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Abstract

Redesigning postnatal care: a randomised controlled trial of protocol-based midwifery-led care focused on individual women's physical and psychological health needs

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Objectives: To develop, implement and test the cost-effectiveness of redesigned postnatal care compared with current care on women's physical and psychological health.
Design: A cluster randomised controlled trial, with general practice as the unit of randomisation. Recruited women were followed up by postal questionnaire at 4 and 12 months postpartum and further data collected from midwife and general practice sources.
Setting: Thirty-six randomly selected general practice clusters in the West Midlands Health Region, UK.
Participants: All women expected to be resident within recruited practices for postnatal care were eligible for inclusion. Attached midwives recruited 1087 women in the intervention and 977 in the control practice clusters.
Interventions: The systematic identification and management of women's health problems, led by midwives with general practitioner contact only when required. Symptom checklists and the Edinburgh Postnatal Depression Scale (EPDS) were used at various times to maximise the identification of problems, and individual care and visit plans based on needs. Evidence-based guidelines were used to manage needs. Care was delivered over a longer period.
Main outcome measures: Women's health at 4 and 12 months, assessed by the Physical and Mental Component Scores (PCS and MCS) of the Short-Form 36 (SF-36) and the EPDS. Women's views about care, reported morbidity at 12 months, health service usage during the year, 'good practice' indicators and health professionals' views about care were secondary outcomes.
Results: At 4 and 12 months postpartum the mean MCS and EPDS scores were significantly better in the intervention group and the proportion of women with an EPDS score of 13+ (indicative of probable depression) was significantly lower relative to controls. The physical health score (PCS) did not differ. Health service usage was significantly less in the intervention group as well as reported psychological morbidity at 12 months. Women's views about care were either more positive or did not differ. Intervention midwives were more satisfied with redesigned care than control midwives were with standard care. Intervention care was cost-effective since outcomes were better and costs did not differ substantially.
Conclusions: The redesigned community postnatal care led by midwives and delivered over a longer period, resulted in an improvement in women's mental health at 4 months postpartum, which persisted at 12 months and at equivalent overall cost. It is suggested that further research should focus on: the identification of postnatal depression through screening; whether fewer adverse longer term effects might be demonstrated among the children of the women who had the intervention care relative to the controls; testing interventions to reduce physical morbidity, including studies to validate measures of physical health in postpartum women. Further research is also required to investigate appropriate postnatal care for ethnic minority groups.

Contents

List of abbreviations

CI	confidence interval
df	degrees of freedom
DVT	deep vein thrombosis
EPDS	Edinburgh Postnatal Depression Scale
GHQ-D	General Health Questionnaire
HV	health visitor
ICC	intra-class correlation
MCS	mental component score
MlWin	Multi-level Modelling for Windows
OR	odds ratio
PAM	profession allied to medicine
PCS	physical component score
PND	postnatal depression
QALY	quality-adjusted life-year
RCT	randomised controlled trial
RDC	research diagnostic criteria
SCAN ICD 10	Schedules for Clinical Assessment in Neuropsychiatry
SD	standard deviation
SE	standard error
SF-36	Short Form with 36 Items
SPSS	Statistical Package for Social Scientists

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Objectives

This study aimed to develop, implement and test the cost-effectiveness of a new model of postnatal care compared with current care on women's physical and psychological health.

Design

This was a cluster randomised controlled trial, with general practice as the unit of randomisation. Recruited women were followed up by postal questionnaire at 4 and 12 months postpartum and further data collected from midwife and general practice sources.

Setting and subjects

Thirty-six general practice clusters were randomly selected and recruited from all those in the West Midlands Health Region and 17 randomly allocated to intervention and 19 to control. All antenatal women within recruited practices were eligible for inclusion, unless not expected to be resident for postnatal care. Attached midwives recruited 1087 women in the intervention and 977 in the control practice clusters.

Intervention

The redesigned care focused on the identification and management of women's health problems and was midwifery-led with general practitioner (GP) contact only if required. Symptom checklists were used at the first home visit, 10 and 28 days, and the Edinburgh Postnatal Depression Scale (EPDS) at 28 days, to maximise identification of problems. This allowed care to be planned, with visit content and frequency flexibly tailored to need, rather than routine. Evidence-based guidelines, including clear GP referral criteria, were developed by the team to assist midwifery management of problems. Care duration was extended, with home visits to 28 days and discharge check at 10–12 weeks, the latter also undertaken by the midwife, who again administered the checklist and EPDS.

Main outcome measures

The primary outcomes were women's health at 4 and 12 months, assessed by the Physical and Mental Component Scores (PCS and MCS) of the Short-Form 36 (SF-36), and the EPDS. Secondary outcomes were women's views about care, reported morbidity at 12 months, health service usage during the year, 'good practice' indicators and health professionals' views about care.

Results

At 4 months postpartum the mean MCS and EPDS scores were significantly better in the intervention group and the proportion of women with an EPDS score of 13+ (indicative of probable depression) was lower relative to controls. Mean PCS did not differ. Assessments of women's views about care were either more positive in the intervention group or did not differ.

At 12 months, MCS and EPDS scores remained significantly better among intervention group women. Fewer women in the intervention group reported depression, fatigue and haemorrhoids as present at 12 months in the intervention group, with no differences for other reported morbidities. GP consultation rates during the year were reduced in the intervention group. Secondary care referrals to medical and surgical specialities did not differ. There were more secondary care contacts with professions allied to medicine (PAMs) in the intervention group but more PAM primary care contacts in the control group. Breastfeeding continuation, contraceptive advice and child immunisation did not differ. The intervention midwives were more satisfied with redesigned care than control midwives were with standard care. The GPs' and health visitors' views about postnatal care did not differ. Intervention care was cost-effective since outcomes were better and costs did not differ substantially.

