values were imputed using the mean value for that variable, for all valid responses.

Midwife visits were counted for each woman in both groups using the community midwive's postnatal record card, which documents care provided during visits. Data on length of visits

TABLE 2 *Measurement and valuation of resource use*

Resource	Measure	Source	Valuation
Postnatal care			
Set-up costs			
SW trainers	Time and grade	Programme manager	Local cost data
SW visits			
Staff	Time and grade	Activity log sheets	Local cost data
Consumables	No. and type	Programme manager	Local cost data
Travel	Mileage	Programme manager	Local cost data
Equipment	No. and type	Programme manager	Local cost data
Overheads			Nationally published estimates[121]
Midwife visits			
Staff	Time and grade	Activity log sheets	Local cost data
Overheads			Nationally published estimates[121]
Other NHS services			
GP services	No. and type	Follow-up questionnaires	Nationally published estimates[121]
Prescriptions	No. and type	Follow-up questionnaires	Trent Drug Information Services
Health visitor services	No. of contacts	Follow-up questionnaires	Nationally published estimates[121]
Hospital services	No. and type	Follow-up questionnaires	Local provider data
Secondary mental health services	No. and type	Community Health Sheffield NHS Trust	Nationally published estimates[121]
External agencies			
Social services	Social worker contacts	Follow-up questionnaires	Nationally published estimates[121]
Personal costs			
Bought medications	No. and type	Follow-up questionnaires	Women's reports
Formula baby milk	Quantity and duration	Follow-up questionnaires	Local cost data

were not available from this source so a separate survey was carried out on all community midwives at the recruiting hospital. Data were returned for 76% of midwives (n = 28), who completed an activity logging sheet, for a complete, randomly selected week, that gave details of time on postnatal- and antenatal-related activity and travel. The midwives' actual salaries were combined with these data to estimate a cost per visit. These included 11.5% employer on costs (recruiting hospital) and 28% overheads.[121] Each midwife visit to women in the trial was then assigned a cost at random, by selecting from the previously calculated distribution of costs per visit.

GP contacts were reported in the follow-up questionnaires. Costs per contact were taken from nationally published estimates[121] as £30 for a home visit, £10 for a surgery visit, and £13 for telephone advice. Women also reported the number and type of prescriptions issued and costs were provided by the Trent Drug Information Services. The number of health visitor contacts was recorded in the follow-up questionnaires and costs for these visits (£46 per hour of client contact) were taken from nationally published estimates.[121] It was estimated that a clinic appointment with a health visitor lasted approximately 30 minutes and cost £8.[121]

Hospital services contacts were reported as inpatient, outpatient, day-patient and accident and emergency (A&E) attendances in the follow-up questionnaires, and were valued using local provider unit cost data, mainly NHS Trust financial returns by speciality.

Number and type of secondary mental health service contacts were provided by Community Health Sheffield NHS Trust for all women recruited into the trial. Apart from hospital inpatient stays, which were costed using local data, all other contacts were valued using nationally published estimates.[121]

Number of social service contacts were reported in both 6-week and 6-month follow-up questionnaires and nationally published estimates (£21 per hour of client-related work) were used to cost these contacts.[121]

Women in the trial provided data on the number, type and cost of all medications purchased at 6 weeks and 6 months. These were combined to calculate total costs of medication per woman and baby. Data on duration of bottle and breastfeeding were collected from follow-up questionnaires at 6 weeks and 6 months. The average quantity of formula baby milk for a totally bottle-fed baby was estimated to be 900 g per week. Women who reported that they were breastfeeding **only** were assumed to purchase no formula milk. Women who reported that they currently breast and bottle fed their baby were assumed to purchase 450 g per week. Local retail costs were used to value the quantity of formula baby milk consumed per baby (£6 per 900 g tin). Although some women in both the intervention (28%) and control (25%) groups claimed free milk vouchers or reduced price milk, the value of these was not deducted from the total costs of formula milk. The receipt of vouchers means that the cost burden falls on the Benefit Agency rather than the women, though the quantity of milk purchased is unaffected. Cost to women of formula milk therefore is overestimated but given the similar proportions who received vouchers, this overestimation will be similar for both groups.

Data about time taken off work by partners, family and friends were collected from a separate short questionnaire. Response rates to this questionnaire were 75% (n = 233) for the intervention and 62% (n = 195) for the control group. Given the difficulties in valuing time off work by individuals outside the trial and applying those costs to the trial women, costs were identified and measured, rather than valued. To provide information to aid service commissioners, therefore, these data on days taken off work whether as annual, special paid or unpaid leave were reported separately.

Economic analysis

The primary analysis compared the aggregate mean NHS cost per woman in each group at 6 weeks and 6 months postnatally. Secondary analysis involved comparisons of aggregate mean personal and social services costs at 6 weeks and at 6 months postnatally. Cost distributions were summarised by their mean, SD, median and quartiles. Given the small number of women who used hospital, social and mental health services, the distribution of total costs was likely to be highly skewed. Non-parametric tests (Mann–Whitney tests) were used to compare the distribution of costs in both groups. Non-parametric bootstrap percentile CIs were calculated to compare the difference in mean total cost between the groups.[111] Final results were subjected to sensitivity analysis of the key assumptions about unit costs and observed variance in resource use.

Chapter 3
Results

Recruitment details

There were 623 women recruited to the trial, including 154 women recruited during a 12-week extension. These represented 37% of the 1672 women approached. *Figure 2* shows the numbers of eligible and recruited women, the reasons for non-eligibility, the reasons women could not be recruited, those who declined to take part and the response to follow-up questionnaires.

Sheffield has been identified as a mining and industrial area, corresponding with North Tyneside as the most similar district.[122] Information for Sheffield Health Authority, mainly

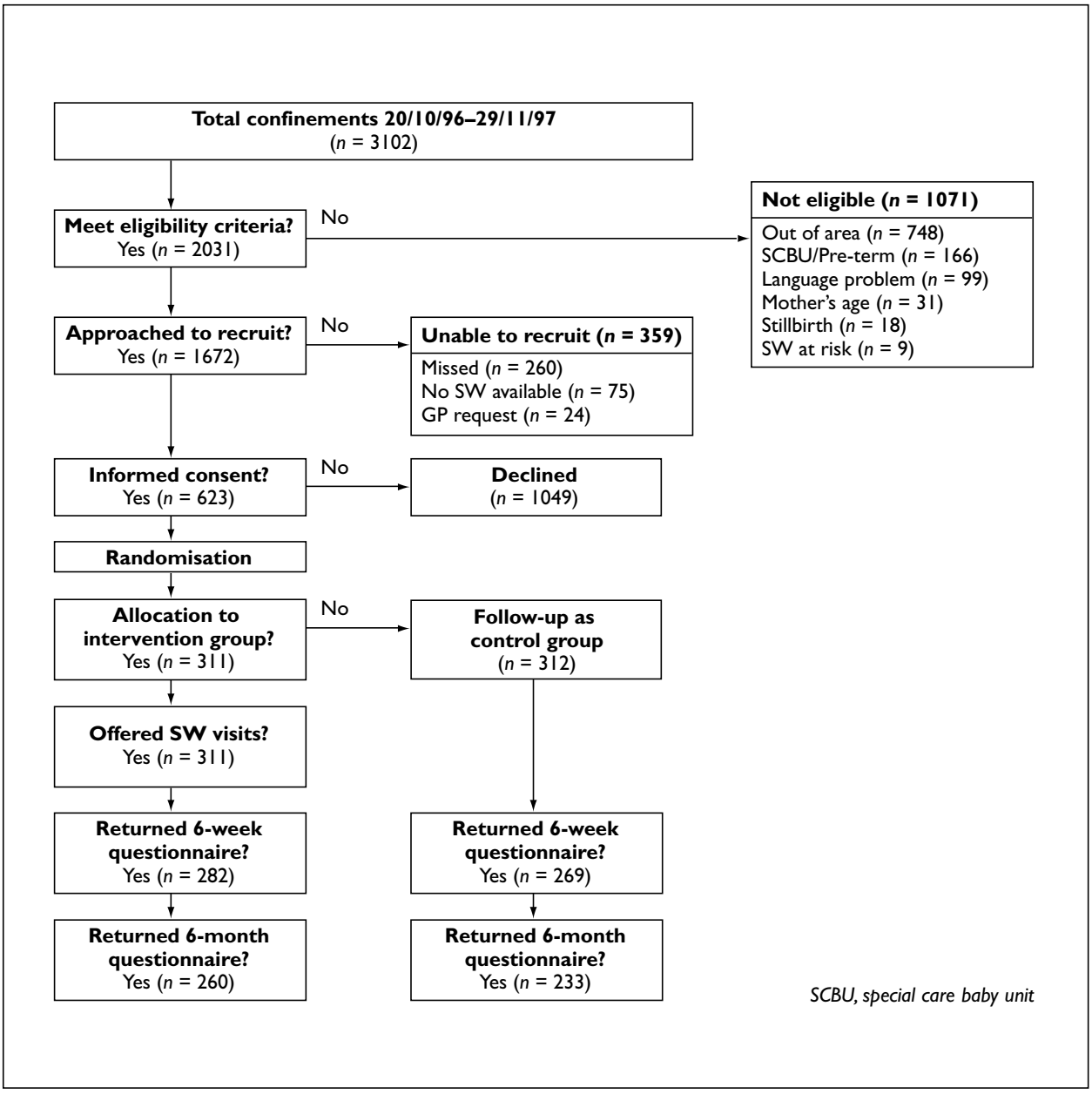

FIGURE 2 *Flow diagram of sample size and follow-up*

from the 1991 census and Health Authority data, indicated that the age structure and proportion of female residents aged 15–44 years was equivalent to the proportion nationally, with a slightly lower (2%) general fertility rate.[123] The percentage of live births by maternal age was similar to the average for England, with slightly more women (2%) in the 20–24 age group and slightly fewer women (2%) in the 25–34 age group[123] (appendix 1).

The percentages of low birthweight babies, infant mortality, perinatal mortality and post-neonatal mortality rates were slightly above the average for England, though the stillbirth rate was slightly lower than the average for England.[123] The underprivileged area scores, index of local condition and rankings for both of these indicated that Sheffield Health Authority was amongst those in the highest category of Jarman scores.[123]

Information on the ethnic mix in Sheffield Health Authority indicated that, as with other features, there are wide variations across Sheffield as a whole. The minority ethnic population for Sheffield overall, as indicated by responses of non-white on the 1991 census,[124] was 5.0% which was very close to the average for England and Wales. Women's postcodes were used to identify their electoral ward and recruited women represented 26 of 29 possible electoral wards in Sheffield. Similar percentages of women from each ward were recruited and declined, showing no recruitment bias by ward, suggesting therefore that socioeconomic circumstances were not a major factor in recruitment. Only a small proportion of women were recruited from the partly rural postal areas of Sheffield 30 and Sheffield 35.

Tables 3 and *4* show the baseline characteristics of the women eligible to enter the trial comparing

TABLE 3 *Characteristics of women who consented and declined*

	Recruited			Declined			*p*-value
	n	**Mean (SD)**	**Median (quartiles)**	***n***	**Mean (SD)**	**Median (quartiles)**	
Age (years)	623	27.8 (5.8)	28.0 (24.0–32.0)	1045	26.7 (5.3)	27.0 (23.0–30.0)	0.001*
Birth weight (g)	623	3439.5 (510.8)	3420.0 (3120.0–3750.0)	1045	3440.9 (498.3)	3440.0 (3100.0–3766.3)	0.96*
Parity	623	1.9 (1.1)	2.0 (1.0–2.0)	972	1.9 (1.0)	2.0 (1.0–2.0)	0.06†

* *p-values from t-test*
† *p-value from Mann–Whitney test*

TABLE 4 *Delivery details of women who consented and declined*

	% Recruited (*n* = 623)	% Declined (max. *n* = 1045)	*p*-value*
Spontaneous onset of labour	70.5	74.1	0.12
Spontaneous vertex delivery	68.1	72.6	0.15
Forceps	4.0	3.2	0.43
Ventouse delivery	9.3	10.0	0.69
Elective Caesarean section	7.9	4.9	0.02
Emergency Caesarean section	10.0	8.6	0.40
Epidural	44.8	42.8	0.46
Pethidine or diamorphine	29.4	30.1	0.79
Entonox	64.7	67.4	0.28
TENS	9.5	5.6	0.004
General anaesthetic	2.9	1.4	0.06
Controlled cord traction	80.1	84.7	0.05
Perineal trauma	39.8	45.2	0.04
Ethnic group: white	92.4	82.3	0.001

* *p-values from* χ^2 *test*

those who consented and were recruited with those who declined to take part, for whom details were available (n = 1046). The recruited women were more likely to be older and white, to have used transcutaneous electrical nerve stimulation (TENS), and to have had an elective Caesarean section (and other features associated with this, such as general anaesthesia). The mean difference in age between the recruited and declined groups was 1 year (95% CI, 0.5, 1.6) though this difference is not clinically important. Similarly, there was some evidence of difference in parity between the recruited and declined groups, but this observed difference is probably not clinically important.

However, it must be concluded that the women recruited were a self-selected group who perceived the need for additional postnatal support and are therefore not entirely representative of all the women eligible to participate.

TABLE 5 *Reasons for declining to take part in the trial*

Reason for declining	*n* (%)
Plenty of help available	158 (50.0)
Do not need or want extra help	43 (13.6)
Living with or going to stay with own mother	31 (9.8)
Partner at home	26 (8.2)
Would like to do own thing or prefer privacy	20 (6.3)
Partner not in favour	8 (2.5)
Prefer not to participate in the research	8 (2.5)
Other visitors already arranged	6 (1.9)
Prefer no strangers in the home	4 (1.3)
Too busy	4 (1.3)
Other	4 (1.3)
Would not wish to offend others	3 (0.9)

The reasons that were given for declining (n = 316) to take part in the trial were that most (50%) already had plenty of help available, or did not need or want extra help, for a variety of reasons (*Table 5*). There were 10% of women who said they would be staying with their own mother after the baby was born and 8% who had a partner with them at home.

Summary

There was a lower level of participation in the trial (37%) than anticipated. There were some differences between women who were recruited and declined. Women who had an elective Caesarean section were more likely to take part. The most frequently reported reason for not taking part was that help was already available at home.

Baseline characteristics of recruited women

Birth details

The women in the two groups were well matched at randomisation with respect to baseline clinical characteristics (*Tables 6* and *7*) except for the use of TENS. By chance more women delivering twins were randomised to the intervention group (nine) than the control group (one). For 159/311 women (51%) in the intervention group and for 146/312 women (47%) in the control group, parity was one child (χ^2 = 1.17 on 1 degree of freedom (df); p = 0.28). For the intervention group, 94% of the women classified themselves as white and in the control group, 91% classified themselves as white (χ^2 = 1.87 on 1 df; p = 0.17).

Equal numbers of women put their baby to the breast after delivery (67.5% in the intervention group and 68.0% in the control group), but the intervention group were more likely to say that the birth experience was bad (*Table 8*).

TABLE 6 *Baseline clinical characteristics*

	Intervention (n = 311)		Control (n = 312)		p-value
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)	
Age (years)	27.5 (5.8)	28.0 (23.0–31.0)	28.0 (5.7)	28.0 (24.0–32.0)	0.33*
Birth weight (g)	3443.8 (544.6)	3430.0 (3075.0–3770.0)	3435.2 (475.5)	3420.0 (3141.3–3737.5)	0.83*
Parity	1.9 (1.1)	1.0 (1.0–2.0)	1.8 (1.0)	2.0 (1.0–2.0)	0.78†

* *p-values from t-test*
† *p-value from Mann–Whitney test*

TABLE 7 *Baseline delivery details*

	% Intervention (*n* = 311)	% Control (*n* = 312)	*p*-value
Spontaneous onset of labour	68.2	72.8	0.21
Induction	23.2	19.6	0.27
Twin birth	2.9	0.3	0.01*
Spontaneous vertex	68.2	67.9	0.39
Forceps	3.5	4.5	0.55
Ventouse delivery	9.3	9.3	0.99
Elective Caesarean section	8.0	7.7	0.87
Emergency Caesarean section	9.6	10.3	0.80
Epidural	42.4	47.1	0.24
Pethidine or diamorphine	28.3	30.4	0.55
Entonox	65.3	64.1	0.76
TENS	12.2	6.7	0.02
General anaesthetic	3.9	1.9	0.15
Perineal trauma	41.2	38.5	0.49

*All p-values from χ^2 test, except *Fishers exact test*

TABLE 8 *Birth experience*

	% Intervention (*n* = 306)	% Control (*n* = 308)
Worst experience ever	8.5	4.9
Bad	13.1	12.3
Neither good nor bad	28.1	28.6
Good	38.9	37.7
Best experience ever	11.4	16.6

χ^2 = 6.03 on 4 df, p = 0.20; $\chi^2_{linear\ association}$ = 3.77 on 1 df, p = 0.05

TABLE 10 *Home ownership*

	% Intervention (*n* = 310)	% Control (*n* = 311)
Being bought (mortgage)	56.1	55.0
Owned outright	1.0	1.6
Rented: council	33.2	35.0
Rented: private	7.7	6.8
Other	1.9	1.6

χ^2 = 0.99 on 4 df, p = 0.91

TABLE 9 *Baseline household characteristics*

	Intervention		Control		*p*-value
	n	% Yes	*n*	% Yes	
One or more children under 16 years	311	53.4	311	57.9	0.23
One or more young people 16–17 years	305	6.2	307	3.9	0.19
One or more adults aged 18 years and over	309	86.4	307	78.2	0.01
Enough room	308	92.2	308	94.8	0.19

The n-values are the number of women who answered the relevant question on the questionnaire

Household details

The women in the two groups were also well matched at randomisation with respect to other characteristics. There was no evidence of differences between the groups in the number of children under 16 years in the household or the number of young people (16–17 years) living in the household (*Table 9*). The intervention group was more likely to have one or more adults over the age of 18 years living in the household than the control group.

In both groups 92% of the women lived in a house or bungalow and more than half were buying their own home and another third rented from the local council (*Table 10*).

Work and income

Less than two-thirds of the women had been in paid work in the 6 months before enrolment in the trial (*Table 11*). In the intervention group previously employed women worked a median 36 hours and earned a median £120 per week. In the control group employed women worked a median 34 hours and earned a median £117 per week.

Using Computer-Assisted Standard Occupational Coding introduced in 1990,[125] the 492 women

TABLE 11 *Baseline socioeconomic characteristics*

	Intervention		Control		*p*-value
	n	% Yes	*n*	% Yes	
Receiving housing benefit	305	28.9	305	28.5	0.93
Central heating in home	306	90.8	308	91.9	0.65
Car available for use	311	78.5	310	75.5	0.38
Paid job in the past 6 months	309	60.5	303	59.4	0.78

p-values from χ^2 *test*

The n-values are the number of women who answered the relevant question on the questionnaire

TABLE 12 *Standard occupational classification*

	% Intervention (*n* = 246)	% Control (*n* = 246)
Managers and administrators	8.1	7.7
Professional	3.3	6.5
Associated professional and technical	12.2	11.4
Clerical and secretarial	30.5	22.8
Craft and related	1.6	2.4
Personal and protective service	16.7	23.2
Sales	12.6	11.8
Plant and machine operatives	5.3	5.7
Other	9.8	8.5

$\chi^2 = 8.83$ *on 8 df,* p = *0.36*

Note: only 492/623 (79%) of women could be classified by standard occupational classification

who gave a job title were classified by major group categories (*Table 12*; appendix 2)

Similar proportions of women in the control and intervention groups were also receiving housing benefit, were in paid work during the previous 6 months and had access to a car or van (*Table 13*).

Social support

The DUFSS was measured at baseline, and the women had a median score of 12.0 in both intervention and control groups. A score of 8.0 would indicate no self-perceived problems with social support.