Conclusions

The redesigned community postnatal care led by midwives and delivered over a longer period resulted in an improvement in women's mental health at 4 months postpartum, which persisted at

12 months and at equivalent overall cost. Subject to consideration and evaluation of local issues of implementation, the evidence would, in the authors' opinion, justify this form of care as standard for postnatal women.

Research recommendations

It is suggested that further research should focus on: the identification of postnatal depression through screening; whether fewer adverse longer term effects might be demonstrated among the children of the women who had the intervention care relative to the controls; testing interventions to reduce physical morbidity, including studies to validate measures of physical health in postpartum women. Further research is also required to investigate appropriate postnatal care for ethnic minority groups.

Chapter 1
Background

Introduction

Almost three-quarters of a million women give birth each year in the UK, all of whom are provided with postnatal care, which has substantial NHS resource implications. There has, however, been little evaluation of the benefits of this care and growing concern on the part of national bodies and health professionals about its content and appropriateness. At the same time, there has been an increasing number of studies showing substantial unmet health needs among women following childbirth.

Postpartum morbidity

Physical morbidity

Until about the past 10 years systematic research into morbidity after childbirth, except in relation to more immediate life-threatening problems, had been scarce. It was generally assumed that, by the 6–8-week postnatal check marking the discharge from maternity services, most women would be back to normal. The occurrence of substantial morbidity, largely unreported to relevant health professionals and persisting well beyond routine maternity care discharge, was documented by members of this study team 12 years ago[1] and has been confirmed in studies in other parts of the UK[2–4] and in other countries.[5,6] MacArthur and colleagues[1] found that 47% of 11,701 women reported experiencing one or more new health problems since the birth, which had lasted for more than 6 weeks, and many lasted much longer. Glazener and colleagues[3] found that 76% of the 1249 women sampled experienced at least one health problem at some time between leaving hospital and the eighth postpartum week. Most commonly reported morbidities are stress incontinence, perineal pain, breast problems, backache, haemorrhoids and constipation, with faecal incontinence, sexual difficulties and headaches less common but by no means rare.

A general finding of most of the studies is that many women have not reported their problems to health professionals either in the postnatal care period or later, nor have they been identified during the course of care provision. Studies of particular health problems, for example dyspareunia, perineal pain, urinary and faecal incontinence, are increasing in number and also show persistent and often undisclosed morbidity.[7–11] Some health problems, such as dyspareunia, perineal pain and incontinence, are more closely associated with the birth itself or with particular delivery factors, whereas others, such as backache or headaches, are probably linked more to the increased demands of child care, although even these may have some links with delivery.[3,5,12–14] In general, the type of longer term morbidity that is documented, although not life-threatening, can have a significant effect on aspects of the lives and well-being of women and their families.[2,6] Some of the conditions are difficult to treat such that they resolve completely, but may be alleviated, and information, discussion and reassurance from a knowledgeable individual could result in women feeling better about them.[15]

Psychological morbidity

Postnatal depression (PND), in contrast to most physical morbidity, has been well documented since the late 1960s. It was defined in the classical study by Pitt[16] as

> "what lies between the extremes of severe puerperal depression, with the risk of suicide and infanticide, and the trivial weepiness of the blues; something occurring frequently, much less dramatic than the former, yet decidedly more disabling then the latter" (p. 1325).

Studies suggest a prevalence range of PND of about 10–15%, depending on definitions and diagnostic criteria used.[17–20] The 'blues' occur in up to 80% of women but are transient and self-limiting, and puerperal psychosis is rare. There has been recent discussion about the extent to which PND can be distinguished from depression among non-puerperal women,[21,22] and studies of risk factors have generally found that it is linked more to social than to hormonal factors.[23] Many predictors have been proposed and studied, with wide disparity in findings, but the two more consistently noted areas of risk are a previous history of emotional disorder and reduced social support, such as having a poor relationship with

the partner[23] or social isolation, with a social network that does not mitigate against psychological ill-health.[24,25]

Like physical health problems, women do not always report PND and it is not always identified either by health professionals or even by close family members. Treatments that are available, both counselling and antidepressant therapy, have been shown to be effective in symptom resolution hence identification is important.[26–28] Depression has recently been found to be associated with physical postpartum health problems.[29] In addition to its effects on the mother, maternal mood disorder is important because numerous studies have indicated adverse effects on the child. Insecure infant attachment at age 18 months has been shown to be more common.[30] Deficits in cognitive development at age 4 years (especially among male children of socio-economically deprived mothers) have also been shown,[31,32] in addition to behavioural disturbances at age 5 years.[33]

Maternity services policy

Towards the end of the twentieth century, widespread concern in the UK about the provision of maternity services generally, prompted a fundamental review by the House of Commons Select Committee.[34] Postnatal care was highlighted as "poorly evaluated and researched, delivered in often inappropriate and fragmented ways and has a dissipated managerial focus which mitigates against efficient use of resources" (p. iv). The establishment of an Expert Maternity Group followed soon after this report, in order to examine policy and make recommendations on maternity care. This culminated in the report 'Changing childbirth',[35] which was formally adopted as a government policy. NHS service providers were asked to set targets, commensurate with the recommendations of the report, to be achieved by 1999.

The general aims of 'Changing childbirth' were to offer women more choice, greater continuity of care, more involvement in the management of their care and a midwifery-led service sensitive to women's individual needs and preferences. These aims applied to postnatal as well as to antenatal and intrapartum care. However, as the Select Committee had noted, the former had received much less attention, despite its importance. Specific recommendations in the 'Changing childbirth' report in relation to postnatal care were that research in this area of care should be broadened; that, in redesigning postnatal services, the need for continuity of care should be placed at the centre; and that attention be turned away from a medical model of care to a woman-centred approach. Both government reports also stressed the need for general practitioners (GPs) and midwives to work together in partnership, avoiding unnecessary duplication of work and competition between the professions.[36]

The Audit Commission was requested to undertake an external audit of the UK NHS maternity services, collecting data from samples of Trusts, GPs and recent mothers, and this was published in 1997. With respect to care after childbirth, the report noted that recovery and adjustment to parenthood were often hampered by the mothers' own health, that many women reported longer term health problems, some of which were associated with particular obstetric intervention, and that for these reasons care during the postnatal period must be properly planned.[37]

Community-based postnatal care

Responsibility in the UK for postnatal care after hospital discharge lies with the primary healthcare team. The increasing trend for shorter hospital stays makes it even more important that community-based care is effective in addressing women's needs. Research into the care given by midwives in this period, however, is very limited. Traditionally, postnatal care has been centred around routine measurements and observations of uterine involution, lochia, temperature, blood pressure and so on. Most postnatal care documentation available to midwives is still dominated by charts to record these measurements, with little space for any other information, and so is likely to encourage the perpetuation of these practices. Current guidance to midwives on postnatal practice is limited. The 'Midwife's code of practice'[38] stated only that the midwife should "care for and monitor the progress of the mother in the postnatal period and give all necessary advice to mother on infant care to enable her to ensure the optimum progress of the new-born infant". The duration of postnatal contact is stated in the 'Midwives' rules'[39] as "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 is requisite". This remains the guidance in the current edition of the 'Midwives' rules and codes of practice'.[40]

Daily midwife home visits to the 10th day were a requirement until 1986, when this was amended to allow selective visiting. In 1992, the UKCC Registrar issued a statement on selective visiting:

> "Each midwife is personally responsible and accountable for the exercise of professional judgement and determining appropriate practice in relation to mother and baby. This, naturally, includes judgements about the number of visits and any additional visits required in the postnatal period. The range of midwifery care, including timing of visits, should be discussed with the mother."[41]

The traditional daily visit pattern, however, still appears to be the norm. As part of the Audit Commission report, a survey of women's views of maternity care was conducted in a random sample of mothers who delivered throughout England and Wales in 1995,[4] and this showed that a traditional pattern of daily visits, or one that was only very slightly amended, still typically occurred. Among the 2406 women who responded (67% response rate), 62% said that they had been visited by the midwife every day (29%), or every day except one (32%), up to day 10 following birth. A further 29% received a visit every other day and only 10% had any other visit pattern. The last visit was made, for 45% of the women, by day 10, and by day 15 for another 34%. This pattern did vary between regions: the proportion who had their last midwife visit at day 10 ranged from 55% in south-east England to only 28% in north-west England.

An earlier survey of postnatal practice in several English health districts also found that selectivity in visiting was variable and that in many cases minimal change had occurred.[42] An in-depth study of what comprised the content of midwifery home visits in two of these districts found that midwives' views on what should be observed daily differed between the districts, especially with regard to checks of temperature, pulse, blood pressure and perineum. Some midwives were performing traditional observations on a daily basis even though they saw little value in this.[43]

Other small studies have found that midwives undertake a wide variety of tasks during their home visits which were often not matched to the mother's perceived needs,[44] and that physical examination of the mother is common and time consuming.[45] It has been suggested that the constraints of tradition and routine may be inhibiting midwives from giving care based on individual needs.[43] A study in Glasgow evaluated the effects of providing postnatal care that was individualised to the needs of women, and with an emphasis on continuity of care. The midwives were given a brief agenda for action, which consisted of reminding them to plan ongoing care with the woman at the home first visit and to ensure that she knew who would provide the next visit. Assessments of 106 women before and another 114 after the new care agenda was introduced found that even with this minimal plan, the midwives made significantly fewer visits (mean intervention visits = 5.7, control = 6.5) and there was a reduction in the proportion of women seeing several (more than three) midwives.[46] The non-randomised design of this study, however, limits the generalisability of the results.

The typical number and range of postnatal home visits that women have within current care are not well documented. Summary statistics on the numbers of postnatal home visits published by the Department of Health[47] show that the average rate per maternity for community postnatal face-to-face contacts was 8.1 in 1997–8 for England and Wales. This includes all contacts with midwives, both domiciliary and in clinics (although the latter are rare), in addition to health visitor contacts. A calculation of midwife domiciliary visits only was 6.6 per maternity. A breakdown by region is also given, which allows a similar calculation to be made for the West Midlands Region, showing 6.9 midwife postnatal home visits per maternity in 1997–8.

Prior to the 6-week maternity discharge, GPs can also make home visits to postnatal women, although not all do this routinely. In the Audit Commission survey,[4] 68% of the women reported that their GP had visited them at home in this capacity.

The 6-week postnatal check, usually undertaken by the GP, marks the discharge from routine maternity care. Uptake of this is high at around 90%.[4,48] The content of this, again largely based around routine examinations, has also been questioned.[49,50] Sharif and colleagues[50] studied 125 women who had routine vaginal examination as part of their postnatal check and found that only in six women was any abnormality detected (and none required treatment). Contraceptive advice is also often offered at the postnatal discharge visit, yet studies indicate that about half of women will have resumed intercourse by then,[7,51] suggesting that discussion of contraception at this visit is therefore too late. In a *British Medical Journal* editorial, Noble proposed that the routine vaginal examination should be discontinued, that the consultation should remain,

but its emphasis should change.[49] Sharif and Jordan[52] suggested a postnatal visit at 2–3 weeks to discuss contraception, infant feeding and common short-term health problems, followed by a visit at 10–12 weeks to identify long-term morbidity, although a more recent randomised controlled trial (RCT) in Australia, which will be described later, found that a GP postnatal consultation at 1 week after the birth had no additional health benefits.[53]

Protocol- and guideline-based care

Information available to midwives to 'guide' their practice in the postnatal period is very limited, as noted earlier, and there is general consensus that current postnatal care consists of much unnecessary activity while failing to identify and manage women's health problems.