Similar percentages of women from each electoral ward were recruited into the intervention group and control group, showing no recruitment bias by ward. The proportion of women in the sample who lived in owner-occupied households was lower than for the proportion of households with dependant children according to 1991 census data (*Table 14*).[124]

TABLE 13 *Income characteristics*

	Intervention		Control		*p*-value
	n	% Yes	*n*	% Yes	
Partner in paid job	260	80.0	241	78.0	0.58
Child benefit	304	47.0	299	49.8	0.49
One-parent benefit	293	6.8	282	6.4	0.83
Income support	305	23.3	299	24.7	0.67
Maternity allowance	305	10.8	300	11.0	0.94
Receive jobseekers allowance	305	3.9	299	3.3	0.70
Other benefit	305	3.9	299	3.7	0.87

p-values from χ^2 *test*

The n-values are the number of women who answered the relevant question on the questionnaire

TABLE 14 *Household characteristics of trial sample compared with census data*

	England (%)	Sheffield (%)	Households with dependant children (%)	Trial sample (%)
Owner occupied	67.6	56.8	65.3	55.5
With no car	32.6	44.9	30.1	22.8
With no central heating	18.5	19.1	11.6	8.6

TABLE 15 *Characteristics of SWs*

SW	Age (years)	Married	Qualifications	Mother	Caring experience
1 (pilot)	24	No	Degree	No	Yes
2	33	Yes	GCSE/O	Yes	Yes
3	28	Yes	None	Yes	Yes – voluntary sector
4	23	No	Degree	No	Yes – voluntary sector
5	23	Yes	GCSE/O	Yes	Yes
6 (pilot)	51	Yes	None	Yes	Yes – informal
7	35	Yes	None	Yes	Yes – informal
8	27	Yes	None	Yes	Yes

Women's personal characteristics

Most women could read and write English without any problems (99%) and for 96% of women recruited, English was their first language. The mean age of leaving school was 16 years, 23% of the women had no exam passes and 45% had no qualifications. More than half the women had GCSE or O' level qualifications and 14% had A' level passes.

Personal support and stressful life events

Some women had no mother alive (8%) and some had no father (15%). There were 14% who had previous mental health problems. In the year preceding the birth of their baby, a third had moved home, 15% had experienced the death of someone close, 6% had had a miscarriage and 5% had been divorced or separated. There were also 12% of women who had experienced a loss of income in the preceding year.

Summary

There were 623 women recruited – 311 in the intervention group and 312 in the control group. The groups were well matched at randomisation by clinical and socioeconomic characteristics.

Support workers

Characteristics

The eight SWs were employed full time on a 12-month fixed-term contract including training and the recruitment phase and they represented a range of characteristics (*Table 15*).

Six of the SWs fulfilled their contracts and two left the project soon after completing their training (one to resume nurse training and one to return to previous employment). As recruitment was slower than expected, the contracts for the remaining five were renewed to cover the extended recruitment. Two SWs reduced to 32 and 25 hours per week, respectively, due to family commitments. When the SWs had no home visits, they worked towards achieving their NVQ competencies, gaining experience in the clinical area on the postnatal ward supporting postnatal women.

Activities

The SWs categorised their activities in the women's homes on an activity log. They logged 1767 visits in total ranging from 224 to 390 visits per SW. The SW logs were used to calculate the frequency and duration of activities in the women's home. Most women had fewer visits than were offered and **according to the SW logs**, 48 women (15%) received ten visits (*Table 16*). There were 37/311 women (12%) who declined their visits at home and were included in the follow-up and analysis.

The activity cited most often during each visit was bottle feeding. The other most frequently occurring activities are shown in *Table 17*. The resource folder appeared to be used very infrequently, with only 0.5% of visits registering its use.

TABLE 16 *Number of SW visits per woman*

No. of visits	No. (%) of women
1	13 (4.2)
2	13 (4.2)
3	19 (6.1)
4	23 (7.4)
5	38 (12.2)
6	27 (8.7)
7	29 (9.3)
8	32 (10.3)
9	32 (10.3)
10	48 (15.4)

TABLE 17 *Most frequently recorded activities during SW visits*

Activity	% of visits
Bottle feeding	75
Talking with the mother about her rest and sleep	70
Talking with the mother about social issues	61
Talking with the mother about her family	53
Washing/ironing	51
Washing-up	45
Cleaning	44
Talking with the mother about the baby sleeping	43
Talking with the mother about the baby's well-being	42
Winding/settling the baby	42

TABLE 18 *Mean time (minutes) spent on each category of activity per SW visit*

Activity	Mean	SD	Range	Total (%)
Housework	53.9	41.6	0–190	95,201 (39.0)
Talking with the mother	39.2	24.6	0–160	58,956 (24.2)
Baby activity	12.3	17.0	0–140	21,646 (8.9)
Activities with other siblings	14.2	34.4	0–270	21,530 (8.8)
Bottle feeding	11.0	16.3	0–110	16,504 (6.8)
Talking about baby	8.8	10.2	0–180	15,578 (6.4)
Discussing breastfeeding	4.6	8.4	0–110	8168 (3.4)
Other activity	3.1	15.2	0–180	5166 (2.1)
Using resource folder	0.7	3.1	0–40	1057 (0.4)

Time spent on each activity

The SWs recorded the total duration of the visit and the amount of time they spent on each sub-category within the general categories of:

- talking with the mother about herself
- talking about feeding or helping to feed the baby
- talking about or helping with the baby
- activities with other siblings
- other practical help, and
- use of a resource folder.

The visits ranged from 10 minutes to 375 minutes. The shortest visit times were for a no access visits or for an initial visit. The visits that were longer than 3 hours were usually when a baby or child was ill, the mother needed to attend a hospital or GP appointment or the SW waited until the GP arrived. The mean times spent on each category of activity are presented in *Table 18*.

Housework

Among all the activity categories, most time (38%) was spent in the housework category, washing and ironing and cleaning. Less time was spent on washing-up, preparing foods, and shopping, and least time was spent making beds.

Talking with the mother

The next most time consuming general activity (23%) was time spent talking with the mother. Most often this involved talking about social or other issues, rest and sleep, family, life with a new baby, physical needs, social needs, labour and delivery, and diet, and least often, emotional needs.

Baby activity

This activity involved 9% of the total time in the home. Winding the baby was most often performed in this category, then bathing, and least often, changing the baby.

Activity with other siblings

This activity involved 8% of total time in the home and most often involved playing with other siblings or supervising them while the mother was absent. Less often the SWs spent time taking the other children to school or nursery, for which they needed a signed consent form from the child's mother. The category also included taking children to the park, dressing, and feeding, and, least often, toileting other children.

Bottle feeding

Although this was the most frequently recorded activity it comprised only 7% of all activity time. Most of the activity in this category involved actually feeding the baby, but included, less often, discussing feeding, making feeds and sterilising and discussing equipment and, least often, helping to wind the baby.

Talking about the baby

This activity took 6% of all the activity time and most often involved concerns about the well-being of the baby, sleeping patterns and settling the baby. Safety and sudden infant death syndrome were discussed least frequently.

Breastfeeding

Only 3% of all the activity time was spent discussing breastfeeding or helping the mother to breastfeed.

Other activity and resource folder

Other activities comprised 2% of total visit time. Although the SWs carried a folder containing up-to-date details of a variety of local agencies, the time spent on the resource folder was less then 1%.

Women's comments on the SWs' visits

There were 282 women in the intervention group (90%) who returned their 6-week questionnaire. They reported 1670 visits from SWs. There were 32 women who reported no SW visits, 56 who reported that they had received all ten SW visits and a further two women reported they had received 12 and 20 visits, respectively (*Table 19*). From this data source, the mean number of visits was 6.0 (SD, 3.3) and the median was seven visits.

Satisfaction with the SWs' visits

Women who returned a 6-week questionnaire answered questions on satisfaction and expectations from the CMSW service. There was a very high level of general satisfaction for the service received for the women and their babies (*Tables 20* and *21*).

When women were asked in an open question the activities they had been able to do because the SW was visiting, they most often reported activities to help them rest and relax (28%) followed by having time for their own personal care (15%) such as having a bath or shower. Only four women (less than 2%) indicated a restriction in activity in going out or sleeping when the SW was visiting. More than 75% of the women thought the service was better than expected (*Table 22*).

TABLE 19 *Number of reported visits from 6-week questionnaire*

No. of visits	*n* (%)
0	32 (11.4)
1	12 (4.3)
2	8 (2.9)
3	15 (5.4)
4	25 (8.9)
5	27 (9.6)
6	17 (6.1)
7	29 (10.4)
8	34 (12.1)
9	25 (8.9)
10	56 (20.0)
Total	**280 (100)**

TABLE 20 *Satisfaction with SW for self at 6 weeks*

Satisfaction level	% (*n* = 232)
Very satisfied	70.3
Fairly satisfied	24.6
Neither	4.7
Fairly dissatisfied	0.0
Very dissatisfied	0.4

TABLE 21 *Satisfaction with SW for baby at 6 weeks*

Satisfaction level	% (*n* = 233)
Very satisfied	70.4
Fairly satisfied	22.3
Neither	6.9
Fairly dissatisfied	0.0
Very dissatisfied	0.4

TABLE 22 *Overall experiences of SWs versus expectations*

Experience	% (*n* = 233)
Much worse than expected	0.0
Worse than expected	2.1
About the same as expected	22.3
Better than expected	35.6
Much better than expected	39.9

TABLE 23 *Frequency of reported conflicting advice between SWs and midwives or health visitors*

Frequency	Midwife	Health visitor
	% (*n* = 226)	% (*n* = 226)
Never	54.9	54.9
Rarely	17.7	17.7
Sometimes	18.6	18.6
Most of the time	6.2	6.2
All of the time	2.7	2.7

Conflicting advice with the midwife did appear to be a problem with more than 25% of the women reporting conflicting advice sometimes from midwives or SWs and from health visitors and SWs (*Table 23*). The information on conflicting advice was not available for the control group.

Professionals' views on SWs

Questionnaires were returned by 49 health visitors (59% response) though many had little involvement due to maternity leave or change of post, and 30 midwives (73% response). The midwives potentially had the greatest contact with the SWs. The following represents a summary of the comments to reflect the key areas emerging from the health visitors' and midwives' replies. Few GPs had any experience of the SWs (33% response) or had many comments to make on the role. The small number of comments that were received were generally positive in terms of the perceived and potential effect for women.

Positive views from health visitors and midwives were about: the practical help the SWs gave, which allowed the women to rest; the companionship and emotional support for isolated women; guidance for young or inexperienced women; and help with other children. They also felt that the SWs allowed the women more time with their baby, particularly for those breastfeeding, and some cited the benefits for women who had twins or a Caesarean section or complex social or health problems.

Health visitors and midwives saw the need for targeting the service to those at greatest need, according to set criteria, such as vulnerable clients or families, those who were isolated, younger women, or those with no partner or other family support.

Health visitors also saw the need for close integration with the primary care team in a primary care base. Some midwives voiced concerns about the threat of erosion of the midwife's role and encroachment on professional boundaries. Some felt a need for greater role clarity.

Disadvantages were seen as invasion of women's privacy, and having an unknown person in their home, anxiety about being ready for the SWs' visit, or how to cope when the visits ceased. Problems for the SWs were seen as travelling, dealing with unpredictable situations or those for which they were unqualified.

SW focus group

A 1-day focus group was held to allow an exchange of ideas on the SWs' experience of working on the project and to develop a consensus on recommendations for the future role of SWs in the community. The transcripts of the session were summarised and a number of themes emerged.

Support and supervision

There were problems with mentorship, availability of NVQ assessors and support meeting, with time wasted travelling at lunchtime.

Training

There was some uncertainty about whether ward SWs or midwives should have provided practical training on the wards. Listening skills and domestic violence should have been included in the core training programme, and the paperwork was difficult at first.

Ward SWs

There was some friction and resentment among existing ward SWs, in part due to the two community midwifery SWs that left. The ward SWs were expected to train the community midwifery SWs and some of them were disappointed that they had not been successful in their application for the community role.

Midwives
There was inconsistency in support for the role from midwives. Some made negative comments in front of the mother, though some in the same team were very positive. Some midwives were also very glad that the SWs had dealt with emergencies in the home.

GPs
GPs were not seen very often, but they did seem to doubt the value of the SW role.

Qualities required for an SW
SWs must be able to get on with people, be 'goodly', have life skills, not appear like a cleaner, have clear written work, and having previous experience with children may be an advantage.

Women who benefited from the SWs' visits
All women appeared to the SWs to benefit, even those who only had cleaning done or just went to bed for a couple of hours. Some women appeared to have never learnt parenting skills, but soon asked for feedback from the SWs.

Recruitment of women and cancelled visits
The SWs felt that those women who had met an SW while in hospital seemed more likely to accept the offer to take part in the research and less likely to cancel visits. Some women were discouraged from accepting the visits either by their midwife or by their own partner. The SWs felt it might have been better if the prospective parents could meet them antenatally or even receive support antenatally.

SW safety
The risk assessments were completed before the SWs had had chance to see the women's equipment. The residual current devices were very useful for some equipment because there were bare wires on irons and the safety of some vacuum cleaners was doubtful. There was no reason to avoid vacuuming the stairs. SWs' partners were concerned about them going out to 'suspect' areas in the dark, but overall there was no need for a personal alarm.

Information required by the SWs before visits
Sometimes SWs were not given enough information about the mother and her family; for example, one baby needed an apnoea monitor and the SW did not know there had been a previous cot death, and another child was seeing a psychiatrist.

Cleaning
Some women wanted the SWs to clean, for example the oven, which would not have been cleaned under normal circumstances, in part because they had been encouraged to do so by some midwives. Other mums, even when the SWs perceived a 'cleaning need' just wanted the SWs to sit and chat.

Recommendations by SWs
- More women should have the information antenatally to improve the uptake rate.
- More clarity about the role for ward SWs, midwives and the women.
- The midwives should be consistent in provision of information to women (leaflets).
- There is a need to be part of a team (such as GP or health visitor) from the beginning and part of team meetings. A community base would be better as there was little peer support.
- More detail about the women and their families should be available, to include: whether there is a partner and where they live, method of feeding, other children and previous losses, the method of delivery, and any problems or trauma.
- Support could be available from the day the women go home, not 28 days after the birth date. Six weeks might be better than 1 month and the intervention should be more flexible to take into account individual women's needs.
- Some of the time on the wards was wasted.
- Training could have been 12 weeks instead of 8 weeks.
- Supervision and mentorship should be improved.
- It would be useful to have support meetings as a group without supervision.
- Travelling time should be included in the day's work.
- The stripy tabard should be modified!
- Possibly a rota for tea-time visits for people whose babies have colic.
- Two visits per day is most comfortable and maximum 15 per week.
- The job is much easier with a car.
- Training should include some education about different cultural backgrounds.
- There could be SWs who could speak non-English languages.

Summary
Most women received six or seven home visits from an SW. The most frequently recorded SW activity was bottle feeding. Most of the SWs' time was spent on housework. There was a very high level of satisfaction with the service provided by the SWs. A number of recommendations were made about the future training and management of the SWs' role.

Main outcomes at 6 weeks

Response rates at 6 weeks

There was an 88.4% response rate to the 6-week questionnaire, with some evidence that the intervention group was more likely to respond than the control group (*Tables 24* and *25*). There was a high level of completion for all questionnaires on the main outcomes with a minimum 93% completion (*Table 26*).

Responders were more likely to be older, by an average of 2.9 years (95% CI, 1.5, 4.3), to have delivered a slightly heavier baby (166.7 g; 95% CI, 41.5, 291.8), to have had a spontaneous delivery, to have fewer children and to have had a singleton birth (*Table 27*). Responders were also more likely to be white, to have had a paid job in the 6 months prior to delivery, to have a mortgage, to have central heating in their home, and to have access to a car.

Main outcomes at 6 weeks

SF-36

For the primary outcome (SF-36, GHP), which was used to determine the sample size for the trial, there was no evidence of a difference in outcomes between the two groups at 6 weeks. The control group had significantly better physical functioning, social functioning and RLP scores than the intervention group, indicating a better self-perceived health status *(Table 28)*. Although not statistically significant, this trend for the control group to have better outcomes than the intervention group was also observed for the mean scores in other domains of the SF-36 (RLE, mental health, vitality, pain, GHP). There was some evidence of 'ceiling effects' of the SF-36 with

TABLE 24 *Response rates for 6-week questionnaire*

	Intervention	Control	Total
	n **(%)**	***n*** **(%)**	***n*** **(%)**
Yes	282 (90.7)	269 (82.6)	551 (88.4)
No	29 (9.3)	43 (13.8)	72 (11.6)
Total	**311 (100)**	**312 (100)**	**623 (100)**
χ^2 *= 3.03 on 1 df,* p *= 0.08*			

TABLE 25 *Reasons for loss to follow-up at 6 weeks*

Reason	***n*** **(%)**
No reply	35 (48.6)
No telephone available to remind	16 (22.2)
Social services involved	9 (12.5)
Moved	8 (11.1)
Unwell or depressed	3 (4.2)
Baby died	1 (1.4)
Total	**72 (100)**

TABLE 26 *Incomplete responses to health status questionnaires at 6 weeks*

	Valid	Missing	Max. % missing (*n* = 623)
Physical functioning	543	80	12.8
Social functioning	549	74	11.9
RLP	535	88	14.1
RLE	534	89	14.3
Mental health	550	73	11.7
Vitality	550	73	11.7
Pain	550	73	11.7
GHP	539	84	13.5
Health change	551	72	11.6
DUFSS	513	110	17.7
EPDS	542	81	13.0
Breastfeeding	548	75	12.0

TABLE 27 *Characteristics of responders versus non-responders to the 6-week questionnaire*

	Responder (*n* = 551)		Non-responder (*n* = 72)		*p*-value
	Mean (SD)	**Median (quartiles)**	**Mean (SD)**	**Median (quartiles)**	
Age (years)	28.1 (5.7)	28.0 (24.0–32.0)	25.2 (5.7)	25.0 (21.0–29.0)	0.001
Birth weight (g)	3458.7 (510.7)	3440.0 (3130.0–3770.0)	3292.1 (490.1)	3300.0 (3027.5–3627.5)	0.009
Parity	1.8 (1.1)	1.0 (1.0–2.0)	2.1 (1.2)	2.0 (1.0–3.0)	0.03*
p-values from t-test, except *Mann–Whitney test*					

TABLE 28 *Health status measures at 6 weeks*

	Intervention			Control			*p*-value	Mean difference (95% CI)
	n	Mean (SD)	Median (quartiles)	*n*	Mean (SD)	Median (quartiles)		
Physical functioning	278	86.9 (16.0)	90.0 (80.0–100.0)	265	89.1 (15.4)	95.0 (85.0–100.0)	0.01	–2.2 (–4.6, 0.5)
Social functioning	281	76.4 (24.1)	77.8 (66.7–100.0)	268	80.2 (23.8)	88.9 (66.7–100.0)	0.03	–3.8 (–7.7, 0.3)
RLP	275	65.2 (39.4)	75.0 (25.0–100.0)	260	73.2 (38.8)	100.0 (50.0–100.0)	0.008	–7.9 (–14.6, –0.9)
RLE	275	77.3 (35.3)	100.0 (66.7–100.0)	259	77.4 (36.6)	100.0 (66.7–100.0)	0.77	0.0 (–6.5, 6.1)
Mental health	282	72.0 (17.5)	76.0 (60.0–84.0)	268	72.7 (17.8)	76.0 (60.0–88.0)	0.60	–0.7 (–3.8, 2.2)
Vitality	282	49.7 (21.3)	50.0 (35.0–65.0)	268	50.3 (20.9)	50.0 (35.0–65.0)	0.81	–0.6 (–4.1, 3.0)
Pain	282	70.7 (24.3)	77.8 (55.6–88.9)	268	73.8 (24.9)	77.8 (55.6–100.0)	0.08	–3.0 (–6.9, 1.1)
GHP	276	75.1 (18.4)	77.0 (67.0–87.0)	263	76.7 (18.6)	82.0 (67.0–92.0)	0.22	–1.6 (–4.7, 1.4)
Health change	282	63.9 (26.1)	62.5 (50.0–75.0)	269	65.6 (26.2)	75.0 (50.0–100.0)	0.39	–2.0 (–6.0, 3.2)
DUFSS	260	16.7 (6.7)	16.0 (11.0–21.0)	253	16.6 (7.4)	15.0 (10.0–21.0)	0.63	0.0 (–1.3, 1.3)
EPDS	276	7.4 (5.2)	7.0 (4.0–10.0)	266	6.7 (5.5)	6.0 (2.0–10.0)	0.05	0.7 (–0.2, 1.6)

p-values from Mann–Whitney test

95% CIs for the mean difference calculated by the bootstrap percentile method

For the SF-36, a higher score indicates better health. Conversely for the DUFSS and EPDS, a higher score indicates poorer health

some women at the top of the 0–100 domain scale, suggesting that the domains might not be sensitive to detect improvements in health from 6 weeks to 6 months *(Figure 3)*.

EPDS

There was some evidence of lower mean EPDS scores in the control group. However, when the scores were categorised as 12 or more (indicating a risk of PND)[107] and 11 or less, there were 17.8% of women in the intervention group and 18% in the control group scoring over the threshold for concern ($\chi^2 = 0.01$, on 1 df; $p = 0.93$; *Figure 4*; *Table 28*).

DUFSS

There was no difference in the mean DUFSS scores (*Figure 5*; *Table 28*).

Breastfeeding

At 6 weeks there was no statistical evidence of differences in breastfeeding rates or duration of breastfeeding between the two groups (*Table 29*).

Women who received no visits

The main analysis was performed as intention to treat, but an exploratory analysis was performed to see whether there was any evidence of differences in main outcomes between the 38 intervention group women who had received no SW visits. There was no evidence of any difference between the women who had received SW visits and those who had no visits.

Use of NHS resources at 6 weeks

There were no differences in GP consultations for mother or baby, prescriptions for mother or baby, medications bought for the mother or baby, or hospital services used for mother or baby (*Tables 30* to *34*).

Use of secondary mental health services and social services at 6 weeks

There was some evidence that more women in the control group used secondary mental health services at 6 weeks than women in the intervention group (*Table 35*). There was little use of social services (3.8% in the intervention group and 2.6% in the control group) and no differences between the groups at 6 weeks.

Satisfaction with services at 6 weeks

At 6 weeks more than 90% women reported a very high level of satisfaction with the midwife (*Table 36*). They also reported a high level of satisfaction with the health visitor (80%) and GP (79%) but there were no differences between the two groups.

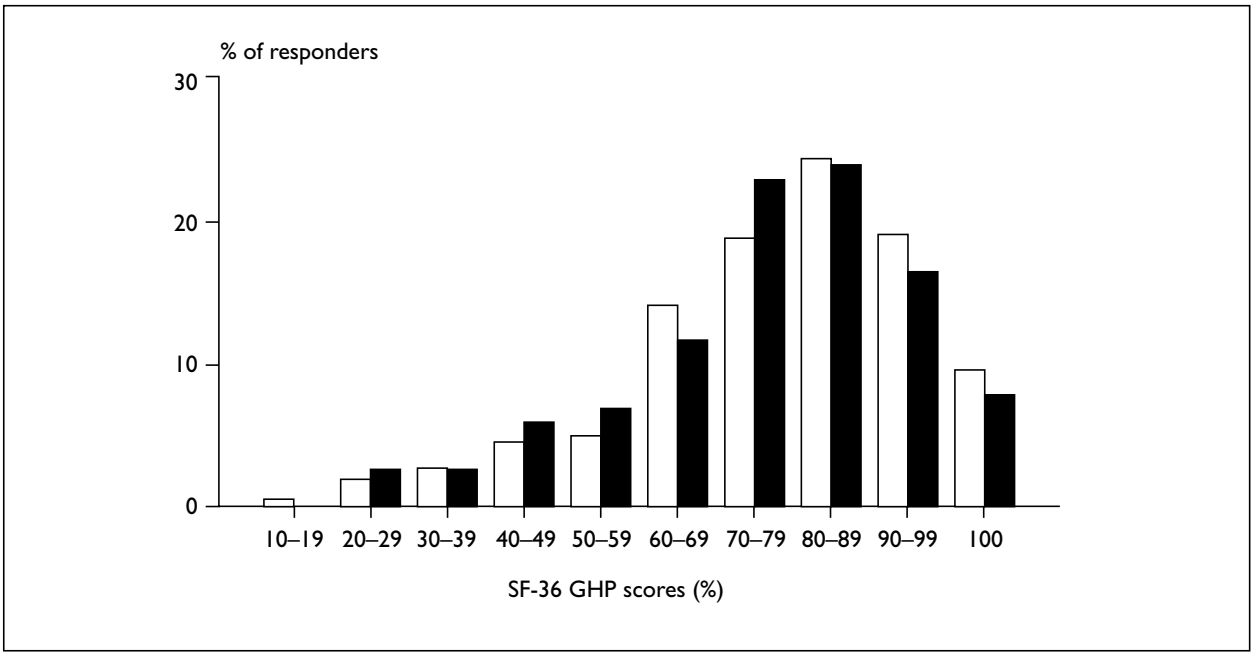

FIGURE 3 *Split bar chart of distribution of SF-36 GHP scores at 6 weeks (□, control (n = 263); ■, intervention (n = 276))*

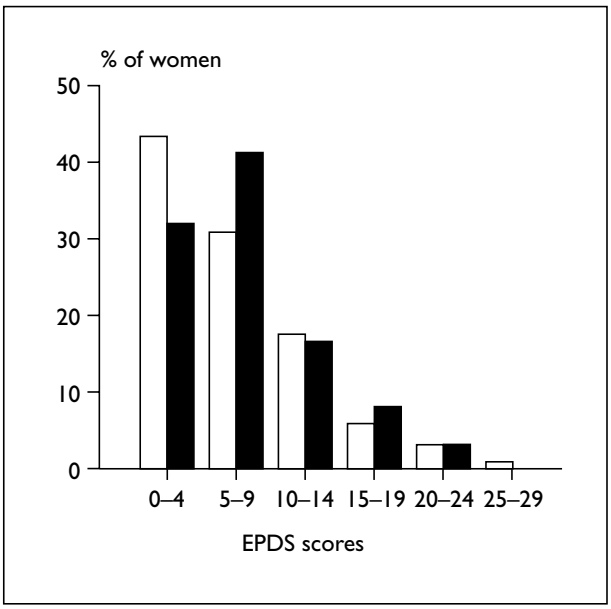

FIGURE 4 *Split bar chart of distribution of EPDS scores at 6 weeks (□, control (n = 266); ■, intervention (n = 276))*

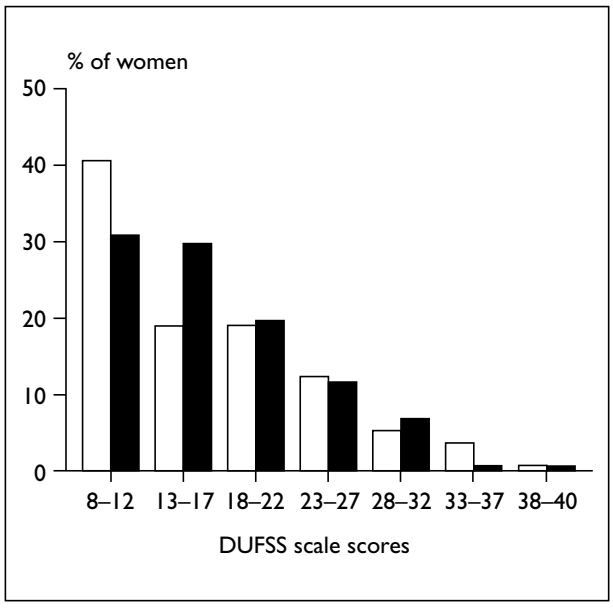

FIGURE 5 *Split bar chart of distribution of DUFSS scores at 6 weeks (□, control (n = 253); ■, intervention (n = 260))*

Indicators of stress and coping

For the questions that sought to determine women's adaptation to life with a baby, at 6 weeks about 14% of women reported little or no control over their life. Up to 10% of women indicated little satisfaction, poor coping and low levels of confidence in mothering. However, as before, there were no differences between the two groups (*Tables 37* to *40*).

TABLE 29 *Breastfeeding at 6 weeks*

	% Intervention (*n* = 280)	% Control (*n* = 268)
Breast milk only	31.1	26.9
Formula milk only	55.0	57.8
Both breast and bottle milk	13.9	15.3
χ^2 = *1.21 on 2 df*, p = *0.55*		

TABLE 30 *Number of GP consultations at 6 weeks for mother*

	Intervention (*n* = 279)		Control (*n* = 268)		*p*-value
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)	
In your own home	0.7 (1.0)	0.0 (0.0–1.0)	0.7 (0.9)	1.0 (0.0–1.0)	0.88
In GP surgery	0.7 (0.9)	1.0 (0.0–1.0)	0.7 (0.9)	0.5 (0.0–1.0)	0.45
By telephone	0.2 (0.6)	0.0 (0.0–0.0)	0.1 (0.4)	0.0 (0.0–0.0)	0.11
Total GP contacts	1.6 (1.5)	1.0 (1.0–2.0)	1.5 (1.5)	1.0 (1.0–2.0)	0.46

p-values from Mann–Whitney test

TABLE 31 *Number of GP consultations at 6 weeks for baby*

	Intervention (*n* = 279)		Control (*n* = 267)		*p*-value
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)	
In your own home	1.0 (1.0)	1.0 (0.0–1.0)	0.9 (0.9)	1.0 (0.0–1.0)	0.28
In GP surgery	1.0 (1.1)	1.0 (0.0–1.0)	1.0 (1.1)	1.0 (0.0–2.0)	0.73
By telephone	0.3 (0.7)	0.0 (0.0–0.0)	0.3 (0.8)	0.0 (0.0–0.0)	0.71
Total GP contacts	2.3 (1.7)	2.0 (1.0–3.0)	2.2 (1.8)	2.0 (1.0–3.0)	0.52

p-values from Mann–Whitney test

TABLE 32 *GP prescriptions and medication use at 6 weeks*

	Intervention		Control		*p*-value
	n	% Yes	*n*	% Yes	
GP prescriptions for mother	280	45.7	269	46.8	0.79
GP prescriptions for baby	272	51.5	263	55.1	0.39
Bought medication for mother	267	14.6	250	16.4	0.57
Bought medication for baby	270	58.9	251	53.0	0.18

p-values from χ^2 *tests*

The n-values are the number of women who answered the relevant question on the questionnaire

TABLE 33 *Use of hospital services by mother at 6 weeks*

	Intervention		Control		*p*-value
	n	% Yes	*n*	% Yes	
Inpatient	279	3.9	265	3.4	0.74
Outpatient	276	5.8	262	3.8	0.28
Day-patient	275	2.5	265	2.7	0.92
A&E	279	2.2	262	2.3	0.91

p-values from χ^2 *tests*

The n-values are the number of women who answered the relevant question on the questionnaire

TABLE 34 *Use of hospital services by baby at 6 weeks*

	Intervention		Control		*p*-value
	n	% Yes	*n*	% Yes	
Inpatient	210	6.2	191	4.2	0.37
Outpatient	278	8.3	262	11.1	0.27
Day-patient	210	6.7	189	5.3	0.56
A&E	278	6.1	261	7.3	0.59

p-values from χ^2 *tests*

The n-values are the number of women who answered the relevant question on the questionnaire

TABLE 35 *Use of secondary mental health services by mother at 6 weeks*

	Intervention		Control		*p*-value
	n	% Yes	*n*	% Yes	
Community mental health nurse	271	0.4	249	2.4	0.06
Psychiatrist	271	0.7	249	0.8	1.00
Psychologist	270	0.0	248	0.4	0.48
Community mental health social worker	270	0.4	249	1.2	0.35

p-values from Fishers exact tests

The n-values are the number of women who answered the relevant question on the questionnaire

TABLE 36 *Women's satisfaction with community midwife at 6 weeks*

	% Intervention (*n* = 275)	% Control (*n* = 253)
Very satisfied	66.5	73.1
Fairly satisfied	27.6	19.8
Neither	2.2	3.6
Fairly dissatisfied	2.5	1.2
Very dissatisfied	1.1	2.4
χ^2 = *7.67 on 4 df,* p = *0.10;* $\chi^2_{linear\ association}$ = *0.35 on 1 df,* p = *0.55*		

TABLE 37 *Control over life at 6 weeks*

	% Intervention (*n* = 279)	% Control (*n* = 263)
None at all	3.2	3.8
A little	11.5	11.0
Some	21.1	17.9
Quite a lot	40.1	43.0
A great deal	24.0	24.3
χ^2 = *1.16 on 4 df,* p = *0.89;* $\chi^2_{linear\ association}$ = *0.09 on 1 df,* p = *0.76*		

TABLE 38 *Satisfaction with life at 6 weeks*

	% Intervention (*n* = 273)	% Control (*n* = 248)
Very satisfied	33.3	33.9
Fairly satisfied	51.6	51.6
Neither	6.2	5.2
Fairly dissatisfied	7.7	7.7
Very dissatisfied	1.1	1.6
χ^2 = *0.49 on 4 df,* p = *0.98;* $\chi^2_{linear\ association}$ = *0.00 on 1 df,* p = *1.00*		

TABLE 39 *Coping with stress and life events at 6 weeks*

	% Intervention (*n* = 273)	% Control (*n* = 248)
Not at all	1.5	2.4
A little	7.7	6.0
Moderately	21.2	17.3
Quite well	47.6	45.2
Very well	22.0	29.0
χ^2 = *4.87 on 4 df,* p = *0.30;* $\chi^2_{linear\ association}$ = *1.92 on 1 df,* p = *0.17*		

TABLE 40 *Confidence in mothering at 6 weeks*

	% Intervention (*n* = 272)	% Control (*n* = 247)
Not at all	1.1	0.4
A little	2.2	3.2
Moderately	10.3	8.5
Quite well	37.9	36.0
Very well	48.5	51.8
χ^2 = *2.17 on 4 df,* p = *0.71;* $\chi^2_{linear\ association}$ = *0.51 on 1 df,* p = *0.48*		

TABLE 41 *Support and advice received within first 6 weeks at home*

	Intervention		Control		*p*-value
	n	% Yes	*n*	% Yes	
Feeding your baby	281	91.5	268	88.8	0.30
How to handle, settle and look after your baby	281	85.8	268	86.1	0.92
Problems with your baby's health and progress	280	91.1	268	87.8	0.20
Your own health and recovery after the birth	281	82.2	268	84.0	0.59

p-values from χ^2 *tests*

The n*-values are the number of women who answered the relevant question on the questionnaire*

TABLE 42 *Support received from partner at 6 weeks*

	% Intervention (*n* = 271)	% Control (*n* = 257)
Very unsupportive	4.8	9.3
Fairly unsupportive	4.1	4.3
Neither	2.6	3.1
Fairly supportive	19.9	20.6
Very supportive	68.6	62.6
χ^2 = *4.78 on 4 df,* p = *0.31;* $\chi^2_{linear\ association}$ = *4.07 on 1 df,* p = *0.04*		

Support at home

There was no difference between the two groups in support and advice received overall at home. More women in the intervention group reported that their partner was supportive (*Tables 41* and *42*).

Subgroup analysis

The seventh research objective was to analyse by risk as far as possible. The trial was not originally powered to detect differences in outcomes between specific subgroups, nor was the intervention targeted specifically at any subgroup. However, an exploratory analysis was performed to see whether there was any evidence of differences in main outcomes between the intervention and control group women by various 'at risk' subgroups at the 6-week follow-up. Women who were 'younger' or 'older' mothers, or who were first-time mothers, or who had a complicated delivery, or who were living alone or without support, or were of lower socioeconomic status were considered to be 'at risk women', or more likely to benefit from a social support intervention.

Socioeconomic group

A number of variables used as proxies for socioeconomic status were used in a subgroup analysis. These were: receipt of housing benefit, receipt of one-parent benefit, receipt of income support, no access to a car or van, and living in council property. At baseline, 88 women in the intervention group said they were receiving housing benefit (87 in control group), 67 said they had no access to a car (76 in control group) and 103 said they were living in rented council property (109 in control group). For all of these subgroups, there was no evidence of any differences in the main outcomes (SF-36, EPDS, DUFSS, duration of breastfeeding) at 6-week follow-up by group. Almost a quarter of the women ($n = 145$) were in receipt of income support, and 6% of women ($n = 38$) were receiving one-parent benefit. Although this analysis included very small numbers, again there appeared to be no statistical differences between the two groups for any of the main outcomes.

Mother's age

Age was categorised into three groups:

- 'younger' mothers, aged below 20 years
- mother aged 20–35 years, and
- 'older' mothers, aged over 35 years.

Within the 'younger' age group ($n = 52$) there was no difference in the primary outcome (SF-36 GHP domain). However, there were significant differences for EPDS score, women in the control group having the lower (better) scores. Within the 'older' age group ($n = 56$) there was no difference in the primary outcome (SF-36 GHP domain). However, there were significant differences for RLP and RLE domains, with women in the control group having the higher (better) scores. When all three age groups were included in a multiple regression model ($n = 539$) there was no evidence of an intervention by age group interaction except for RLP dimension ($p = 0.045$). Amongst the 'older' two age groups, women in the control group had the better quality of life, whereas in the 'youngest' age band this trend was reversed with the intervention group having the higher (better) quality of life. However, there was no evidence of an interaction in the primary outcome, SF-36 GHP domain ($p = 0.94$).

Parity

Main outcomes were also examined by parity. In the subgroup of primiparous women ($n = 305$), there was no reliable statistical evidence of differences in outcomes (SF-36, EPDS, DUFSS, duration of breastfeeding) between the intervention and control groups, except on the SF-36 role physical domain, where again the control group had the better score.

Multiple regression analysis with adjustment for potential risk variables at 6 weeks

To examine all the risk factors together, using all the women ($n = 420$), a series of multiple linear regressions was carried out. In these regression analyses the eight domains of the SF-36 and the EPDS score at 6 weeks were the dependent variables. The 12 potential predictors included the above variables and group, age, level of health visitor intervention and adults at home.

Risk factors were considered statistically significant (and associated with the dependent variable) if they had a two-tailed *p*-value less than or equal to 0.05 and were considered to tend towards a difference if they had two-tailed *p*-values between 0.05 and 0.10.

Table 43 shows the results of the exploratory multiple regression analysis. After adjusting for the potential risk factors, there was no statistical evidence of differences in outcomes by group except for the SF-36 RLP domain. In this model, after adjustment for other covariates the effect of the intervention was to reduce the RLP score by –7.3 points (95% CI, –14.6, –0.1). That is, the intervention group had a poorer RLP score than control group after adjustment for the potential risk factors.

TABLE 43 *Exploratory multiple regression analysis of SF-36 and EPDS scores at 6 weeks*

Dependant variable	*n*	R^2	Significant predictors*	Group effect (*p*-value)†
Physical functioning	416	0.09	Normal delivery ($p = 0.001$)	0.59
Social functioning	419	0.07	Normal delivery ($p = 0.003$) Level of health visitor support ($p = 0.04$)	0.34
RLP	411	0.15	Age ($p = 0.05$) Normal delivery ($p = 0.001$) Group ($p = 0.05$)	0.05
RLE	412	0.04	Age ($p = 0.07$) Level of health visitor support ($p = 0.01$)	0.67
Mental health	420	0.05	Level of health visitor support ($p = 0.001$)	0.73
Vitality	420	0.07	Normal delivery ($p = 0.001$) Level of health visitor support ($p = 0.01$)	0.46
Pain	420	0.07	Normal delivery ($p = 0.001$) Parity ($p = 0.06$)	0.78
GHP	411	0.08	Normal delivery ($p = 0.03$) Level of health visitor support ($p = 0.004$) Parity ($p = 0.001$)	0.89
EPDS	415	0.08	One-parent benefit ($p = 0.06$) Level of health visitor support ($p = 0.001$) Support available ($p = 0.09$)	0.33

* *The 12 covariates in the model were: group, one-parent benefit, age, normal delivery, level of health visitor support, support available from partner/father/mother/friends, car available, adults in house, parity, house rented from council, receiving income support, receiving housing benefit*

† *Intervention effect, after adjustment for the other 11 covariates in the model*

This reflects the results of the unadjusted univariate analysis (see *Table 28*).

Covariates that appeared to be associated with the SF-36 domains were spontaneous delivery, age, parity and level of health visitor intervention. The signs of the regression coefficients for the covariates indicated that for all domains of the SF-36, a spontaneous delivery was associated with better health. Conversely, increasing age, parity and level of health visitor intervention were associated with poorer health.

High levels of health visitor intervention were associated with higher EPDS scores and the availability of support and receipt of one-parent benefit were associated with lower EPDS scores.

The low values of R^2 in all models (≤ 0.15) indicate that most of the variability in the health status outcomes is not explained by the 12 covariates.