The use of clinical practice guidelines in general has shown that these can be effective both in altering practice and influencing patient outcome,[54] although there is little work specifically in the area of maternity care. Lilford and colleagues[55] have demonstrated, in a RCT of antenatal history taking, that structured questionnaires, incorporating a checklist, provided more and better information and also improved clinical response to risk factors. Lomas and colleagues[56] examined various methods of encouraging compliance with a guideline for the delivery management of women with previous Caesarean section and found the greatest clinical effect when guideline use was encouraged by opinion leader education. A systematic review of clinical guidelines in general suggested that changes in clinical practice were more likely to be seen in studies where guidelines were disseminated by educational intervention (seminars, educational outreach visits and use of local opinion leaders) with concurrent implementation strategies.[54,57] The authors of the review also produced a set of desirable attributes to be taken into account; these can then be used to develop specific areas of practice. In a later systematic review of 102 trials,[58] 10 types of intervention to improve clinical effectiveness were assessed. Outreach visits by a trained person who met practitioners in their practice setting to provide information were the most effective intervention. Most studies using educational printed material alone (including distribution of guidelines) failed to demonstrate change in professionals' behaviour or patient outcomes.

Costs of postnatal care

Annual total expenditure on maternity services is estimated at just over £1 billion.[59] Data allowing the estimation of postnatal care as a proportion of this are not available, but will represent a substantial sum. At the time of study design, there was little direct evidence about postnatal midwifery activity and its cost in relation to individual women. Routine annual costs data are available only for maternity services as a whole (i.e. antenatal, intrapartum and postnatal) and for hospital and community services as a group. This is divided by the number of births per year to derive an average expenditure per birth per year of £1822 for 1996–7.[59] No RCTs had reported on midwife visits or costs. Twaddle and colleagues[46] recorded postnatal midwife activity in their temporal comparison of individualised care, but although they translate the reduction in visits per woman to potential savings, no direct costs were estimated. Data on individual postpartum women's care by GPs and secondary care services were similarly scarce. Maternity care payments to GPs are based on the fulfilment of a set of service obligations rather than for itemised activities.

Other intervention studies

At the time that the present trial was funded, there had been no other trials examining interventions of modifications to care within the postnatal period that had as one of the objectives the improvement of women's health. There was, however, some evidence available from trials of supportive care given during pregnancy and/or labour and the effects of this on aspects of women's postnatal health.

A RCT of antenatal home-based social support, provided by a midwife for women with a history of babies of low birth weight (<2500 g), in addition to infant and delivery outcomes, compared maternal outcomes at 6 weeks postpartum.[60] Among the intervention group (n = 243), relative to controls (n = 234), (response rates at 6 weeks were 96 vs 92%), the mothers were less likely to report being depressed after birth (40 vs 47%), feel that they had low/no control over life (28 vs 37%), report their health as not being 'good' or 'very good' (30 vs 39%) and to have consulted their GP (27 vs 32%). A RCT in South Africa of lay caregiver support during labour, in addition to measuring birth outcomes, showed a lower postpartum anxiety score, a higher self-esteem score and less postpartum depression at 6 weeks

postpartum, among the women who had the intrapartum support ($n = 74$) compared with controls ($n = 75$).[61,62]

Several relevant trials commenced or were under way at around the same time as the present study began. Contact was maintained between investigators and comparable outcome measures were used where appropriate. These studies will be described, with any results now available, in Chapter 4.

Summary

Government recommendations clearly stated the need for wide-ranging changes to maternity services and highlighted the poor evaluation and often inappropriate and fragmented delivery of postnatal care. A midwife-led service with continuity of care and the involvement of women that is sensitive to the women's individual needs and preferences was at the centre of the reforms. Many women currently experience, but do not report, physical and emotional problems after childbirth, some of which are persistent. Postnatal care does not address these needs, while continuing to devote much time and resources to routine practice, including observations and examinations which are often unnecessary. Guidance offered to midwives on postnatal care is brief and unstructured. Protocol-based care (care using guidelines) has been shown to be effective in many areas of clinical practice and in relation to some areas of maternity care. There was some evidence from trial interventions of supportive care in pregnancy or labour, showing that this could have a benefit on maternal postpartum health. It was proposed that a trial of a redesigned model of protocol based midwifery-led care in the postnatal period was therefore warranted.

Aim and objectives of the study

The aim of the study was to develop and implement a redesigned model of postnatal care and to test the effectiveness and cost of this model compared with current care in an RCT. The research hypothesis was that the attributes of the new model of care would have a positive effect on women's physical and emotional health and well-being in the year after birth, and that it would be delivered with a more appropriate use of NHS skills and resources.

The specific objectives were:

1. to develop and implement the model of redesigned postnatal care
2. to compare between study groups:
   (a) the measures of women's health [Short Form 36 (SF-36) mental component score (MCS) and physical component score (PCS) and the Edinburgh Postnatal Depression Scale (EPDS)] at 4 and 12 months postpartum
   (b) the women's views about care
   (c) the women's reported morbidity at 12 months postpartum
   (d) 'good practice' indicators, such as breastfeeding, contraception and immunisation
   (e) the views of the health professionals
   (f) health service usage up to 12 months after birth
   (g) direct NHS costs incurred by the women
3. within the intervention arm to assess the extent of implementation of the redesigned care.

Chapter 2
Method

Study design

The study was a cluster RCT with general practice as the unit of randomisation. Women recruited to the trial were followed up at 4 and 12 months postpartum by questionnaire to assess primary outcomes. Baseline data were collected from the women and the obstetric units and other outcome data from the midwife and GP records.

A cluster design was necessary because the intervention comprised the delivery by midwives of a new package of postnatal care, which included a text of evidence-based reviews, and it would have been impossible for them to provide two types of care without there being a substantial and unacceptable risk of contamination of trial groups. Community midwives, as the lead providers of the care, generally work in teams allocated to particular general practices and share care of women on days off, holidays and busy periods, so randomisation of midwives would have also resulted in a high contamination risk. It was necessary, therefore, that the unit of randomisation be the general practice. All midwives allocated to the practice provided all the women with either redesigned or current care, depending on trial allocation (described later). In some cases, where midwives were responsible for care in more than one recruited practice, both practices were included as one practice cluster (see later).

The original study design was for a three-arm trial. Both intervention arms included midwifery-led, evidence-based care, but in one the midwife would visit routinely to 10–14 days and perform the postnatal check at 6–8 weeks, whereas in the third arm they would visit to 28 days and the postnatal check would take place at 10–12 weeks. Following discussion with health service professionals and on further reflection, it was accepted that the discrimination of health effects attributable to the extension alone was unlikely and only one intervention group was used.

Ethics committee approval

All 17 ethics committees in the West Midlands Health Region were approached for approval, because prior to recruitment of the general practices it was not known from which health districts patients would be recruited. All of the committees gave approval.

Setting

The trial took place throughout the West Midlands Health Region, which is the largest in England and Wales and represents one-tenth of the population, with over 5.2 million residents. The region has a wide demographic spread and includes inner-city environments, which contain deprived communities, large towns and rural areas. The wide demographic spread of the region enhances the generalisability of study findings.

Population

General practices (clusters)

The general practices invited to take part in the trial were randomly selected from a list of all GPs within the West Midlands Health Region. Individual GPs rather than practices were selected in order to allow a sample that was proportionate to practice size. The process of cluster recruitment involved several tiers of consent. For a practice to participate, however, the agreement of all partners was required. The agreement of the Midwifery Managers in the NHS Trusts that employed the midwives, and also that of the attached midwives, were also required. A few practices also wanted the agreement of their attached health visitors, although their care was not directly influenced by implementation of the intervention. It was estimated that about 40 general practices were required (see later) and that full agreement to take part would be reached in about one-third. At the pilot stage, a test list of 125 randomly selected GPs showed that, without stratification, a range of practices representative of practice size and socio-demographic patient characteristics was generated.

The GPs who were selected were contacted by letter, followed by a telephone call, and then visited, usually to present the study at a practice meeting. This process was undertaken alongside seeking the agreement of the Midwifery Managers of all the Trusts in the Region.

Women

Midwives attached to the trial practices were asked to recruit all pregnant women registered at the practice antenatally from about 34 weeks gestation. The only exclusion criterion was a woman knowing she would not be resident in the area to receive postnatal care. Language was not an exclusion criterion and whether the women would understand well enough to be consented was left to the judgement of the midwives, but translated research materials were not provided. Estimates of the number of eligible women within each general practice cluster were obtained from practices and from health authorities. The midwife explained the trial individually to each woman and gave her an information leaflet and a consent form. This could be signed straight away for the midwife to return, or a prepaid envelope could be given to the woman to return it herself to the study office. Recruitment up to the first postnatal home visit was permitted since for various organisational reasons, or because of early delivery, some women might not be able to be approached antenatally. Some women, although informed antenatally and agreeable to taking part, might forget to return their consent form, so midwives were asked to check this at the first home visit. The midwives in each practice cluster were asked to recruit all women over a minimum of a 12-month period. The total recruitment period, however, was longer than this because some midwifery trusts agreed but wished, for organisational reasons, to delay implementation in a few practices, and was from October 1997 to April 1999.

Allocation to trial group

Given that randomisation was by cluster, the number of clusters being allocated between groups represents a small 'sample'. It is advisable to balance the allocation to trial groups according to any factors known or believed to be associated with study outcomes. The randomisation procedure, generally accepted as most appropriate for this, minimisation,[63] was used in this study. Two factors were included, socio-economic deprivation and midwife caseload. The primary study outcome of health and well-being is generally associated with socio-demographic characteristics and this may also apply to postpartum health. The measure used to balance for this was Townsend score, an index of socio-economic deprivation based on the postcode of the general practice. Only the first four digits of the postcode that indicate ward level were used, so the Townsend score was for a larger geographical area not necessarily coterminous with the practice but indicative of the surrounding area. (There were three clusters which included two general practices and for these the address of the largest practice was used.) If the redesigned postnatal care was found to take more midwifery time, implementation may be affected by the size of the practice's maternity caseload, as might delivery of GP postnatal care.

Allocation of the general practices to study group was undertaken by a member of the Birmingham Clinical Trials Unit, a group that was independent from the trial team. A customised computer program was prepared by them and allocation was carried out at the midwife training days (see later).

It was clearly not possible for the midwives or the women to be blind to trial group allocation. For data input and analysis blinding would have been possible. Since the main outcomes were composite scores, however, it is unlikely that these were amenable to contrived manipulation. Although discernment of group was theoretically possible during analysis, integrity in the uniform treatment of data, irrespective of group allocation, was maintained.

Content of intervention

The trial intervention comprised a redesigned model of community postnatal care that was wide-ranging and incorporated changes based on the research findings summarised in the background, and compatible with UK government maternity care recommendations. It was midwifery-led and designed to enable care to be tailored flexibly according to the individual needs of the women. Its focus was on the identification and management of women's physical and psychological health rather than on routine observations. Health visitor care and midwife care of the baby were not altered in this trial. The key features of the redesigned model are described below.