The assumptions underlying the multiple regression analysis were:

- The values of the dependent variable total spend should have a normal distribution for each value of the predictor variables.
- The variability of total spend should be the same for each value of the predictor variables.
- An underlying linear relationship between dependent variable (total spend) and predictor variables should exist.

If the above assumptions hold, then the residuals should have a normal distribution (with a mean of zero). The residuals of the model were checked for evidence of correlation, non-normality and heteroscedacity (non-constant variance).

Stepwise selection procedure

An alternative modelling approach was to include those variables that were 'statistically important'. A stepwise selection procedure with a *p*-value of 0.05 for entry into the model and a *p*-value of 0.10 for removal from the model was used to select the 'statistically important' predictor variables of health status. After each change in a set of variables included in the regression model, the contribution of each variable was assessed. After

TABLE 44 *Stepwise multiple regression analysis using potential risk covariates*

Dependant variable	*n*	R^2 *	Significant predictors† coefficient (95% CI)	Group effect (95% CI)‡
Physical functioning	416	0.08	Normal delivery 8.3 (5.2, 11.4) Age –0.3 (–0.5, –0.0)	–0.9 (–3.8, 1.6)
Social functioning	419	0.04	Normal delivery 7.7 (2.8, 12.6) Age –0.5 (–0.9, –0.1)	–2.8 (–7.3, 1.8)
RLP	411	0.13	Normal delivery 26.8 (19.1, 34.4) Age –0.9 (–1.5, –0.2)	–7.7 (–14.7, –0.6)
RLE	412	0.01	Age –0.6 (–1.2, –0.0)	–1.5 (–8.4, 5.3)
Mental health	420	0.00		–0.1 (–3.0, 3.2)
Vitality	420	0.04	Normal delivery 7.8 (3.4, 12.1) Age –0.4 (–0.8, –0.1)	0.5 (–3.5, 4.6)
Pain	420	0.06	Normal delivery 12.6 (7.7, 17.5) Parity –2.5 (–4.8, –0.3)	–0.6 (–5.1, 3.8)
GHP	411	0.05	Normal delivery 4.2 (0.4, 7.9) Parity –3.6 (–5.4, –1.9)	–0.7 (–4.1, 2.8)
EPDS	415	0.004		0.7 (–0.3, 1.6)

* *R^2 with any significant covariates in the model and the group variable*
† *Potential predictors were: one-parent benefit, age, normal delivery, level of health visitor support, support available from partner/father/mother/friends, car available, adults in house, parity, house rented from council, receiving income support, receiving housing benefit*
‡ *Intervention effect, after adjustment for any other significant covariates in the model*

'statistically significant' predictor variables were included in the model, the treatment group variable was added and its impact assessed.

The intervention group had a worse RLP score than the control group after adjustment for age and spontaneous delivery, by –7.7 points (95% CI, –14.7, –0.6) *(Table 44)*.

Covariates associated with the SF-36 domains, were spontaneous delivery, age and parity. The signs of the regression coefficients for the covariates indicated that for all SF-36 domains, a spontaneous delivery was associated with better health. Increasing age and parity were associated with poorer health status.

Using the stepwise selection procedure no covariates were significantly associated with the EPDS score. Again the low values of R^2 in all models (≤ 0.13) indicate that the majority of the variability in the health status outcomes is not explained by the covariates.

Risk of PND

Women who scored 12 or more were considered to be at a higher risk of PND.[107] When the EPDS scores were categorised as 'low' and 'high' risk a multiple linear logistic regression was used. When all covariates and the intervention group variable were entered in a logistic regression model the only significant predictor of risk was level of health visitor intervention ($p = 0.0002$). Women who were assessed as requiring high levels of health visitor intervention were 2.2 times (95% CI, 1.4, 3.3) more likely to be at risk of PND, after adjustment for the other covariates in the model. There was no increased risk of PND associated by group ($p = 0.89$).

Summary

There was an 88% response rate to the 6-week follow-up questionnaire. There was no statistical evidence of a difference in the primary outcome measure, the SF-36 GHP domain. There was some statistical evidence of a difference in three other SF-36 domains in favour of the control group. There was no statistical evidence of a difference between the two groups in the mean EPDS scores, the DUFSS scores or duration of breastfeeding. There were also no differences in use of GP, hospital or secondary mental health services, prescription or medications bought for the mother or her baby. Subgroup analysis of various 'at-risk groups' showed that only age appeared to have an effect on EPDS and some SF-36 domains.

Health visitor 3-month follow-up questionnaire

Response rate and completion rate for health visitor 3-month questionnaire

There were 570/623 forms returned by health visitors (91% response). The reasons for loss to follow-up at 3 months include women moving house and changing GP, and therefore health visitor caseload within Sheffield, and also moving out of the trial area and abroad.

Level of health visitor intervention

Almost half of the families (47%) were assessed (by the health visitors' subjective assessment) as requiring a medium level of health visitor intervention in the first 12 weeks since the baby was born, and 38% were assessed as requiring a low level of intervention, but 15% were assessed as requiring a high level of intervention (*Table 45*). There was no evidence of a difference between the groups.

TABLE 45 *Level of health visitor intervention at 3 months*

	% Intervention (*n* = 277)	% Control (*n* = 283)
High	15.9	13.8
Medium	49.8	44.5
Low	34.3	41.7
χ^2 = *3.27 on 2 df,* p = *0.20;* $\chi^2_{linear\ association}$ = *2.66 on 1 df,* p = *0.10*		

Frequency of health visitor contacts at 3 months

Most women had two or three health visitor home visits in the first 3 months after their baby was born, ranging from one to 19 visits (mean, 3.4; SD, 1.9). Nearly all women (94%) attended the clinic to see a health visitor (mean number of visits, 2.6; SD, 1.9). Only one-fifth of women attended the clinic and did not see a health visitor. There was no difference in the number of contacts with the health visitor between the groups (*Table 46*).

Breastfeeding rates at 3 months

Many women (40%) did not breastfeed their baby and nearly a quarter were still breastfeeding at 12 weeks. The mean number of weeks breastfed was 5 in the intervention group and 4 in the control group (*Table 47*). This difference was not statistically significant, but could be of clinical importance.

Use of resources at 3 months

GP

Only 1% of babies were reported to have not attended for their baby check. Fewer than 3% of mothers were reported not to have attended for their postnatal examination, with no difference by group.

TABLE 46 *Frequency of visiting by health visitor*

	Intervention			Control			*p*-value
	n	Mean (SD)	Median (quartiles)	*n*	Mean (SD)	Median (quartiles)	
Visited at home by health visitor	282	3 (2)	3 (2–4)	285	3 (2)	3 (2–4)	0.11
Attended clinic to see health visitor	265	3 (2)	2 (2–3)	274	3 (2)	2 (1–3)	0.41
p-*values from Mann–Whitney test*							

TABLE 47 *Breastfeeding at 3 months*

	Intervention			Control			*p*-value
	n	Mean (SD)	Median (quartiles)	*n*	Mean (SD)	Median (quartiles)	
No. of weeks breastfed	276	5 (5)	4 (0–12)	276	4 (5)	2 (0–12)	0.20
p-*value from Mann–Whitney test*							

The health visitors reported 10% of babies who had a delay in their immunisations at 2 months and 20% who had a delay at 3 months, but there was no statistical difference between the groups (*Table 48*).

Health visitors reported that more than one-third of women had required treatment from her GP in the 12 weeks since her baby was born (*Table 49*). They reported that a quarter of all women had only one episode of illness, but 14% had more than one episode of illness requiring treatment.

Almost half of the babies had treatment from their GP in the first 12 weeks (*Table 50*). The health visitors reported that almost one-third of all babies had only one episode of illness, but 17% had more than one episode of illness requiring treatment.

Hospital

28% of women attended hospital for either their baby or themselves within the first 12 postnatal weeks (*Table 51*); 17% attended once and 11% attended more than once. Less than 3% of women were known to have been an inpatient themselves and 6% had been seen as an outpatient. Less than 1% of women were known to have attended A&E for themselves.

There were 8% of babies seen in hospital as inpatients, 12% as outpatients and 5% in A&E. There was a significantly higher attendance at A&E for their baby by the control group (*Table 52*).

Social and other services

There were 4% of women who had used social services, ranging from one to ten times within the first 12 weeks. Some of these contacts predated the birth of the most recent baby. One-fifth of women had used some other service or support group in the first 12 weeks after their baby was born. This included First-Time Mother's group (9.7%), Community Mental Health Team (1.7%), or other services (6.5%) such as Family Service Unit, Home Start, mother and toddler group, National Childbirth Trust, Newpin, nursery nurse, postnatal support group, and young mothers service, which each comprised less than 1% of respondents.

Summary

There was a 91% completion rate of the 3-month health visitor questionnaire. There was no difference in the first 3 months in the number of times women were visited at home (three times) or

TABLE 48 *Delay in immunisation status*

Delay	Intervention	Control	*p*-value
	n (%)	*n* (%)	
At 2 months	277 (8.7)	274 (10.6)	0.44
At 3 months	167 (19.8)	181 (21.0)	0.78
p-values from χ^2 *test*			

TABLE 49 *Treatment required from GP by mother at 3 months*

	% Intervention (*n* = 162)	% Control (*n* = 168)
No treatment	63.0	58.9
One or more treatments	37.0	41.1
$\chi^2 = 0.56$ *on 1 df,* p = *0.45*		

TABLE 50 *Treatment required from GP by baby at 3 months*

	% Intervention (*n* = 194)	% Control (*n* = 200)
No treatment	51.0	52.0
One or more treatments	49.0	48.0
$\chi^2 = 0.04$ *on 1 df,* p = *0.85*		

TABLE 51 *Use of hospital and other services by mother at 3 months*

	Intervention		Control		*p*-value
	n	% Yes	*n*	% Yes	
Inpatient	250	2.4	234	2.6	0.91
Outpatient	250	7.2	233	4.3	0.17
A&E	250	0.8	234	0.4	1.00*
Social services	262	4.6	262	4.4	0.94
Other services	236	19.1	239	20.5	0.70

p-values from χ^2 *test, except* *Fishers exact test

The n-values are the number of women who answered the relevant question on the questionnaire

TABLE 52 *Use of hospital services by baby at 3 months*

	Intervention		Control		*p*-value
	n	% Yes	*n*	% Yes	
Inpatient	249	8.8	235	7.7	0.64
Outpatient	249	12.0	234	11.5	0.86
A&E	249	2.8	235	7.2	0.03*

p-values from χ^2 *tests, except* *Fishers exact test

seen at a health visitor clinic (twice) between the two groups. The 1-week difference in breast-feeding in favour of the intervention group seen at 6 weeks follow-up was maintained at 3-months health visitor follow-up. There were 15% of families assessed by health visitors as requiring high levels of intervention.

Main outcomes at 6 months

Response rates at 6 months

There was a 79.1% (493/623) overall response rate to the 6-month follow-up questionnaire (*Tables 53* and *54*) and 8.9% more of the intervention group than the control group women responded.

The responders were significantly more likely to be older, have had a heavier baby, have only one child and to have a lower DUFSS score than non-responders (*Table 55*). They were also more likely to have had an emergency Caesarean section than non-responders (11.2% versus 5.4%). They were significantly more likely to be white, have a mortgage, have had a paid job in the 6 months prior to delivery and have access to a car than non-responders.

The 6-month responders appear to have had slightly poorer physical functioning and RLP SF-36 scores at 6 weeks than the non-responders (*Table 56*). The non-responders had poorer mental health domain scores.

When the 6-week SF-36 scores of the 6-month non-responders were examined, the mean social functioning and role limitation scores for women in the control group were significantly higher than those of 6-month non-responders in the intervention group (at 6 weeks).

Completion rates at 6 months

There was a very high minimum level of completion of 92% among the returned questionnaires (*Table 57*).

Health status outcomes at 6 months

At 6 months, the intervention and control groups had similar health status as measured by the SF-36, EPDS and DUFSS (*Table 58*). The width of the CIs for the difference between the mean scores of the two groups were narrow, within ten points for all domains of the SF-36 and EQ-5D (0–100 scale) and within three points for the EPDS and DUFSS (scales 0–30 and 8–40, respectively). This may, however,

TABLE 53 *Response rate to 6-month questionnaire*

	Intervention	Control	Total
	n **(%)**	***n*** **(%)**	***n*** **(%)**
Yes	260 (83.6)	233 (74.7)	493 (79.1)
No	51 (16.4)	79 (25.3)	130 (20.9)
Total	**311 (100)**	**312 (100)**	**623 (100)**
χ^2 = *7.51 on 1 df,* p = *0.006*			

TABLE 54 *Reasons for loss to follow-up of 130 women at 6 months*

	n **(%)**
No reply	52 (40.0)
No telephone available to remind	38 (29.2)
Moved	26 (20.0)
Social services involved	12 (9.2)
Unwell or depressed	1 (0.8)
Baby died	1 (0.8)
Total	**130 (100)**

TABLE 55 *Baseline birth details of responders versus non-responders at 6 months*

	Responder			Non-responder			*p*-value
	n	**Mean (SD)**	**Median (quartiles)**	***n***	**Mean (SD)**	**Median (quartiles)**	
Age (years)	493	28.3 (5.6)	28.0 (25.0–32.0)	130	25.5 (5.7)	25.0 (21.0–29.0)	0.001
Birth weight (g)	493	3460.1 (521.3)	3440.0 (3120.0–3780.0)	130	3361.3 (462.5)	3380.0 (3090.0–3660.0)	0.05
Parity	493	1.8 (1.0)	1.0 (1.0–2.0)	130	2.1 (1.3)	2.0 (1.0–3.0)	0.02*
DUFSS	477	13.6 (5.9)	12.0 (9.0–16.0)	118	15.8 (7.1)	14.0 (10.0–20.0)	0.001*

p-values from t-test, except *Mann–Whitney test

TABLE 56 *The 6-week health status measures of responders versus non-responders at 6 months*

	Responder			Non-responder			*p*-value
	n	Mean (SD)	Median (quartiles)	*n*	Mean (SD)	Median (quartiles)	
Physical functioning	465	87.3 (16.0)	95.0 (80.0–100.0)	78	91.8 (13.6)	97.5 (90.0–100.0)	0.003
Social function	470	78.2 (24.1)	88.9 (66.7–100.0)	79	78.8 (23.8)	88.9 (66.7–100.0)	0.74
RLP	460	67.8 (39.6)	100.0 (25.0–100.0)	75	77.3 (36.3)	100.0 (50.0–100.0)	0.04
RLE	461	77.7 (35.4)	100.0 (66.7–100.0)	73	75.3 (39.3)	100.0 (66.7–100.0)	0.94
Mental health	471	73.2 (16.7)	76.0 (64.0–84.0)	79	67.2 (21.7)	68.0 (48.0–88.0)	0.05
Vitality	471	49.8 (21.1)	50.0 (35.0–65.0)	79	50.8 (21.0)	50.0 (35.0–70.0)	0.78
Pain	471	71.7 (24.5)	77.8 (55.6–88.9)	79	75.0 (25.0)	77.8 (66.7–100.0)	0.20
GHP	461	76.2 (18.2)	80.0 (67.0–90.0)	78	73.4 (20.5)	78.5 (62.0–87.0)	0.53
Health change	471	64.8 (25.9)	75.0 (50.0–75.0)	80	65.6 (27.4)	62.5 (50.0–100.0)	0.78
DUFSS	444	17.0 (7.0)	15.0 (11.0–21.0)	69	17.0 (8.0)	16.0 (10.0–23.0)	0.96
EPDS	463	6.9 (5.0)	6.0 (3.0–10.0)	79	8.3 (6.9)	7.0 (2.0–13.0)	0.30

p-*values from Mann–Whitney test*

For the SF-36 and EQ-5D, a higher score indicates better health. Conversely for the DUFSS and EPDS, a higher score indicates poorer health

TABLE 57 *Completion rates for 6 months health status questionnaires (*n *= 493)*

	Valid	Missing	% Missing
Physical functioning	488	5	1.0
Social function	490	3	0.6
RLP	488	5	1.0
RLE	485	8	1.6
Mental health	481	12	2.4
Vitality	480	13	2.6
Pain	488	5	1.0
GHP	485	8	1.6
Health change	491	2	0.4
DUFSS	465	28	5.7
EPDS	481	12	2.4
EQ-5D	453	40	8.1

be an example of regression towards the mean.[126] That is, women with high health status scores at 6 weeks will tend on average to have 6-month health status scores closer to the overall mean at 6 months. Similarly, women with low scores at 6 weeks will tend on average to have higher 6-month scores closer to the overall mean at 6 months.

EPDS

Although there appeared to be no statistical evidence of a difference in mean EPDS scores at 6 months, when the scores were categorised as 12 or more (indicating a risk of PND) and 11 or less, there were 18.9% of women in the intervention group and 21.6% of women in the control group scoring over the threshold for concern ($\chi^2 = 0.52$ on 1 df; $p = 0.47$).

Breastfeeding

At 6 months there was no statistical evidence of differences in breastfeeding rates or duration of breastfeeding between the intervention and control groups (*Table 59*).

Use of resources at 6 months

At 6 months there is some evidence that control group women were more likely to have had a GP consultation at home than those in the intervention group (*Table 60*). The total number of GP contacts for the women was similar between the control and intervention groups.

At 6 months there was some evidence that intervention group babies had a greater number of total GP contacts than the control group babies (*Table 61*).

TABLE 58 *Health status measures at 6-month follow-up*

	Intervention			Control			*p*-value	Mean difference (95% CI)
	n	Mean (SD)	Median (quartiles)	*n*	Mean (SD)	Median (quartiles)		
Physical functioning	258	89.8 (16.8)	95.0 (85.0–100.0)	230	91.2 (15.1)	100.0 (90.0–100.0)	0.23	–1.5 (–4.2, 1.2)
Social functioning	257	83.6 (22.0)	88.9 (75.0–100.0)	233	84.0 (23.6)	100.0 (77.8–100.0)	0.36	–0.4 (–4.7, 4.0)
RLP	259	80.2 (32.5)	100.0 (75.0–100.0)	229	82.1 (32.6)	100.0 (75.0–100.0)	0.34	–1.9 (–7.2, 3.5)
RLE	257	82.4 (31.7)	100.0 (66.7–100.0)	228	79.5 (35.5)	100.0 (66.7–100.0)	0.57	2.8 (–3.4, 8.3)
Mental health	254	72.8 (17.3)	76.0 (64.0–84.0)	227	74.0 (17.5)	76.0 (64.0–88.0)	0.30	–1.2 (–4.3, 1.8)
Vitality	252	56.1 (21.1)	60.0 (40.0–75.0)	228	54.7 (21.3)	60.0 (40.0–73.8)	0.49	1.4 (–2.5, 5.1)
Pain	256	81.0 (22.7)	88.9 (66.7–100.0)	232	82.8 (23.2)	88.9 (69.4–100.0)	0.22	–1.9 (–5.8, 2.2)
GHP	255	76.0 (19.4)	82.0 (65.0–92.0)	230	76.9 (20.4)	82.0 (67.0–92.0)	0.38	–0.9 (–4.5, 2.7)
Health change	259	67.4 (23.0)	75.0 (50.0–100.0)	232	64.8 (24.2)	50.0 (50.0–75.0)	0.26	2.6 (–1.6, 6.7)
DUFSS	240	17.1 (6.8)	16.0 (11.2–22.0)	225	16.7 (7.3)	15.0 (10.0–21.0)	0.29	0.4 (–0.9, 1.8)
EPDS	252	6.6 (5.1)	5.0 (3.0–10.0)	229	6.7 (5.6)	5.0 (2.0–10.0)	0.73	–0.1 (–1.0, 1.9)
EQ-5D	244	86.2 (17.0)	84.8 (79.6–100.0)	209	85.9 (19.3)	100.0 (79.6–100.0)	0.57	0.3 (–3.1, 3.6)

p-values from Mann–Whitney test

For the SF-36 and EQ-5D, a higher score indicates better health. Conversely for the DUFSS and EPDS, a higher score indicates poorer health

95% CIs for the mean difference calculated by the bootstrap percentile method

TABLE 59 *Breastfeeding rates at 6 months*

	% Intervention (*n* = 260)	% Control (*n* = 233)
Breast milk only	12.7	12.0
Formula milk only	80.0	79.4
Both breast and bottle milk	7.3	8.6
χ^2 = 0.30 on 2 df, p = 0.86		

Use of prescriptions at 6 months

Tables 62 and *63* show similar levels of GP prescriptions and medications bought for use by the women and babies between the groups at 6 months.