Midwifery-led

The care was midwifery-led, with GP contact only if the midwife considered that this was required, or if it was requested or preferred by the woman or the GP. This included the midwife undertaking all of the postnatal home visits and the postnatal maternity discharge check.

Symptom checklists and EPDS

Since research has shown that many women do not report health problems to health professionals,

nor are they always identified during the delivery of care, a symptom checklist was used as part of the intervention alongside usual clinical judgement. An abbreviated version of the checklists was used at the first visit, to assess more immediate symptoms, then the full list at the 10- and 28-day visits and again at the postnatal discharge check. The EPDS was also completed at the 28-day visit and at the discharge check to screen for postnatal depression. The particular symptoms or problems included on the checklist were the main ones shown by the literature to occur after birth and those for which the guidelines were developed (see below). From this information, care plans were made, after discussing needs with the woman. A proposed schedule of visits was made, which would be amended according to the needs of the woman as care progressed.

Evidence-based guidelines

To assist midwives in the management of women's health problems, a set of evidence-based guidelines were developed by the study team, now published as a book.[64] The particular guideline areas were determined from research on postpartum morbidity. The 10 guidelines, most of which covered several symptoms within the same area, were as follows:

- endometritis and abnormal bleeding
- perineal pain and dyspareunia
- Caesarean section wound care and pain relief
- breastfeeding issues (painful nipples, engorgement, insufficient milk, thrush, blocked milk duct, inverted nipples, mastitis, abscess)
- urinary problems (stress incontinence, urinary tract infection, detrusor instability, urinary retention and voiding difficulties, urinary fistulae)
- bowel problems (constipation, haemorrhoids, anal fissure, faecal incontinence, third-degree tear)
- depression and other psychological morbidity (PND, blues, puerperal psychosis)
- fatigue
- backache ('simple' backache, nerve root pain, symphysis pubis pain)
- headache (postpartum headache, post-dural puncture headache, hypertensive disorders, sub-arachnoid haemorrhage).

For each symptom or problem, the evidence on postpartum prevalence, risk factors and management were presented, then the management evidence was translated into a practical 'What to do' section. This section was also summarised in leaflet format for the midwife to use easily within day-to-day practice. The guidelines were developed in accordance with the principles established from best evidence on delivering scientifically valid guidelines.[54,57] A standard hierarchy of best evidence was followed in the guideline development and each guideline was peer reviewed by one or more national experts. Since the guidelines were devised for the midwifery management of postnatal health, they assume a level of prior knowledge applicable to midwife training.

Extended care

The last home visit was planned to be at about 28 days, rather than the usual 10–14 days, and the discharge check at 10–12 weeks, rather than the usual 6–8 weeks. By dispensing care over a longer period it was considered that women and midwives would be more able to appraise their health needs fully, thus increasing the likelihood of detecting and managing problems. The intention was not to increase the number of visits because the period was longer, but to schedule them flexibly according to need, some women needing more visits than would currently be made, but others needing fewer.

GP role

In the redesigned care package, routine GP home visits and the 6–8-week GP discharge check were not required, with contact only by midwife referral or if preferred by the woman or the GP. The guidelines incorporated clear GP referral criteria. Other specific issues generally covered by GPs, including discussion about contraception, immunisation and registration of the infant with the practice, were also incorporated into the midwife care package at appropriate times.

Health visitor role

Alteration of the role of the health visitor was not part of the intervention, but information on number of health visitor visits was collected from the women and the opinions of health visitors attached to trial practices were surveyed at the end of the trial.

Training of midwives

Training days

The midwives attached to the recruited practices attended a training day provided by the study team (this was accredited by the English National Board). Midwifery managers were able to claim the cost of bank staff to cover the clinical work of attending midwives, although most did not claim.

Four training days were held and midwives attended in groups of about 15.

Care was taken in training that equal attention was given to intervention and control midwives to minimise the possibility of a differential 'Hawthorne effect'. During the morning of the training day the presentations and discussions covered the background to the study and the role of RCTs in the provision of best quality evidence. This part of the training was attended by the whole group of midwives. Allocation of practices to study group was undertaken during the morning and there were separate afternoon sessions for the intervention and control group midwives. The midwives from practices allocated to the intervention group were provided with the information and guidance needed to deliver the redesigned care and complete the documentation required for the study. For the control midwives the minimal study data that they were to collect required only a brief explanation, so the main focus of their afternoon training session was to emphasise the importance and role of the control group within a trial. This was illustrated through discussion and critical appraisal of different studies of midwifery practice, with and without adequate controls. Both groups of midwives were supplied with a brief written summary of what was required of them. The intervention midwives were provided with a copy of the evidence-based guidelines shortly after the training day.

There were four general practices, which, because of midwifery Trust reorganisation, could not commence the trial at the time originally planned. In these practices, and for midwives who joined or replaced colleagues at recruited practices during the trial period, training took place at a location within the Trust or the practice. A similar training format was used but was given by only one study team member.

Ongoing contact

Again taking care to pay equal attention to the midwives in both groups, various measures were instituted to encourage and maintain midwife recruitment of women throughout the trial:

- A study research midwife was available each weekday by telephone to answer any queries.
- The midwives in each practice were visited every 2 months by a study research midwife.
- A monthly newsletter was sent to all midwives detailing the progress of the trial, and other items of interest, such as research findings from other maternity care studies.

Outcome measures

Primary outcome measures

The primary outcome measures of the study used to compare the health and well-being of the women at 4 months and 12 months postpartum were the PCS and MCS of the SF-36 and the EPDS.

SF-36

The SF-36 was first designed to measure physical and mental health status in a study of medical outcomes in the USA[65] and has been validated for use in several countries including the UK.[66,67] It is a short questionnaire with 36 items that can be self-completed or administered by an interviewer and takes about 5 minutes to complete. It measures eight health domains: physical functioning, role limitation physical, social functioning, vitality, pain, mental health, role limitation emotional, and general health perception. The summary measures used as primary outcomes in this study, the PCS and the MCS, are generated through an algorithm adapted to UK population data, which aggregates the relevant components of the questionnaire.[68]

There is no index of health status specifically available for a postpartum population. The SF-36 was chosen since it is considered to be sensitive to health changes within a general population, rather than concentrating on more extreme health states,[66] in addition to being relatively simple to self-complete. Several other studies of postpartum health designed at around the same time also adopted this measure, so that SF-36 data on other postpartum populations are now available. The original US scale has had minor word modifications for use in the UK and this was the version used.[66]

EPDS

In addition to the EPDS, studies have used a variety of depression scales to identify PND, including the Beck Depression Inventory, the Research Diagnostic Criteria and Goldberg's General Health Questionnaire.[20] These other scales are general population depression scales, and because certain of the assessed items, such as sleep or appetite disturbance, are not considered abnormal in a postpartum woman, they may not be entirely applicable following childbirth. The EPDS was developed specifically to detect the presence of depression in the postnatal period.[69] It was not designed as a diagnostic instrument, but to be used as a first-line screening tool, followed by referral to the GP to make the decision to

diagnose and/or treat or to seek the opinion of a psychiatrist.

The initial validation of the EPDS against the research diagnostic criteria (RDC)[70] found a sensitivity of 78%, a specificity of 86% and a positive predictive value of 73% at a cut-off score of 12/13, within a population of high-risk women.[69] A subsequent large postnatal community-based study found the EPDS validated against the RDC to have a sensitivity of 68%, a specificity of 96% and a positive predictive value of 67% at the 12/13 cut-off score.[71] In the first of these validation studies the EPDS was completed during a home-based interview and in the latter it was in a postal questionnaire.

There were various reasons why we decided that the EPDS was the most appropriate scale for use as an outcome measure in this study. To our knowledge, there were no other depression scales specifically developed for postpartum women. In addition to being acceptable to health professionals, the EPDS is acceptable to women and simple for them to complete.[72] This was important, since the scale was to be self-completed within a postal questionnaire. This method of EPDS completion by women was shown to be successful in other studies.[71]

The authors of the EPDS originally intended that it should be administered at the 6–8-week postnatal check, but it was realised that this would fail to identify some depressed women, since onset can be after this.[21] Cox,[73] in discussing the further development of EPDS use, recommended that women be screened three times within the first 6 months to maximise detection and at 5–6, 10–14 and 20–26 weeks. The scale has been used in research studies at various different times.[5,27,74] Within postnatal care the EPDS is mainly used by health visitors, although it was also designed for use by other primary healthcare team members, including midwives.

The EPDS has 10 items, each of which has four possible responses, and the woman is asked to choose the response that comes closest to how she has felt during the previous 7 days. The scoring is straightforward, with a maximum score of 30 and a score of 12 or greater being considered to identify women who require further investigation of possible depression. When used as an outcome measure, in keeping with other studies, we have taken a view that use of a score of 13 or greater represents a more cautious estimate of the women likely to be depressed.

Secondary outcome measures

There were several secondary study outcome measures collected at 4 and 12 months postpartum. We considered any validated measurement tools that were available for these, which were limited, and either because of their excessive length (validated primary outcome measures had to take precedence) or because they were not appropriate for the aspects of assessment specific to the study, we found none to be acceptable and measures were developed for the trial.

Women's opinions about care

The measures used to assess the women's views about their postnatal care included general assessments and views about particular aspects. Overall satisfaction with care from the community midwives was scored as very satisfied or satisfied compared with very dissatisfied, dissatisfied or neither satisfied nor dissatisfied. **Care relative to expectations** was scored as much better or better compared with much worse, worse or the same. A **planning care score** was derived from women's views of the appropriateness of the number of their midwife home visits, their extent of involvement in planning care and their overall view on whether care was planned. A **continuity of care score** was based on the number of different midwives making visits, how often the woman knew the name of the next midwife to visit and how often she felt she received conflicting advice. A **maternity discharge consultation score** was based on the women's general satisfaction with this visit or consultation, the extent to which health problems were discussed and whether they felt the timing was right, too early or too late. **Ability to discuss health symptoms** reflected feeling able to talk to midwives about all or most symptoms compared with none, a few or only some. **Difficulty in talking about symptoms** with the midwife was scored as any difficulties or none.

Reported morbidity

The reported presence of several specified morbidities (based on those in the symptom checklists) at 12 months postpartum was the main assessment of women's reported morbidity and ascertained in their questionnaires. For the morbidities of a short-term nature (Caesarean section wound problems, breastfeeding problems, heavy vaginal bleeding and uterine infection), any postpartum occurrence was the assessment used.

Other secondary outcomes

Several indicators were considered relevant to midwife or GP good postnatal practice. **Breastfeeding continuation** was assessed by

comparing continuation rates at 4 and 12 months and mean feeding duration, as reported by the women. Since **contraceptive advice** is traditionally given by GPs in postnatal care, there was concern that this was still covered in the intervention group. The midwife role was to elicit whether contraception was required and to refer the woman to the GP or family planning clinic as appropriate. Advice on the need for **infant immunisation** was a similar concern, and the completeness of the baby's schedule was assessed at 12 months after birth from GP records.