Use of NHS services

Tables 64 and *65* show similar levels of hospital service use by mothers and babies between the intervention and control groups at 6 months.

There was a trend for greater use of secondary mental health services by the women in the control group, but unlike the 6-week outcomes, this was no longer statistically significant (*Table 66*). The use of social services was also very similar between the intervention and control groups at 6 months (*Table 67*).

Validation of use of GP and hospital services

The Patient Focused Information system was used to identify which of 292 women had used the recruiting hospital within 6 months postnatally. Their medical records were then examined to investigate the use of services.

Hospital services at 6 weeks

In the first 6 weeks, 2% of women had been an inpatient, mainly in the Department of Obstetrics and Gynaecology. One per cent of women had used outpatients departments and 2% had been a ward attendee in the Department of Obstetrics and Gynaecology. A&E services were used by only 3/292 women within the first 6 weeks for conditions not related to childbirth. Services used for the

TABLE 60 *GP consultation at 6 months for mother*

	Intervention			Control			*p*-value
	n	**Mean (SD)**	**Median (quartiles)**	***n***	**Mean (SD)**	**Median (quartiles)**	
In your own home	210	0.0 (0.1)	0.0 (0.0–0.0)	183	0.1 (0.4)	0.0 (0.0–0.0)	0.006
In GP surgery	208	0.9 (1.3)	0.0 (0.0–1.0)	180	0.9 (1.5)	1.0 (0.0–1.0)	0.75
By telephone	209	0.0 (0.2)	0.0 (0.0–0.0)	182	0.1 (0.3)	0.0 (0.0–0.0)	0.28
Total no. of GP contacts	210	0.9 (1.3)	0.0 (0.0–1.0)	183	1.1 (1.7)	1.0 (0.0–1.0)	0.47

p-values from Mann–Whitney test

TABLE 61 *GP consultation at 6 months for baby*

	Intervention			Control			*p*-value
	n	**Mean (SD)**	**Median (quartiles)**	***n***	**Mean (SD)**	**Median (quartiles)**	
In your own home	210	0.2 (0.4)	0.0 (0.0–0.0)	183	0.1 (0.4)	0.0 (0.0–0.0)	0.55
In GP surgery	207	1.6 (1.6)	1.0 (1.0–2.0)	178	1.4 (1.6)	1.0 (0.0–2.0)	0.07
By telephone	209	0.3 (0.9)	0.0 (0.0–0.3)	182	0.3 (0.8)	0.0 (0.0–0.0)	0.09
Total no. of contacts	210	2.1 (2.0)	2.0 (1.0–3.0)	188	1.7 (1.9)	1.0 (0.0–2.0)	0.03

p-values from Mann-Whitney test

TABLE 62 *Prescription use at 6 months*

	Intervention	Control	*p*-value
	***n* (%)**	***n* (%)**	
For mother: % Yes	257 (38.5)	229 (44.5)	0.18
For baby: % Yes	255 (74.1)	232 (73.7)	0.92

p-values from χ^2 *tests*

TABLE 63 *Medicines bought at 6 months*

	Intervention	Control	*p*-value
	***n* (%)**	***n* (%)**	
For mother: % Yes	259 (16.6)	232 (15.5)	0.74
For baby: % Yes	259 (61.4)	232 (65.2)	0.80

p-values from χ^2 *tests*

TABLE 64 *Use of hospital services by mother at 6 months*

	Intervention		Control		*p*-value
	n	**% Yes**	***n***	**% Yes**	
Inpatient	260	1.2	233	2.1	0.49*
Outpatient	259	9.7	229	8.3	0.60
Day-patient	259	5.4	229	5.7	0.90
A&E	259	1.5	229	3.5	0.17

p-values from χ^2 *tests, except* *Fisher's exact test

The n-values are the number of women who answered the relevant question on the questionnaire

TABLE 65 *Use of hospital services by baby at 6 months*

	Intervention		Control		*p*-value
	n	**% Yes**	***n***	**% Yes**	
Inpatient	260	6.5	233	8.2	0.49
Outpatient	258	14.3	229	17.0	0.41
Day-patient	258	6.6	229	9.6	0.22
A&E	259	12.4	229	13.1	0.81

p-values from χ^2 *tests*

The n-values are the number of women who answered the relevant question on the questionnaire

TABLE 66 *Use of secondary mental health services by mother at 6 months*

	Intervention		Control		*p*-value
	n	**% Yes**	***n***	**% Yes**	
Community mental health nurse	259	1.9	229	4.4	0.12*
Psychiatrist	259	1.2	229	1.3	1.00
Psychologist	259	0.0	227	0.9	0.22
Community mental health social worker	259	0.0	229	1.3	0.10

p-values from Fisher's exact test, except * χ^2 *test*

The n-values are the number of women who answered the relevant question on the questionnaire

TABLE 67 *Use of social worker services at 6 months*

	% Intervention (*n* = 259)	% Control (*n* = 229)
Yes	3.5	1.3
No	96.5	98.7

$\chi^2 = 2.38$ *on 1 df,* p = *0.12*

babies in the first 6 weeks at the recruiting hospital included three outpatient appointments, six inpatient nights, two ward attendees and two day-patient attendees.

Hospital services at 6 months

Only 1% of women had been an inpatient and 2% had been a day-patient in the Departments of Obstetrics and Gynaecology and Surgery. The 9% of women who had used outpatient services in the first 6 months comprised 7% who had used the Department of Obstetrics and Gynaecology, 1% who had used the Department of Surgery and four other departments. A&E services were used by 11 women on 14 occasions within the first 6 months. Services used for the 292 babies in the first 6 months at the recruiting hospital, included 12 outpatient appointments and three ward attendees.

Children's hospital

At the local children's hospital there were 28/623 (4.5%) babies who were inpatients for a total of 82 nights within the first 6 months. These were mainly in the general paediatric department but 1% were in the paediatric surgical unit. Outpatient services were used by 32/623 (5.1%) babies on 66 occasions in total, covering a range of departments. A&E services were used by 50/623 babies (8.0%) on 57 occasions.

The interpretation of the following results was based on the premise that the GP notes were an accurate record of contacts with women. There was some evidence that at the 6-week follow-up women were likely to over-report GP contacts by a mean 0.5 of a contact (95% CI, 0.2, 0.7) compared with the contacts reported in the GP notes. Based on a sample of 266 paired, self-completed 6-week questionnaire responses and GP notes, the women reported a total mean 3.8 (SD, 2.6) GP contacts (for mother and baby). This compared with 3.4 (SD, 2.3) mean total GP contacts recorded in the GP notes. There was no reliable evidence that there was any bias in over-reporting contacts between the groups at 6 weeks. The mean 'over-reporting' was 0.6 (SD, 2.0) contacts for the 116 women in the control group and 0.4 (2.4) contacts for the 150 women in the intervention group (mean difference, 0.2; 95% CI, –0.4, 0.7; $t = 0.67$ on 1 df; $p = 0.51$).

There was some evidence that at the 6-month follow-up all women were more likely to under-report GP contacts by 0.2 of a contact compared with the contacts reported in the GP notes, based on a sample of 198 paired self-completed 6-month questionnaire responses and GP notes. There was no reliable evidence that there was any bias in under-reporting contacts between the groups at 6 months with a mean difference of 0.2 contacts (95% CI, –1.0, –1.3; $t = 0.31$ on 196 df; $p = 0.75$).

When the analysis was repeated for the 186 women who replied at 6 weeks and 6 months, there was, again, over-reporting of GP contacts at 6 weeks and under-reporting at 6 months but there was no difference between the two groups. For the 6-month period, the difference between GP records and self-reports was –0.1 contacts (95% CI, –0.7, 0.5).

Indicators of stress and coping at 6 months

For the questions that sought to determine women's experiences of life with a baby, the responses indicated that women had more control over their life at 6 months than they had at 6 weeks, but there were no differences by group (*Table 68*). There were no statistically significant differences between the two groups, though marginally higher levels of satisfaction were reported in the intervention group (*Table 69*).

TABLE 68 *Control over life at 6 months*

	% Intervention (*n* = 259)	% Control (*n* = 232)
None at all	1.9	2.6
A little	5.0	9.9
Some	20.1	16.4
Quite a lot	43.6	41.8
A great deal	29.3	29.3
χ^2 = 5.24 on 4 df, p = 0.26; $\chi^2_{\text{linear association}}$ = 0.83 on 1 df, p = 0.36		

TABLE 69 *Satisfaction with life at 6 months*

	% Intervention (*n* = 259)	% Control (*n* = 232)
Very satisfied	32.4	37.1
Fairly satisfied	52.9	44.8
Neither	9.7	7.8
Fairly dissatisfied	2.7	6.9
Very dissatisfied	2.3	3.4
χ^2 = 8.03 on 4 df, p = 0.09; $\chi^2_{\text{linear association}}$ = 0.39 on 1 df, p = 0.53		

TABLE 70 *Change in health status from 6 weeks to 6 months*

	Intervention			Control			*p*-value*	Mean difference (95% CI)†
	n	Mean change (SD)	Median change (quartiles)	*n*	Mean change (SD)	Median change (quartiles)		
Physical functioning	248	3.6 (14.9)	0.0 (0.0–10.0)	214	3.8 (12.7)	0.0 (0.0–10.0)	0.40	–0.2 (–2.8, 2.4)
Social function	248	6.9 (25.6)	0.0 (0.0–22.2)	219	4.3 (25.3)	0.0 (0.0–11.1)	0.17	2.6 (–2.0, 7.0)
RLP	245	15.7 (43.1)	0.0 (0.0–50.0)	210	11.9 (40.5)	0.0 (0.0–25.0)	0.44	3.8 (–3.8, 11.5)
RLE	245	5.4 (38.9)	0.0 (0.0–0.0)	209	1.8 (40.9)	0.0 (0.0–0.0)	0.37	3.7 (–3.8, 11.0)
Mental health	246	0.4 (16.3)	0.0 (–8.0–8.0)	213	0.3 (16.8)	0.0 (–8.0–9.0)	0.99	0.1 (–2.6, 3.3)
Vitality	244	6.9 (21.6)	5.0 (–5.0–20.0)	214	5.4 (21.0)	5.0 (–5.0–20.0)	0.35	1.5 (–2.6, 5.5)
Pain	248	10.9 (25.2)	11.1 (0.0–22.2)	218	10.7 (26.9)	11.1 (0.0–22.2)	0.85	0.2 (–4.6, 5.2)
GHP	243	1.1 (14.6)	0.0 (–5.0–8.0)	210	–0.4 (16.7)	0.0 (–5.0–10.0)	0.93	1.6 (–1.2, 4.6)
DUFSS	222	–0.1 (6.4)	0.0 (–4.0–2.0)	202	–0.2 (5.7)	0.0 (–3.0–3.0)	0.96	0.1 (–1.0, 1.3)
EPDS	240	0.6 (4.9)	0.0 (–2.0–3.0)	214	–0.2 (5.3)	0.0 (–2.0–2.0)	0.35	0.8 (–0.1, 1.8)

**p-values from Mann–Whitney test; p-values for difference in mean health change between groups adjusted for 6-week scores: physical functioning = 0.85; RLP = 0.51; Pain = 0.98; GHP = 0.26; vitality = 0.45; social function = 0.29; RLE = 0.31; mental health = 0.92; EPDS = 0.08; DUFSS = 0.84*

†95% CIs for the mean difference were calculated by the bootstrap percentile method

For the SF-36, EPDS and DUFSS a positive mean change indicates a health gain from 6 weeks to 6-month follow-up. A positive mean difference would indicate the intervention group had a greater health gain than the control group

Over a quarter of women in both groups had attended a mother and toddler group and around 12% had attended a postnatal support group, but again, there were no differences between the two groups.

Change in health status over time

It was possible to examine the change in self-perceived quality of life between 6 weeks and 6 months. The results of the analysis of the change in health status scores are presented in *Table 70*. On no domain was there a statistically significant differential 'health gain' between the intervention and control groups. On four domains of the SF-36 (physical functioning, RLE, mental health, GHP) the health change was small, less than six points (on a 0–100 scale). The health change in the EPDS and DUFSS was less than one point on their respective scales (0–30 and 8–40).

An ANCOVA was undertaken to adjust the change in health status score for the initial score at 6 weeks. On no health domain was there a significant difference between the intervention and control groups in health gain over 6 weeks to 6 months, even after adjustment for the 6-week initial health status.

TABLE 71 *Change in health status from 6 weeks to 6 months categorised as worse, same or better*

	Intervention group				Control group			
	n	**% Worse**	**% Same**	**% Better**	***n***	**% Worse**	**% Same**	**% Better**
Physical functioning	248	20.2	31.9	48.0	214	21.5	36.4	42.1
Social functioning	248	22.6	31.5	46.0	219	20.5	41.6	37.9
RLP	245	15.9	46.9	37.1	210	13.3	54.8	31.9
RLE	245	13.9	61.6	24.5	209	14.8	64.6	20.6
Mental health	246	42.7	11.0	46.3	213	40.8	13.1	46.0
Vitality	244	27.0	11.1	61.9	214	33.2	12.1	54.7
Pain	248	21.4	26.2	52.4	218	19.3	27.5	53.2
GHP	243	37.9	17.7	44.4	210	36.2	19.0	44.8
DUFSS	222	46.4	13.5	40.1	202	46.0	13.9	40.1
EPDS	240	37.5	14.2	48.3	214	40.2	14.5	45.3

Table 71 shows the classification of the change in health status as worse, same, or better, by group. For almost half of the women, the DUFSS scores were worse at 6 months and for more than 40% of the women their SF-36 mental health scores were worse at 6 months. More women in the intervention group than in the control group had improved SF-36 domains of physical functioning, social functioning, RLP, RLE and vitality at 6 months.

Summary of 6-month follow-up

There was a high response to follow-up (79%) and the two groups had similar self-perceived health status as measured by the SF-36, the EPDS and the DUFSS questionnaire. There was no difference in the duration of breastfeeding. Use of GP services for the mother was similar for both groups, but babies in the intervention group had more total GP contacts than those in the control group. Prescription use for mother and baby did not differ significantly between groups. The use of hospital services for the mother and baby was similar between groups. There were no differences between groups in use of secondary mental health services or social services. Women appeared to have more control over their life at 6 months than at 6 weeks, but there were no differences between groups in the women's responses to proxy questions on adaptation to life with a new baby.

Comparison of costs per group

Given that health outcomes were similar for both groups at 6 weeks and at 6 months, the economic analysis is limited to a comparison of costs between the intervention and control groups.

TABLE 72 *Resource use per SW visit*

	n	**Mean (SD)**	**Median (quartiles)**
Length of visit (minutes)	1765	143 (37)	150 (120–180)
Administration and travel time (minutes)	1765	24 (26)	19 (0–45)
No. of visits	1765	6 (3)	7 (5–9)

*Note: Only those women who received at least one visit from an SW were included in this analysis (*n = *273)*

Costs of the CMSW service

SWs spent on average 143 minutes per visit in the woman's home and the median length of a visit was 150 minutes (*Table 72*). Mean administration and travel time combined was 24 minutes per visit.

Staff time was the most costly element of a visit, comprising 84% of the total cost (*Table 73*). The remaining cost items were travel expenses (8% of total costs), education and training (5%), and equipment (3%). The mean cost of an SW visit was £27.70 (SD, £6.20) with a median value of £28.20.

In the 14 months that the CMSW service was provided, six SWs made a total of 1765 visits to 273 women. By summing the cost of all visits, for all women, the total costs of the CMSW service for this period came to £48,960. *Figure 6* shows the distribution of costs per visit for those women in the intervention group who received at least one visit.

TABLE 73 *Costs per SW visit*

Resource	*n*	Mean cost (SD) (£)	Median (quartiles) (£)	Total cost (£)	% of total costs
Staff time	1765				
Length of visit		20.0 (5.2)	21.0 (16.8–25.2)	35,304	72.1
Travel and administration		3.4 (3.7)	2.7 (0–6.3)	6006	12.3
Travel expenses	1765	2.1 (0.0)	2.1 (2.1–2.1)	3724	7.6
Education and training	1765	1.3 (0.0)	1.3 (1.3–1.3)	2283	4.7
Equipment	1765	0.9 (0.0)	0.9 (0.9–0.9)	1642	3.4
Total cost per visit	1765	27.7 (6.2)	28.2 (23.2–31.6)	48,960	100

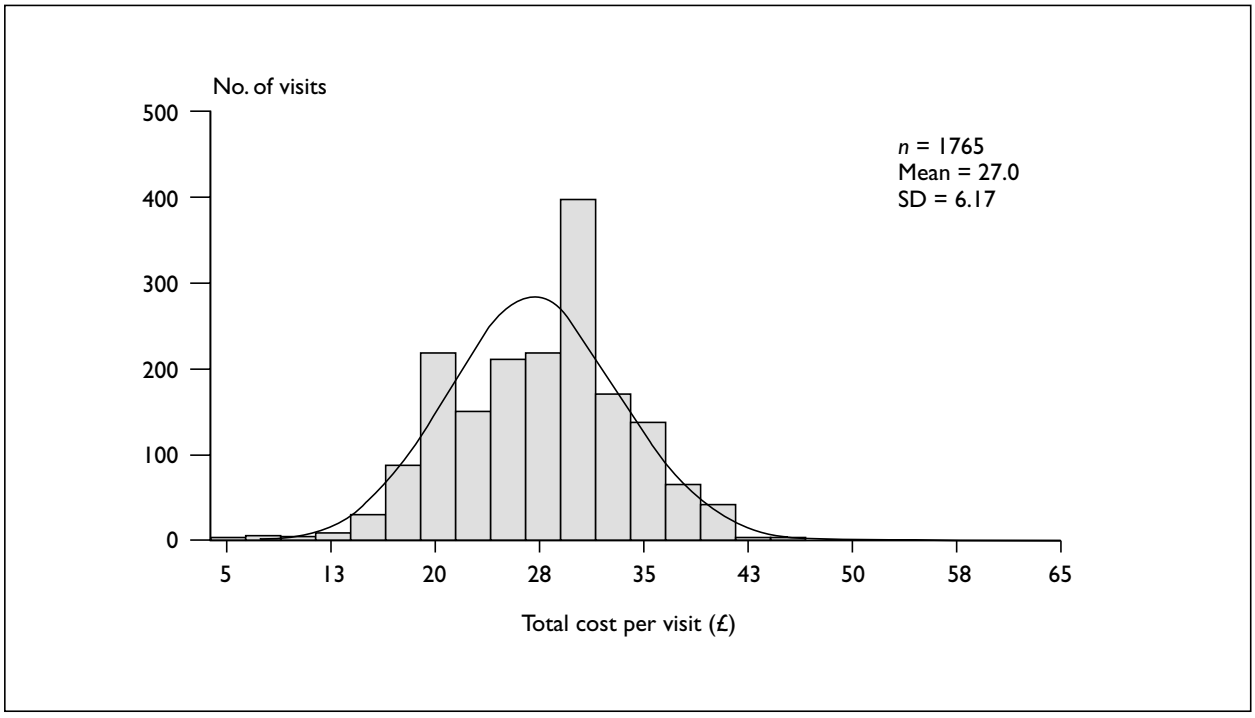

FIGURE 6 *Distribution of costs per SW visit*

On average, women received six visits each. The mean cost per woman receiving SW visits was £179.30 (SD, £83.30), with a median cost of £182.10. Between the 25th and 75th percentiles costs ranged from £119.70 and £242.20 per woman. These costs were calculated only for those women who received at least one visit. The distribution of costs per woman are shown in *Figure 7*.

Other NHS costs

Resource use and costs

Cost results were analysed at 6 weeks and at 6 months to coincide with the measurement of health outcomes. *Tables 74* and *75* show NHS resource use and costs, respectively, at 6 weeks, for both groups. With the exception of the CMSW service, which was provided only to the intervention group, there were no statistically significant differences between the two groups in terms of resource use or costs, for any NHS service for which data were collected.

The total NHS costs for all trial participants at 6 weeks were highly skewed (*Figure 8*).

Community midwife costs

The women in both groups received eight visits on average from the community midwife in the first 28 days after delivery. The mean cost for this service, for the intervention group, was £193 (SD, £53) and for the control group £191 (SD, £49).

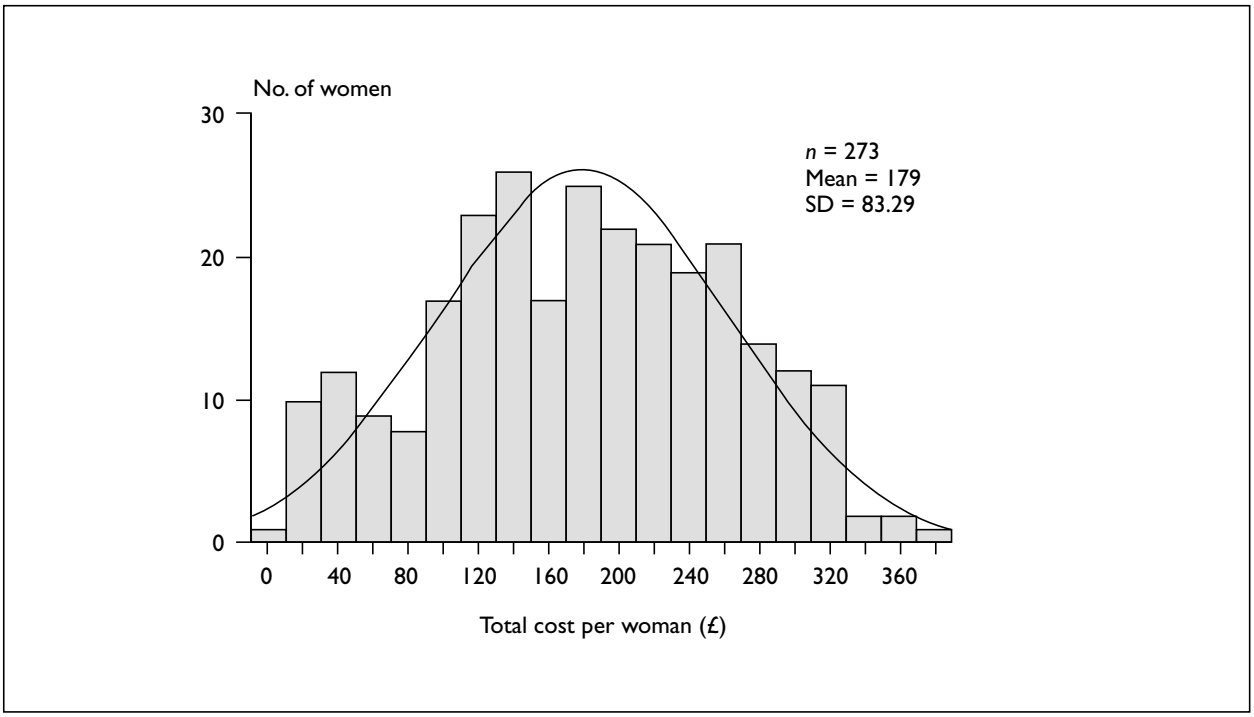

FIGURE 7 *Distribution of costs per woman of SW visits*

TABLE 74 *NHS resource use at 6 weeks, per woman*

Resource	Intervention (*n* = 282)		Control (*n* = 269)		*p*-value*	Mean difference (95% CI)†
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)		
SW visits	5.8 (3.3)	6.0 (3.0–9.0)	0.0	0.0		
Community midwife visits	8.1 (1.9)	8.0 (7.0–9.0)	8.0 (1.8)	8.0 (7.0–9.0)	0.67	0.01 (–0.27, 0.33)
Health visitor visits	2.4 (1.2)	2.0 (2.0–3.0)	2.4 (1.3)	2.0 (2.0–3.0)	0.59	–0.04 (–0.24, 0.17)
Child health clinic visits	1.0 (0.0)	1.0 (1.0–1.0)	1.0 (0.0)	1.0 (1.0–1.0)	1.00	0.00 (0.001, 0.001)
GP contacts for baby	2.3 (1.7)	2.0 (1.0–3.0)	2.2 (1.8)	2.0 (1.0–3.0)	0.57	0.07 (–0.22, 0.36)
GP contacts for self	1.6 (1.5)	1.0 (0.8–2.0)	1.5 (1.5)	1.0 (0.5–2.0)	0.53	0.11 (–0.13, 0.36)
GP prescriptions baby	0.8 (0.9)	1.0 (0.0–1.0)	0.9 (1.0)	1.0 (0.0–1.0)	0.27	0.10 (–0.27, 0.06)
GP prescriptions self	0.7 (1.0)	0.0 (0.0–1.0)	0.7 (0.9)	0.0 (0.0–1.0)	0.90	0.04 (–0.12, 0.20)
Hospital contacts baby	0.3 (0.9)	0.0 (0.0–0.0)	0.3 (0.8)	0.0 (0.0–0.0)	0.38	–0.01 (–0.16, 0.14)
Hospital contacts self	0.2 (0.6)	0.0 (0.0–0.0)	0.1 (0.5)	0.0 (0.0–0.0)	0.18	0.05 (–0.04, 0.14)
Secondary mental health contacts	0.0 (0.3)	0.0 (0.0–0.0)	0.1 (0.4)	0.0 (0.0–0.0)	0.38	–0.02 (–0.09, 0.03)

* *p-values from Mann–Whitney test*

† *95% CIs for the mean difference calculated by the bootstrap percentile method*

Notes:

1. Hospital contacts include inpatient stays, day-patient attendance, outpatient attendance and A&E attendance

2. Secondary mental health contacts: inpatient, outpatient, community psychiatric nurse, occupational therapist and consultant contacts

3. Mean SW visits will differ from figures in Table 72 *as some women received no visits*

TABLE 75 *NHS costs at 6 weeks, per woman*

Resource	Intervention (*n* = 282)		Control (*n* = 269)		*p*-value*	Mean difference (95% CI) (£)†
	Mean (SD) (£)	Median (quartiles) (£)	Mean (SD) (£)	Median (quartiles) (£)		
SW visits	160.4 (97.6)	167.4 (94.2–233.3)				
Community midwife visits	193.3 (52.8)	188.8 (156.9–220.7)	191.1 (49.2)	190.0 (156.3–224.6)	0.97	2.12 (–5.96, 10.54)
Health visitor visits	105.4 (51.7)	89.0 (89.0–133.4)	107.2 (55.8)	89.0 (89.0–133.4)	0.59	–1.84 (–11.09, 7.96)
Child health clinic visits	7.7 (0.0)	7.7 (7.7–7.7)	7.7 (0.0)	7.7 (7.7–7.7)	1.00	0.00 (0.001, 0.001)
GP contacts baby	41.6 (31.7)	38.7 (19.3–58.0)	39.3 (31.7)	29.0 (19.3–51.3)	0.28	2.38 (–2.64, 7.43)
GP contacts self	29.5 (31.5)	29.0 (7.3–38.7)	28.1 (30.0)	29.0 (4.8–38.7)	0.77	1.50 (–3.76, 6.70)
Prescriptions baby	1.2 (2.0)	0.2 (0.0–1.9)	1.8 (4.5)	0.4 (0.0–2.0)	0.24	–0.53 (–1.17, –0.02)
Prescriptions self	2.3 (8.4)	0.0 (0.0–1.6)	2.7 (7.1)	0.0 (0.0–1.7)	0.64	–0.41 (–1.64, 0.90)
Hospital contacts baby	68.4 (269.4)	0.0 (0.0–0.0)	51.3 (185.6)	0.0 (0.0–0.0)	0.44	17.25 (–24.05, 58.15)
Hospital contacts self	24.2 (95.0)	0.0 (0.0–0.0)	24.6 (124.0)	0.0 (0.0–0.0)	0.19	–0.44 (–20.80, 17.28)
Secondary mental health contacts	1.0 (12.1)	0.0 (0.0–0.0)	2.0 (19.5)	0.0 (0.0–0.0)	0.38	–1 .07 (–4.05, 1.52)
Total	**635.0 (325.5)**	**579.1 (462.3–694.3)**	**456.0 (291.3)**	**386.6 (321.3–471.8)**	**0.001**	**179.58 (125.85–232.34)**

* *p-values from Mann–Whitney test*

† *95% CIs for the mean difference calculated by the bootstrap percentile method*

Notes:

1. Hospital contacts: inpatient, day-patient, outpatient and A&E attendance

2. Secondary mental health contacts: inpatient, outpatient, community psychiatric nurse, occupational therapist and consultant contacts

GP costs

The mean costs of GP contacts for the baby, for the intervention and control groups were £42 (SD, £32) and £39 (SD, £32) respectively, at 6 weeks. Mean costs for contacts for the women at 6 weeks were £30 (SD, £32) and £28 (SD, £30) for the intervention and control groups, respectively.

Prescription costs

Mean costs of prescriptions for the baby, at 6 weeks, for the intervention group were £1 (SD, £2) and for the control group it was £2 (SD, £5). For the women in the intervention group the mean costs of prescriptions were £2 (SD, £8) and for the control group the mean costs were £3 (SD, £7).

Health visitor costs

On average, all women in the trial received two visits each from the health visitor in the first 6 weeks after delivery. The mean cost for the intervention group at 6 weeks was £105 (SD, £52) and for the control group was £107 (SD, £56).

Child health clinic costs

All women attended one child health clinic with their babies in the first 6 weeks. The mean cost was £8 (SD, £0) for both groups.

Hospital costs

At 6 weeks the mean number of hospital contacts for the baby, in both groups, was 0.3, with a median of zero. Mean hospital costs in the intervention group were £68 (SD, £269) and for the control group they were £51 (SD, £186). At 6 weeks the mean number of hospital contacts for women in the intervention group was 0.2 compared with 0.1 in the control group. Most women had no contact with a hospital for either the baby or themselves in the first 6 weeks. Mean costs at 6 weeks were £24 (SD, £95) and £25 (SD, £124) for the intervention and control groups, respectively.

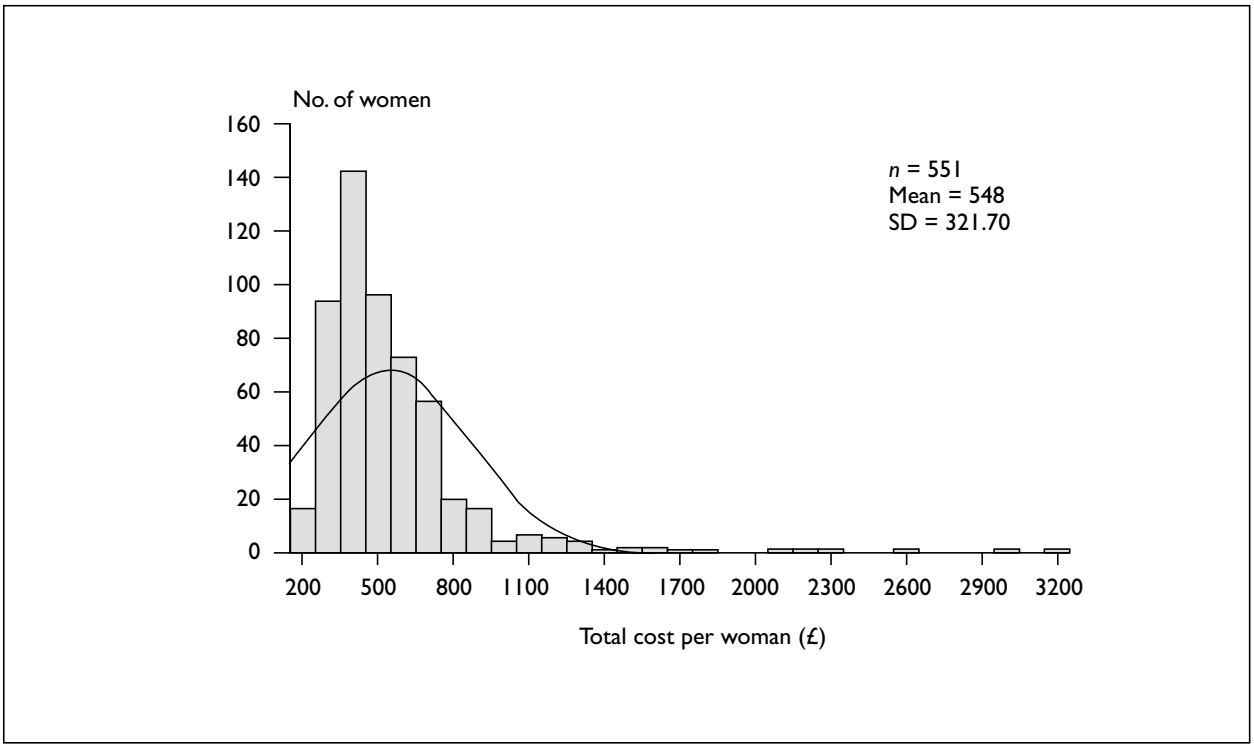

FIGURE 8 *Distribution of total NHS costs per woman at 6 weeks*

Secondary mental health service costs

At 6 weeks the mean number of secondary mental health contacts for women in the intervention group was 0.02 compared with 0.05 in the control group. Over three-quarters of women had no secondary mental health contacts. Mean costs were £1 (SD, £12) for the intervention group and £2 (SD, £20) for the control group. Median costs were zero for both groups.

Total NHS costs

At 6 weeks the mean total cost to the NHS for the intervention group was £635 (SD, £326) compared with £456 (SD, £291) for the control group. The mean difference between the groups was £180 (95% CI, £126, £232) and was statistically significant ($p = 0.001$). Excluding the additional cost of the SW in the intervention group the mean cost was £475 (SD, £314) for the intervention group and £456 (SD, £291) for the control group. There was no statistically significant difference between the groups ($p = 0.32$).

Social services costs

The mean number of contacts with local authority social workers was 0.07 for the intervention group and 0.04 for the control group at 6 weeks. Most women had no contact with social services. Mean costs were £1 (SD, £11) for the intervention group and £1 (SD, £8) for the control group. There was no statistically significant difference between the two groups in terms of resource use or costs ($p = 0.16$).

Personal costs

Medication

At 6 weeks the mean cost of over-the-counter medicine was £2 (SD, £2) for medicines purchased for the baby by women in both the intervention group and the control group (*Tables 76* and *77*). At 6 months the corresponding costs were £5 (SD, £5) for the intervention group and £4 (SD, £4) for the control group. At 6 weeks the mean cost of medicine purchased over the counter was £0.30 (SD, £1.00) for women in the intervention group and £0.60 (SD, £2.00) for women in the control group.

Formula milk

Women in each group spent on average £22 in the first 6 weeks on formula milk for their babies. Because of similar breastfeeding rates at 6 weeks, there were no statistically significant cost differences between the groups

Days taken off work by partner or others

On average 7 days were taken off work in the first month by partners and family and friends to help the mother at home after the baby was born (*Tables 78* and *79*). There was no difference between the two groups in days taken off work by

TABLE 76 *Personal resource use at 6 weeks, per woman*

Resource	Intervention (*n* = 282)		Control (*n* = 269)		*p*-value*	Mean difference (95% CI)†
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)		
Medicines purchased for baby	0.8 (0.8)	1.0 (0.0–1.0)	0.7 (0.8)	0.0 (0.0–1.0)	0.11	0.10 (–0.02, 0.24)
Medicines purchased for self	0.2 (0.4)	0.0 (0.0–0.0)	0.2 (0.4)	0.0 (0.0–0.0)	0.73	–0.01 (–0.08, 0.05)
Tins of formula milk	3.7 (2.7)	6.0 (0.0–6.0)	3.9 (2.6)	6.0 (0.0–6.0)	0.37	–0.22 (–0.66, 0.22)

* *p-values from Mann–Whitney test*
† *95% CIs for the mean difference calculated by the bootstrap percentile method*

TABLE 77 *Personal costs at 6 weeks, per woman*

Resource	Intervention (*n* = 282)		Control (*n* = 269)		*p*-value*	Mean difference (£) (95% CI)†
	Mean (SD) (£)	Median (quartiles) (£)	Mean (SD) (£)	Median (quartiles) (£)		
Medicines purchased for baby	1.9 (2.1)	1.8 (0.0–3.0)	1.6 (1.9)	0.0 (0.0–2.9)	0.07	0.33 (–0.01, 0.67)
Medicines purchased for self	0.3 (1.0)	0.0 (0.0–0.0)	0.6 (2.0)	0.0 (0.0–0.0)	0.50	–0.24 (–0.52, –0.01)
Tins of formula milk (900 g)	21.5 (15.6)	34.8 (0.0–34.8)	22.8 (15.1)	34.8 (0.0–34.8)	0.37	–1.23 (–3.65, 1.25)
Total	**23.8 (15.8)**	**34.8 (4.1–37.2)**	**25.0 (15.5)**	**34.8 (6.1–36.7)**	**0.74**	**–1.10 (–3.53, 1.39)**

* *p-values from Mann–Whitney test*
† *95% CIs for the mean difference calculated by the bootstrap percentile method*

TABLE 78 *Days taken off work by partners in the first month after the baby was born*

Leave (days)	Intervention (*n* = 215)		Control (*n* = 177)		*p*-value*	Mean difference (95% CI)†
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)		
Paid annual leave	3.5 (5.9)	0.0 (0.0–6.0)	2.8 (4.3)	0.0 (0.0–5.0)	0.29	0.66 (–0.29, 1.67)
Paid special leave	1.2 (2.4)	0.0 (0.0–2.0)	1.8 (3.1)	0.0 (0.0–3.0)	0.17	–0.53 (–1.07, 0.07)
Unpaid leave	1.3 (5.1)	0.0 (0.0–0.0)	1.0 (2.5)	0.0 (0.0–0.0)	0.79	0.40 (–0.28, 1.16)
Total leave days	**6.0 (7.3)**	**5.0 (0.0–9.0)**	**5.5 (5.1)**	**5.0 (0.0–10.0)**	**0.61**	**0.52 (–0.77, 1.82)**

* *p-values from Mann–Whitney test*
† *95% CIs for the mean difference calculated by the bootstrap percentile method*
Note: Only those women who had a partner are included in this table

TABLE 79 *Days taken off work by others in first month after the baby was born*

Leave (days)	Intervention (*n* = 233)		Control (*n* = 195)		*p*-value*	Mean difference (95% CI)†
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)		
Annual leave with pay	0.9 (3.6)	0.0 (0.0–0.0)	0.7 (2.0)	0.0 (0.0–0.0)	0.26	0.21 (–0.29, 0.74)
Special leave with pay	0.0 (0.0)	0.0 (0.0–0.0)	0.2 (1.2)	0.0 (0.0–0.0)	0.01	–0.17 (–0.38, –0.03)
Unpaid leave	0.0 (0.2)	0.0 (0.0–0.0)	0.1 (1.2)	0.0 (0.0–0.0)	0.09	–0.13 (–0.30, –0.00)
Total days	**0.9 (3.6)**	**0.0 (0.0–0.0)**	**1.0 (2.6)**	**0.0 (0.0–0.0)**	**0.08**	**–0.07 (–0.67, 0.55)**

* *p-values from Mann–Whitney test*
† *95% CIs for the mean difference calculated by the bootstrap percentile method*

partners. Family and friends appeared to take more special leave with pay in the control group and the difference was statistically significant ($p = 0.01$), but given the small amount of time involved this difference is of little practical importance.

Sensitivity analysis

The results of between-group comparisons of follow-up contacts with the NHS were fairly robust; that is, the resource use data that were collected for both the control and intervention groups were stochastic in nature, and the statistical analysis showed no differences in NHS resource use between the two groups. The main source of uncertainty relates to the SW visits, though the data collected for length and number of visits were of very high quality, and the sample was sufficiently large to produce relatively narrow CIs for costs. The only scope for cost reduction in the CMSW service would be an increase in technical efficiency, which is discussed below.

In the main analysis, a discount rate of 5% was used to calculate the equivalent annual cost of training and education. The convention is to use a rate of 5% and to perform a sensitivity analysis that includes 0% and 3%.[115] *Table 80* shows the effects that the discount rates of 0% and 3% have on the mean cost per visit, mean cost per woman, and total cost of the service. At most, the mean cost per visit could be reduced by £0.25 by using a discount rate of 0%. The mean cost per woman could be reduced by £1.58 at most.

The CMSW service was designed to allow women ten visits over a 28-day period with a recommended maximum visit time of 180 minutes, though SWs could use their discretion. The median visit time was 150 minutes, and lower and upper quartiles were 120 minutes and 180 minutes, respectively. Sensitivity analysis was used to estimate how costs would change if the visit time was limited to a maximum of 120 minutes.

In the main cost analysis, to calculate the costs of education and training per visit, it was assumed that a whole time equivalent SW would make 2.5 visits per day, on average. If this figure was increased to three visits per day due to shorter maximum visit times, this would also have an impact on the cost of education and training. Implemented together, these changes would have the effect of lowering the cost of a visit by £4.29 (from £27.74 to £23.45) and the cost per woman by £27.73 (from £179.34 to £151.61) (*Table 80*).

Resource use and costs at 6 months

Tables 81 and *82* show resource use and costs for NHS services at 6 months. As with data at 6 weeks there were no statistically significant cost differences between the two groups for any NHS services for which data were collected, with the exception of the CMSW service.

At 6 months the cost difference between the groups was still statistically significant (£179; 95% CI, £80, £272), though the 95% CI had widened. The mean total cost was £815 (SD, £565) for the intervention group and £639 (SD, £500) for the control group.

Tables 83 and *84* show social service contacts and costs at 6 months, respectively, and *Tables 85* and *86* show personal costs at 6 months. There were no statistically significant differences between the groups in terms of social services or personal costs.

Summary

Tables 87 and *88* show summary cost results. At 6 weeks and at 6 months the intervention group experienced higher NHS costs than the control group (£179 difference) and the differences between the two groups was statistically significant ($p = 0.001$). There were no statistically

TABLE 80 *Results of sensitivity analysis*

	Mean cost per visit (£)	Median cost per visit (£)	Total costs (£)	Mean cost per woman (£)
Trial discount rate: 5%	**27.74**	**28.16**	**48,960**	**179.34**
Discount rate: 3%	27.64	28.06	48,784	178.70
Discount rate: 0%	27.49	27.92	48,528	177.76
Patient-specific length of visit (maximum 180 minutes)	**27.74**	**28.16**	**48,960**	**179.34**
2 hours maximum **and** three visits minimum per day per SW	23.45	22.20	41,389	151.61

significant differences between the two groups for social services or personal costs.

The explanation for the conflicting results between the *p*-values (obtained from the Mann–Whitney test) and CIs for summary social services costs is that different statistics were calculated assuming two different hypotheses were to be true (equality of distributions versus equality of means). The lower and upper limits of the CIs are very close to zero, indicating the results are consistent with a very small effect on social services costs, which may be of little practical or clinical importance.

The results of this trial suggest that the incremental cost of introducing a CMSW service would comprise mainly the costs of setting-up and running the service. There was no evidence that the women receiving the new CMSW service used fewer or more NHS services than those who received standard postnatal care from a midwife. There was little evidence to suggest that different conclusions would result from studies undertaken elsewhere. Incremental costs could vary between providers according to local unit costs and on whether the programme was targeted according to need.

TABLE 81 *NHS resource use at 6 months, per woman*

Resource	Intervention (*n* = 252)		Control (*n* = 219)		*p*-value*	Mean difference (95% CI)†
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)		
SW visits	5.8 (3.2)	6.0 (3.0–9.0)				
Community midwife visits	8.0 (1.9)	8.0 (7.0–9.0)	8.0 (1.8)	8.0 (7.0–9.0)	0.62	–0.02 (–0.36, 0.33)
Health visitor visits	2.4 (1.1)	2.0 (2.0–3.0)	2.4 (1.3)	2.0 (2.0–3.0)	0.93	–0.02 (–0.24, 0.21)
Child health clinic visits	1.0 (0.0)	1.0 (1.0–1.0)	1.0 (0.0)	1.0 (1.0–1.0)	1.0	0.00 (0.001, 0.001)
GP contacts for baby	4.5 (3.1)	4.0 (3.0–5.8)	4.2 (3.0)	4.0 (2.0–5.0)	0.15	0.26 (–0.27, 0.85)
GP contacts for self	2.5 (2.4)	2.0 (1.0–3.0)	2.7 (2.7)	2.0 (1.0–3.0)	0.23	–0.19 (–0.66, 0.26)
Prescriptions for baby	2.1 (1.6)	2.0 (1.0–3.0)	2.1 (1.7)	2.0 (1.0–3.0)	0.77	–0.02 (–0.31, 0.27)
Prescriptions for self	1.3 (1.6)	1.0 (0.0–2.0)	1.4 (1.6)	1.0 (0.0–2.0)	0.23	–0.14 (–0.41, 0.14)
Hospital contacts baby	1.0 (2.3)	0.0 (0.0–1.0)	0.9 (1.7)	0.0 (0.0–1.0)	0.58	0.08 (–0.31, 0.45)
Hospital contacts self	0.4 (1.1)	0.0 (0.0–0.0)	0.4 (1.1)	0.0 (0.0–0.0)	0.49	0.06 (–0.14, 0.23)
Secondary mental health contacts	0.2 (1.5)	0.0 (0.0–0.0)	0.3 (1.5)	0.0 (0.0–0.0)	0.77	–0.03 (–0.29, 0.24)

* *p-values from Mann–Whitney test*

† *95% CIs for the mean difference calculated by the bootstrap percentile method*

Notes:

1. Hospital contacts include inpatient stays, day-patient attendance, outpatient attendance and A&E attendance

2. Secondary mental health contacts: inpatient, outpatient, community psychiatric nurse, occupational therapist and consultant contacts

3. Mean number of SW visits will differ because of different sample sizes

TABLE 82 *NHS costs at 6 months, per woman*

Resource	Intervention (*n* = 252)		Control (*n* = 219)		*p*-value*	Mean difference (£) (95% CI)†
	Mean (SD) (£)	Median (quartiles) (£)	Mean (SD) (£)	Median (quartiles) (£)		
SW visits	160.2 (97.6)	162.6 (91.9–234.0)				
Community midwife visits	192.7 (53.0)	188.2 (156.7–221.5)	190.7 (49.2)	224.4 (155.0–224.4)	0.91	1.99 (–7.60, 11.30)
Health visitor visits	104.9 (49.1)	89.0 (89.0–133.4)	1060.0 (56.2)	89.0 (89.0–133.4)	0.93	–1.46 (–11.38, 7.87)
Child health clinic visits	7.7 (0.0)	7.7 (7.7–7.7.)	7.7 (0.0)	7.7 (7.7–7.7)	1.00	0.001 (0.001, 0.001)
GP contacts for baby	68.4 (45.0)	58.7 (39.0–89.1)	64.4 (44.8)	52.0 (30.0–90.0)	0.20	3.77 (–4.45, 11.79)
GP contacts for self	39.8 (37.9)	30.0 (10.0–57.1)	43.8 (43.0)	32.7 (19.3–54.5)	0.29	–4.09 (–11.03, 3.09)
Prescriptions for baby	4.3 (6.0)	2.4 (0.5–5.6)	5.2 (9.8)	2.2 (0.5–5.9)	0.98	–0.94 (–2.50, 0.42)
Prescriptions for self	5.9 (14.5)	0.8 (0.0–5.0)	9.4 (22.0)	1.5 (0.0–7.5)	0.06	–3.70 (–7.45, –0.20)
Hospital contacts baby	170.5 (485.1)	0.0 (0.0–89.0)	140.0 (367.8)	0.0 (0.0–89.0)	0.73	31.76 (–45.86, 110.63)
Hospital contacts self	54.4 (157.5)	0.0 (0.0–0.0)	59.3 (231.5)	0.0 (0.0–0.0)	0.52	–4.66 (–46.60, 29.75)
Secondary mental health contacts	6.5 (54.0)	0.0 (0.0–0.0)	11.9 (69.3)	0.0 (0.0–0.0)	0.41	–5.35 (–16.51, 5.21)
Total	**815.2 (564.7)**	**672.3 (519.5–868.3)**	**638.9 (500.4)**	**471.7 (367.4–669.1)**	**0.001**	**178.61 (79.60, 272.40)**

* *p-values from Mann–Whitney test*
† *95% CIs for the mean difference calculated by the bootstrap percentile method*

Notes:
1. Hospital contacts include inpatient stays, day-patient attendance, outpatient attendance and A&E attendance
2. Secondary mental health contacts: inpatient, outpatient, community psychiatric nurse, occupational therapist and consultant contacts

TABLE 83 *Social services resource use at 6 months, per woman*

Resource	Intervention (*n* = 252)		Control (*n* = 219)		*p*-value*	Mean difference (95% CI)†
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)		
Social worker contacts	0.2 (1.5)	0.0 (0.0–0.0)	0.0 (0.2)	0.0 (0.0–0.0)	0.16	0.19 (0.03, 0.41)

* *p-value from Mann–Whitney test*
† *95% CI for the mean difference calculated by the bootstrap percentile method*

TABLE 84 *Social services costs at 6 months, per woman*

Resource	Intervention (*n* = 252)		Control (*n* = 219)		*p*-value*	Mean difference (£) (95% CI)†
	Mean (SD) (£)	Median (quartiles) (£)	Mean (SD) (£)	Median (quartiles) (£)		
Social worker contacts	4.5 (31.8)	0.0 (0.0–0.0)	0.6 (4.4)	0.0 (0.0–0.0)	0.16	3.87 (0.47, 8.53)

* *p-value from Mann–Whitney test*
† *95% CI for the mean difference calculated by the bootstrap percentile method*

TABLE 85 *Personal resource use at 6 months, per woman*

Resource	Intervention (*n* = 252)		Control (*n* = 219)		*p*-value*	Mean difference (95% CI)†
	Mean (SD)	Median (quartiles)	Mean (SD)	Median (quartiles)		
Medicines purchased for baby	1.8 (1.4)	2.0 (1.0–3.0)	1.7 (1.4)	2.0 (1.0–3.0)	0.42	0.10 (–0.16, 0.34)
Medicines purchased for self	0.3 (0.7)	0.0 (0.0–0.0)	0.4 (0.7)	0.0 (0.0–1.0)	0.46	–0.04 (–0.17, 0.10)
Tins of formula milk (900 g)	8.7 (4.3)	12.0 (6.0–12.0)	8.6 (4.3)	12.0 (6.0–12.0)	0.90	0.01 (–0.80, 0.77)

* *p-values from Mann–Whitney test*
† *95% CIs for the mean difference calculated by the bootstrap percentile method*

TABLE 86 *Personal costs at 6 months per woman*

Resource	Intervention (*n* = 252)		Control (*n* = 219)		*p*-value*	Mean difference (£) (95% CI)†
	Mean (SD) (£)	Median (quartiles) (£)	Mean (SD) (£)	Median (quartiles) (£)		
Medicines purchased for baby	4.7 (4.8)	4.2 (1.6–6.6)	4.2 (3.7)	3.4 (1.5–6.6)	0.40	0.50 (–0.32, 1.28)
Medicines purchased for self	0.9 (2.5)	0.0 (0.0–0.0)	1.3 (2.8)	0.0 (0.0–1.0)	0.32	–0.33 (–0.83, 0.18)
Tins of formula milk (900 g)	50.2 (24.8)	70.0 (34.8–69.6)	50.1 (24.8)	69.7 (34.8–69.7)	0.90	–0.01 (–4.36, 4.38)

* *p-values from Mann–Whitney test*
† *95% CIs for the mean difference calculated by the bootstrap percentile method*

TABLE 87 *Summary costs at 6 weeks, per woman*

Resource	Intervention (*n* = 282)		Control (*n* = 269)		*p*-value*	Mean difference (£) (95% CI)†
	Mean (SD) (£)	Median (quartiles) (£)	Mean (SD) (£)	Median (quartiles) (£)		
NHS costs	635 (326)	579 (462–694)	456 (291)	387 (321–471)	0.001	179 (129, 232)
Social services costs	1 (11)	0 (0–0)	1 (8)	0 (0–0)	0.45	0.6 (–1.0, 2.3)
Personal costs	24 (16)	35 (4–37)	25 (15)	35 (6–37)	0.74	–1.09 (–3.5, 1.4)

* p-*values from Mann–Whitney test*
† *95% CIs for the mean difference calculated by the bootstrap percentile method*

TABLE 88 *Summary costs at 6 months, per woman*

Resource	Intervention (*n* = 252)		Control (*n* = 219)		*p*-value*	Mean difference (£) (95% CI)†
	Mean (SD) (£)	Median (quartiles) (£)	Mean (SD) (£)	Median (quartiles) (£)		
NHS costs	815 (565)	672 (519–868)	639 (500)	472 (367–669)	0.001	179 (80, 272)
Social services costs	5 (32)	0 (0–0)	0.6 (4.4)	0 (0–0)	0.16	3.8 (0.5, 8.5)
Personal costs	56 (26)	70 (39–75)	56 (25)	70 (39–74)	0.86	0.45 (–4.14, 5.05)

* p-*values from Mann–Whitney test*
† *95% CIs for the mean difference calculated by the bootstrap percentile method*

Chapter 4
Discussion

Methodology

Primary outcomes

The trial was established to identify positive outcomes for the women in the intervention group. Both a generic and a condition-specific outcome measure were used, together with a measure of social support. However, the data indicate that, at 6 weeks, there were no improvements in self-perceived health status for women in the intervention group for any of the measures used. Moreover, there was an indication that some domains of health status in the intervention group may have worsened in relation to the control group. There are a number of possible interpretations of these findings.

Assignment

Reviewing the factors affecting internal validity, the concealed randomisation process appears to have been effective in distributing known characteristics evenly between the two groups. While it was not possible to blind the women to group allocation, there was no evidence of any systematic bias at any stage of the follow-up process or in the women's responses to the questions. Data collection for the validation of use of services was blinded to group allocation.

Sample size and recruitment

The achieved sample size had 80% power to detect the pre-determined, least clinically important difference between the two groups. It was estimated before the trial began, that 3200 women would give birth, including 400 who did not live in the research area. It was estimated that at most, 30.5% of women would be excluded, due to stillbirth (1%), birthweight less than 2.5 kg (7%), admission to a special care baby unit (9%) and problems with the English language (13%). A consent to participate rate was estimated as 75%. The lower than expected take-up (37%) could be explained, in part, by not all women receiving information about the trial antenatally.

The aim of providing women with information about the trial in the antenatal period was to allow them time to consider participating in the trial. Antenatal randomisation was not appropriate. Before the trial commenced, great efforts were made to inform midwives of the trial aims to gain their full support for the trial and to explain their role in providing research information leaflets to pregnant women. This was supplemented by regular feedback and consultation with the midwives and their managers. Support was not universal, however, and there was resistance to the research from some midwives; it appeared that some were 'gate-keeping' women's access to information. While some midwives warmed to the trial as it progressed, others maintained considerable reservations throughout. The provision of antenatal information was therefore affected by those midwives who did not distribute the research information leaflet as requested.

> "Thank you for my SW. I really hope funding is approved to make this a regular event after each baby. Friends I've talked to having babies said they would've taken part in the survey if they'd been given advance notice of the scheme and not just told about it the day of giving birth. Perhaps it could be mentioned at the antenatal clinics from 36 weeks? Please thank X for her time, care and patience. I have fully breastfed for 6 months now and she deserves much of the credit for this success; a happy baby and a happy me! THANK YOU" (157).

For the midwives, taking time to discuss the research with women was an additional, unresourced responsibility that was not a priority in relation to their clinical work. Midwives' reluctance to discuss participation in an RCT have previously been reported.[127] Although the detailed exploration of midwives' concerns was outside the remit of the trial, a survey of healthcare professionals' views on the CMSW service revealed that midwives perceived a threat of erosion of their role. These factors could have contributed to the reservations and resistance of some midwives, and these issues require further exploration.

Recruitment was monitored weekly throughout the trial and it became evident that recruitment was slower than planned. To maximise the provision of information to women who would be having a baby in the recruitment interval, a mail-shot system using the maternity unit's database (Protos) was used, leaflets were provided at

parent education sessions and advertisements were posted in GP surgeries. Recruitment also began at weekends and public holidays.

The reasons given by 201/316 women (64%) for not participating in the trial was mainly the availability of plenty of support, or that they would be staying with their mother, or would have a partner at home. Posting research information leaflets to women's home addresses from the start of the trial, instead of relying on the midwives, may have ensured women's access to the information before their baby was born and before their arrangements had been made for home support. Some women (24/316; 7%) wanted to maintain their privacy. This may have been a feature for other women who either declined to take part or proceeded to decline visits once they had been recruited.

> "I really found the support worker a great help and comfort. I was quite worried before she came that she was sent to judge me on how I was coping with my young baby. However, my mind was soon put to rest. It was just so nice to have that extra help with anything I wanted doing and also someone who gave you some really helpful tips with all the best intentions in the world. The service provided was a great help and should be made available to anyone who wants it" (134).

Despite approval for the trial from the Research Ethics Committee, the Local Medical Committee, and support from the academic Department of General Practice, one GP practice also opposed the trial and prohibited recruitment of women registered there for at least 50% of the trial recruitment phase. Until this was resolved, this also contributed to a loss of potential recruits in the order of 5%.

While the trial had originally been planned to recruit on weekdays only, very early in the course of the trial, recruitment also commenced during the evenings, at weekends and on public holidays. This comprehensive approach resulted in the inclusion of a number of women eligible for recruitment who would otherwise have been missed. A small number of women were also recruited following a home birth or early transfer home.

Intervention

The intervention was very clearly defined and closely monitored and delivered within the first 28 days within pre-set parameters. It would be possible to completely reproduce the service including SW recruitment and selection and the detail of the training programme. Acceptance of the intervention was greater than 90% with most women having six or seven SW visits. However, 38 women (12%) had no SW visits, and while it was difficult to determine exact reasons, the feedback from the SW focus group suggested that several factors were involved: some women were able to cope better at home than they had anticipated; others were influenced by their partners suggesting that they could manage without an outsider's help; others by a minority of midwives suggesting that they could cope without an SW. Other events such as family bereavement meant that it was inappropriate for the SW to visit.

Women were overwhelmingly positive about the intervention.

> "I think everybody should have the opportunity to have a support worker – I was able to cope much better during the first few weeks, because of the help I had – I don't think anyone can realise how much there is to do with their first baby and carry on with everything else as well. Thank you to X. I hope SWs are still available when I have my second child!!" (215).

From the whole range of help available at home, the women rated the SWs as the **most** supportive. They were highly satisfied with the CMSW service; levels of satisfaction at 6 weeks exceeded marginally those reported for midwives and by 15% those reported for health visitors. The detailed feedback from the women indicated an appreciation of all elements within the role. It fulfilled a range of needs for the women who participated.

> "I thought that the CMSW scheme was excellent. It helped me so much and gave me so much confidence in caring for my baby. Everything about it was perfect from bathing and dressing my baby, doing bits of housework for me, preparing a sandwich and making me a drink. And just having someone call everyday who really seemed to care and you could talk to. I am sure if I didn't have this support I would have found it difficult to cope at first. I am 100% sure the service must help people not get depressed. I have got arthritis and also don't have any family or friends near to help so I found it brilliant. I just wish it could have lasted longer even if I had to pay a bit towards it. Since my SW stopped coming, my husband has found it very hard to fit the housework in and I find this has got me down a bit as my grandmother died recently, so he has had to sort everything out so our house has got neglected and everywhere needs doing. I hope you are successful and this scheme continues because it is invaluable. Even the midwives coming every day don't match up to this service. Thank you so much and I am so grateful I was selected" (158).

Although it was intended that the resource folders carried by the SWs would reinforce health education messages, including the promotion of a safe environment, very little time was spent using them and it was not possible to assess any direct benefit from the folder.

> "Found the help, advice from community midwifery SW very helpful – in the giving of advice in form of leaflets, books on breastfeeding, the CMSW who visited me was a very friendly, supportive person, who at the end of the 10 days, felt more like a friend than a stranger. Hope the CMSW scheme is continued as it provides an excellent service" (503).

When women were asked in an open question about the activities they had been able to do because the SW was visiting, they most often reported activities to help them rest and relax (28%) and having time for their own personal care (15%), such as having a bath or shower.

> "I would just like to say the SW who came to help me was fantastic. I had twins by Caesarean so I couldn't move around too good, she sent me off to bed and when I'd get up the house would be straight, ironing done, babies bathed and my 3 year old amused. X was brilliant! I think the SW idea is good and hope you can carry it on" (205).

Only four women indicated a restriction in activity in going out or sleeping because the SW was visiting.

A small number of women even volunteered a willingness to pay for such a service. In light of the results of this trial, a willingness to pay study could be considered as a follow-up, by placing a financial value on the intangible benefits of the service.[119]

> "The reason things seem negative at the moment is because S had a really bad attack last week generally, everything is OK. The CMSW is an excellent concept and should be available on request. It could be funded by a sliding scale of payment in relation to the mothers' ability to pay and continued until the mother feels well and confident enough to 'go it alone'. I thank you for the use of the service and especially X, who was a great service of help and comfort in those early days – her smile could cheer me up at any time" (211).

Many women commented that they would have preferred the intervention to have lasted more than 28 days; the most frequently mentioned time was 6 weeks. This would not have been realistic given the support mechanism and management structure designed for working with the midwives who have responsibility for 28 days postnatally. However, a different management infrastructure, such as the primary healthcare team, could facilitate a 6-week service.

Many of the health visitors and midwives suggested on their questionnaires that the intervention should have lasted for at least 6 weeks, and a 3-month duration of postnatal visiting was suggested by some women. A longer duration of intervention or more intensive visiting programme may have had more immediate health benefits for women. Antenatal contact with an SW from late pregnancy may facilitate the establishment of a supportive relationship that could continue postnatally. The prior knowledge of the availability of an SW could allow the family to better plan their availability for the new mother, for example when her partner or her own mother might take time off work. The effect of all these features could be evaluated separately or combined in one trial.

Sources of bias

Possible sources of bias include the GPs' and health visitors' knowledge that women were participating in the trial and their group allocation. As information was available in the trial on women's EPDS scores at 6 weeks, the health visitors requested feedback to ensure that they were not unaware of a woman's risk. The notification of the high-risk EPDS scores may have affected healthcare input by GPs and health visitors between 6 weeks and 6 months. In a trial like this, it might have been more appropriate to inform health visitors and GPs only of positive scores on item 10 (the thought of self-harm) and not the overall score.

Another possible source of bias might have been introduced by the difference in follow-up response rates, which were higher for the intervention group at 6 weeks (by 4.5%) and at 6 months (by 8.9%).

External validity

Among the 1669 women who met the eligibility criteria and were invited to participate in the trial, 623 (37%) consented to take part. Among those who consented, the loss to follow-up was low, with only a 12% non-response to the 6-week questionnaire and a 21% non-response to the 6-month questionnaire. There was evidence that women who had more than one child and the mothers of recent twins were less likely to respond, suggesting that lack of available time prevented women from returning their questionnaires. There were 38/623 women (6%) who could not be contacted by telephone and a further 26/623 (4%) who were known to have moved house at

6 months. Health visitors, the Community Trust child health records department, and the health visitor for the homeless provided some forwarding addresses. Some women who were reminded by phone thought they were not included in the trial as they had not been offered SW visits. Others were not happy about their allocation to the control group and both of these factors may have accounted for the lower response rate in the control group.

> "I think if a CMSW had been available to me, provided I paid rather than the hit or miss system you have with the envelopes. I would rather have found the money for it at some point. I think you could change the way you award them, to everyone having access to it but some may have to pay and some may get it free due to their circumstances. I think that would have been better for me" (21).

Outcome measurement

It is possible that the generic tool SF-36 was inappropriate for the purpose of measuring outcomes in this trial, being too insensitive to distinguish outcomes between the two groups. Ceiling effects for some domains, particularly RLE and RLP, meant that for some women there was no potential for measuring improvement between 6 weeks and 6 months. At the time of planning the trial, no tools were identified that had been used to evaluate women's experiences of motherhood. There was insufficient time to develop and validate such a tool for the purpose of the trial. Moreover, the outcomes that new mothers themselves value need to be established. No other tool was available at the time which could confer advantages over the condition-specific EPDS to assess risk of PND. The DUFSS tool was originally designed in North Carolina to measure social support in a general primary care setting and was validated with mainly white, married women aged under 45 years. The use of the tool in a postnatal group of women has not been reported but no other more appropriate tools were identified.

Two summary measures of the SF-36 were developed while the trial was in progress, the Mental Component Scale and Physical Component Scale. Reporting all the dimensions presents a fuller picture of the women's quality of life. An analysis of the outcomes of both scales at 6 weeks showed a statistically significant difference in the Physical Component Scale ($p = 0.006$) and a non-significant difference in the Mental Component Scale between the intervention and control group, with the control group having the higher (better) scores. The physical scale places greater weight on the physical functioning, RLP, and bodily pain dimensions of the SF-36, which also showed evidence of a difference at individual dimension level. The mental scale places greater weight on the mental health, RLE and vitality dimensions of the SF-36, which showed no significant difference. The summary measures seem to broadly reflect the results of the analysis for the separate individual dimensions.

Although the women may have experienced a positive effect while the intervention was still in progress, the 6-week follow-up assessment may have occurred too long after the visits ceased to detect any positive outcomes. This 6-week time-point was used because the EPDS had been validated for use at this time, and also for comparability with other trials. Alternatively, positive effects of the intervention may have become evident beyond 6 months as health benefits accrued.

Interpretation of the outcomes

The model tested in this trial emphasised emotional and instrumental support offered postnatally. This differed from Oakley's trial[50] where midwives provided support that offered a minimum package of listening visits. The needs of mothers for support are clearly different when they are adapting to life with a new baby than when they are anticipating the labour and birth. The outcome measures used in this postnatal trial were well validated tools used in previous health services research and were different to those used in other trials of social support and maternity, which mainly focused on the birth experience.

Although women expect that the early days with a new baby will be tiring, recent qualitative research suggests that some women may not wish to ask for help and may not wish to be seen to be exploiting the goodwill of other women[128] and therefore may not derive benefit from any additional support offered.

Women who had been visited and supported by both the community midwife and SW during the first month may have experienced a withdrawal effect when the SW intervention ceased.

> "I feel that all new mothers or new mothers with two children under 5 should receive help with such things as shopping, housework, and be given more information on child and illness. My worst time was after a month as my midwife and CMSW stopped coming all at the same time and I felt lost and afraid of doing the wrong thing. They should be more available or advertised more" (163).

Another trial that offered an intervention of a stroke family care worker also found no significant difference in physical outcomes in patients or carers between intervention and control group. Patients in the intervention group tended to be more helpless and possibly more depressed.[129] The authors postulate that the provision of support induced a passive response instead of improving the patients' coping skills. A similar process could have operated in the CMSW trial, whereby women in the control group mobilised all their available support, which continued to operate at 6 weeks. For the women in the intervention group, the presence of the SW may have delayed or disrupted this mobilisation of personal support and coping mechanisms so that at 6 weeks they were coping less well than the women in the control group.

The perception of greater support from the partners of women in the intervention group in this trial echoes the findings from Oakley and co-workers.[50,51] The Oakley RCT of research midwife-provided social support in pregnancy found an enduring effect of support from partners in the intervention group who were significantly more likely to help in childcare and with housework, shopping and cooking.

Breastfeeding

Contrary to earlier findings[72] that additional visits by health workers have a positive impact on duration of breastfeeding and suggestions that community-based support is beneficial, there was no statistically reliable evidence of a difference in breastfeeding duration in this trial. A recently published survey of 906 women[130] found that regular childcare support from a female relative was a factor associated with early cessation of breastfeeding. The level of availability of support from a female relative is likely to exceed that offered by an NHS worker. The effective components of female support in promoting the continuation of breastfeeding should be identified in future research.

A 1-week difference in mean duration of breastfeeding in favour of the intervention group was observed at both 6 weeks' and 6 months' follow-up. The difference was also evident from the health visitor data at 3 months. Although no health gain has been documented for a single week improvement, from a public health perspective, were this to be achieved for a whole population it is possible that there would be some worthwhile benefits.

> "CMSW. Found the support given by this person invaluable and I think I would not have breastfed as long as I did had she not been there" (185).

Subgroup analysis

To identify where targeting could yield the greatest positive effect, based on the measures used in this trial, analysis of subgroups of women with different risk factors was performed. This analysis also failed to find any evidence of a beneficial effect from the intervention in the subgroups. It may not be possible to compensate for levels of disadvantage with such a brief, dilute form of social support.

The SF-36 questions about role limitation physical indicated that 43% of women in the intervention group said they had accomplished less than they would have liked, compared with 32% in the control group. The evidence that RLP was consistently worse in the intervention group might suggest that the SW role of facilitating rest over-emphasised a restriction in physical activity.

Use of services

There was a consistently greater use of A&E services in the control group for both mother and baby at both 6 weeks and 6 months, but this did not achieve statistical significance. The wider public health importance of this outcome could not be explored in the trial. Similarly, there was a consistent trend for women in the control group to make greater use of secondary mental health services at both 6 weeks and 6 months, but this was statistically significant only for the community mental health nurse at 6 weeks. Over the longer term, the public health importance attached to these mental health outcomes on a population basis would relate to child development and associated costs to the NHS. For the use of GP and hospital services there was no clear pattern of difference in use of services.

Validation of women's reports of service use

The trial assumed that all GP contacts were accurately entered in the women's records. The over-reporting of GP contacts in the order of 0.5 contacts by women who returned a questionnaire at 6 weeks compared with a sample of records examined, would appear to be of little economic importance. There was no evidence of any bias in reporting the use of GP services by group. At 6 months the under-reporting in the order of 0.2 contact by the women who returned a questionnaire would also appear to be of little economic importance.

The difference could be attributable to a recall problem or it could be that the women non-responders at 6 months had more contact with the GP.

Validation of women's reported use of hospital services was only possible in the recruiting hospital where the delivery had taken place. It was not possible to accurately validate use of services in all the other six hospitals that women may have accessed in the area. However, as there appeared to be no difference between groups, the absence of data related to women's use of other hospitals' services appears to be of little importance. These findings would suggest that such a validation exercise would not be required in future similar research.

Cost outcomes

NHS cost differences at 6 weeks

The mean NHS cost difference between the two groups at six weeks was £180. There were no differences in resource use between the two groups at 6 weeks or at 6 months for any NHS services other than the SW visits. The CMSW service therefore was responsible for the cost differences between the intervention and control groups.

Follow-up questionnaire response rates were higher for the intervention group at 6 weeks (by 4.5%) and 6 months (by 8.9%). This suggests that bias could be a problem if the intervention group non-responders differed from control group non-responders in their use of services. From analysis of 6-week data there was no evidence that this was the case.

There was some evidence from comparisons of self-reported data and GP records data, that women over-reported the number of GP contacts for the baby and under-reported contacts for themselves. However, since there were no systematic differences between the groups in under- or over-reporting, the effect on costs would be to increase or decrease costs by the same proportion for each group.

The use of local cost estimates might produce different results to this trial, which used nationally published estimates as a substitute for local costs. The likely cost differences would arise through the impact on costs of the CMSW programme rather than through any other NHS services, as there were no statistically significant differences in use of other NHS services between the two groups.

Costs of the CMSW service

The analysis showed that 84% of the costs of a SW visit comprised staff time costs. If commissioners of health services want to introduce this type of programme at the lowest possible cost then staff grade, length of visit, and travel and administration time will come under most scrutiny because they have the biggest impact on costs. Travel time could be reduced if all SWs travelled by car and not public transport to women's homes. However, the reduction in travel time costs might be more than offset by an increase in travel expenses after the introduction of car use for all SWs. There was little room for flexibility with regard to staff grade as SWs were appointed on NHS grade B of the clinical grading scale.

Sensitivity analysis showed that by reducing the maximum visit time to 120 minutes and increasing SW visits to three per day would lower the cost per woman by £28 (from £180 to £152). However, there are concerns about the viability of this scenario as a realistic service option. Most of the time three visits per day would not be feasible for all SWs. Furthermore, the purpose of the SW was to spend time listening and to provide practical help. Imposing a maximum of 2 hours per visit might prevent the SW achieving these objectives.

As discounting was used only in the calculation of the education and training cost (which comprises 5% of the total cost of a visit), the impact of altering the discount rate to 0% and 3% would have little impact on the over all cost of an SW visit. If the programme was introduced elsewhere, the training programme developed in Sheffield could be used for training SWs elsewhere. This would have the effect of lowering the cost of education and training per SW visit. However, with costs of developing the package comprising only 20% of total education and training costs, again this would have little impact on the overall cost of a visit.

Cost summary

The results of this trial suggest that the incremental cost of introducing a CMSW service would comprise mainly the costs of setting-up

and running the service. There was no evidence that the women receiving the new CMSW service used fewer or more NHS services than those who received standard postnatal care from a midwife. There was little evidence to suggest that different conclusions would result from studies undertaken elsewhere. Incremental costs could vary between providers according to local unit costs and on whether the programme was targeted according to need.

Chapter 5
Conclusions

- Women valued and were highly satisfied with the CMSW service.
- There was no difference in health status between groups for the primary outcome, the SF-36 GHP domain at 6 weeks or 6 months postnatally.
- There was no improvement in self-perceived health status in the intervention group using the SF-36, EPDS, DUFSS or EQ-5D or in breastfeeding rates at 6 weeks or 6 months postnatally.
- There was little difference between groups in use of NHS services, and costs were similar in both groups for use of services at 6 weeks or 6 months postnatally.
- There was an additional cost to the intervention group for the CMSW service.

Recommendations for research

The needs of women from minority ethnic communities and those who do not speak English should be included in future work examining social support for pregnant women and new mothers.

Women's needs for social support antenatally and postnatally

We recommend further work to improve the understanding of women's need for social support antenatally and postnatally, and the process by which women mobilise and access personal support during pregnancy and the early postnatal months.

Development of appropriate outcome measures

Given the limitations of generic self-perceived health status measurements for use with women postnatally, we recommend the use of outcomes that new mothers identify and value, to be incorporated into tools to measure women's need for social support antenatally and postnatally.

Measurement of women's need for social support

We recommend work to quantify the variation in need for social support antenatally and postnatally to identify any high-risk groups who might gain the greatest potential benefit from additional support.

Breastfeeding support and mental health outcomes

The most effective components of professional and social support in facilitating the continuation of breastfeeding and promoting positive mental health outcomes have yet to be established. We recommend further work to establish these features and quantify the cost-effectiveness of additional support focusing on these outcomes.

The effectiveness of different models of social support

In view of the suggestion that a 10-day intervention may have been too dilute, and in light of the development of appropriate outcome measurements, a trial should be performed to establish the effectiveness of an intervention focusing on women's need for support, combining antenatal contact with an SW and a more sustained, intensive postnatal SW visiting programme.

Willingness to pay

Women's significant satisfaction with the CMSW service and the unprompted comments that there could be a financial payment for the service, suggest that an exercise assessing willingness to pay for such a postnatal SW service could now be performed.

Research and healthcare professionals

Further research is required to explore the reasons why some midwives and other health-care professionals feel unable to support the progress of health services research and to define processes that would facilitate their involvement.

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Appendix 1

Public health estimates

TABLE 89 *Public Health CDS-A1. Estimates of resident population: mid 1993*

Males and females	15–24 years	25–44 years	Total
	n (%)	*n* (%)	
England	6,397,706 (13)	14,310,952 (29)	48,532,705
Trent Regional Health Authority	638,060 (13)	1,380,328 (29)	4,765,555
Sheffield Health Authority	76,746 (14)	156,841 (29)	531,928

TABLE 90 *Public Health CDS-A1. Estimates of resident population: mid 1993*

Females	15–24 years	25–44 years	Total
	n (%)	*n* (%)	
England	3,111,375 (13)	7,070,552 (29)	24,750,972
Trent Regional Health Authority	308,278 (13)	677,888 (28)	2,413,771
Sheffield Health Authority	35,941 (13)	74,742 (28)	268,894

TABLE 91 *Public Health CDS-B1 and CDS-B2*

	General fertility rate: 1993	Total period fertility rate: 1993
England	62.5	1.76
Trent Regional Health Authority	61.7	1.76
Sheffield Health Authority	60.5	1.76

TABLE 92 *Public Health CDS-B4. Live births by maternal age: 1993*

	16–19 years	20–24 years	25–34 years	35–39 years	40+ years	Total
	n (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	
England	40,662 (6)	142,475 (22)	385,971 (61)	56,004 (9)	10,036 (2)	636,473
Trent Regional Health Authority	4519 (7)	15,121 (25)	35,959 (59)	4329 (7)	725 (1)	60,809
Sheffield Health Authority	448 (7)	1643 (25)	3947 (59)	547 (8)	92 (1)	6691

TABLE 93 *Public Health CDS-B5 and CDS-B6*

	% of live births in NHS hospitals: 1993	% of births in 1993 < 1500 g	% of births in 1993 < 2500 g
England	93.3	1.2	7.0
Trent Regional Health Authority	94.9	1.3	7.2
Sheffield Health Authority	97.6	1.4	7.7

TABLE 94 *Public Health CDS-C10. Mortality rates in infancy (per 1000 live births): 1993*

	Under 1 year
England	6.3
Trent Regional Health Authority	7.0
Sheffield Health Authority	9.0
South of Tyne	10.0

TABLE 95 *Public Health CDS-C8 and CDS-C9*

	Perinatal mortality rates (per 1000 live births): 1993	Postneonatal mortality rates (per 1000 live births): 1993
England	8.9	2.1
Trent Regional Health Authority	8.6	2.3
Sheffield Health Authority	9.7	2.8

TABLE 96 *Public Health CDS-B7 (Stillbirth rate per 1000 total births) and CDS-B9 (Stillbirths by maternal age: 1993)*

	Stillbirth rate						
	Per 1000 total births: 1993	16–19 years	20–24 years	25–34 years	35–39 years	40+ years	Total
		n (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	
England	5.7	295 (8)	816 (23)	1991 (55)	394 (11)	112 (3)	3621
Trent Regional Health Authority	5.3	30 (9)	78 (24)	176 (55)	28 (9)	9 (3)	322
Sheffield Health Authority	5.4	3 (8)	6 (17)	20 (56)	5 (14)	2 (6)	36

TABLE 97 *Public Health CDS-A3 and CDS-A4*

	Underprivileged area score		Index of local conditions	
	Score	Rank	Index	Rank
Trent Regional Health Authority	–5.69	6/8	–1.35	5/8
Sheffield Health Authority	15.02	17	9.27	21
East London and the City	61.93	1	28.20	1
Mid Surrey	–31.57	112	–21.43	109

Appendix 2

Computer-Assisted Standard Occupational Coding

TABLE 98

Major group		General nature of qualification, training and experience for occupations in the major group
1	Managers and administrators	A significant amount of knowledge and experience of the production processes, administrative procedures or service requirements associated with the efficient functioning of organisations and businesses.
2	Professional occupations	A degree or equivalent qualification, with some occupations requiring postgraduate qualifications and/or a formal period of experience-related training.
3	Associate professional and technical occupations	An associated high-level vocational qualification, often involving a substantial period of full-time training or further study. Some additional task-related training is usually provided through a formal period of induction.
4	Clerical and secretarial occupations	A good standard of general education. Certain occupations will require further additional vocational training to a well-defined standard (e.g. typing or shorthand).
5	Craft and related occupations	A substantial period of training, often provided by means of a work-based training programme.
6	Personal and protective service occupations	A good standard of general education. Certain occupations will require further additional vocational training, often provided by means of a work-based training programme.
7	Sales occupations	A general education and a programme of work-based training related to sales procedures. Some occupations require additional specific technical knowledge but are included in this major group because the primary task involves selling.
8	Plant and machine operatives	The knowledge and experience necessary to operate vehicles and other mobile and stationery machinery, to operate and monitor industrial plant and equipment, to assemble products from component parts according to strict rules and procedures and subject assembled parts to routine tests. Most occupations in this major group will specify a minimum standard of competence that must be attained for satisfactory performance of the associated tasks and will have an associated period of formal experience-related training.
9	Other occupations	The knowledge and experience necessary to perform mostly simple and routine tasks involving the use of hand-held tools and in some cases, requiring a degree of physical effort. Most occupations in the major group require no formal educational qualifications but will usually have an associated short period of formal experience-related training. All non-managerial agricultural occupations are also included in this major group, primarily because of the difficulty of distinguishing between those occupations that require only a limited knowledge of agricultural techniques, animal husbandry, etc. from those that require specific training and experience in these areas. These occupations are defined in a separate minor group.

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