Health professionals' views about care

The instruments used to assess health professionals' views relating to the community postnatal care were specifically developed for the trial. The small number of health professionals prohibited meaningful multi-level cluster-adjusted comparisons and categorisation of responses obscured small but possibly relevant differences. The main assessments, satisfaction with postnatal care organisation and the roles of the three professional groups involved in care, were collected using a five-point Likert-type scale. There were comparisons between average scores for these allocated numerical values (4 for very satisfied down to 0 for very dissatisfied) summarised for each cluster.

Health service usage

The main assessment of the effect of the intervention on healthcare usage was a comparison of the women's rates of use of GP and secondary care services.

Data collection

Four main types of data were collected from various sources:

- baseline data
- primary and secondary outcome data
- process data
- cost data.

Baseline data

Consent form

In addition to the signature confirming consent, the consent form recorded the women's date of birth and home address, including the postcode. The postcode was used to obtain the Townsend score of the woman's area of residence to provide a baseline socio-demographic indicator.

Demographic questionnaire

This questionnaire was brief and given by the midwife to the woman at the first home visit for her to complete and return to the study office in a prepaid envelope. From it, information was obtained on other adults in the house, age of leaving full-time education, home ownership and an assessment of the level of social support. This social support assessment, derived for the study, used five items of information to devise a score: the woman's rating of the amount of help from her partner; availability of a relative or friend to contact if upset/concerned; availability of a local contact with a baby; availability of practical help at home if needed; and duration of residence in the area.

Hospital delivery notes

Mode of delivery, parity and perineal trauma were collected by the study team from the delivery register of each obstetric unit. For the few home births this was obtained from GP records.

Midwife information

Baseline cluster data were provided by the midwives at the training day prior to study allocation, some of which (practice maternity caseload and address to calculate Townsend score), as already described, were used in the minimisation procedure to allocate to study group. Information was also obtained on the number of midwives in all the practices covered by the midwife and number of GP partners (the latter was confirmed later from the practices). Since most general practices had more than one midwife, a cluster midwife qualification score had to be derived. This was achieved by categorising all the post-registration qualifications recorded by the midwives into four groups; none, short course, more substantive course up to certificate level, and diploma and degree. Four team members, one with expertise in midwifery education, undertook this process. The highest qualification for each midwife in the cluster was aggregated and a cluster average obtained. These average cluster scores were then partitioned into three qualification levels: higher, medium and lower.

Outcome data

Follow-up questionnaires

The primary study outcome measures, the SF-36 and the EPDS, were collected by postal questionnaire sent to the women at 4 and 12 months postpartum. The women's views about their postnatal care were also obtained in the 4-month questionnaire, and the 12-month questionnaire also included information on morbidity and breastfeeding history.

General practice records

Information on all GP consultations and secondary referrals throughout the first year was required to

assess the effect of the redesigned care on healthcare usage outside of postnatal care and for assessment of NHS costs for the economic analysis. It was impracticable to ask GPs to complete additional records of their contacts with the women so these data were abstracted by the study team from general practice records. Agreement from GPs that this would be abstracted from women's practice records was part of the process of general practice recruitment. Although the women had been informed at the time of their initial consent to the study that their longer term health would be evaluated through questionnaires and health service data, because of subsequent changes in the data protection legislation, it was considered prudent to obtain specific written consent from the women for their data to be abstracted from GP records. By this point, the only remaining opportunity to obtain this was on the 12-month questionnaire, so a specific consent form was posted with each 12-month questionnaire.

Health professional questionnaires

At the end of the intervention period, postal questionnaires were sent to all midwives and GPs involved in the trial practices to obtain their views about the care provided. Although health visitor practice was not part of the intervention, the health visitors attached to the trial practices were also surveyed.

Process data

Data on the process of delivering the postnatal care were required for two main purposes. One was to inform the cost-effectiveness analysis with data collected from both groups. The other was to consider the extent to which the implementation of the redesigned care actually occurred within the intervention arm. Obtaining detailed information on health professionals' practice in relation to study participants, to allow workload comparison, evaluation of implementation of the intervention and for costing, could require onerous completion of paperwork. In addition, documentation of care within a research context can, in itself, induce change in practice. Given these constraints, the strategy used was to obtain direct information from health professionals on the elements of care most likely to change and to have greatest influence on the cost-effectiveness comparison – believed to be the woman's contacts with the community midwife and with her GP.

Midwife records

The intervention midwives completed detailed documentation for each home visit. These records were designed in consultation with midwife managers to be acceptable to the legal requirements for the Trusts so that they could be completed instead of usual records and a copy kept by the Trust. From these records, the total number of home visits made to the intervention group women and their duration were obtained, in addition to further data relevant to assessing the process of care implementation. For the control midwives, it was important only to collect minimal additional documentation of care data, otherwise, as mentioned above, this in itself could have comprised a form of intervention. The control midwives, therefore, continued to complete their usual Trust records, the only addition being a separate study diary in which they noted the woman's name and the date and duration of each visit.

It was expected that control midwives would have less direct prompts to record data, since it was additional to usual recording, and possibly less motivation to do so since the emphasis was on not changing care. The data from midwife diaries were therefore augmented by diaries completed by the women.

Women's diaries

The women in both groups were given their diary by the midwife at their first home visit and asked to record every visit to the house by all health professionals, including the midwives, during the first 28 postpartum days. They were not asked to record duration of these visits.

Follow-up questionnaire

In the 4-month questionnaire, the women were asked to record the number of home visits from their GP and health visitor to obtain further comparable visit data and to consider any possible effect of the intervention on health visitor contact.

Cost data

Direct NHS costs were calculated using generic costs.[75] The activity data from the midwives and general practices formed the main substance for costing care in each study group. Duration of visits was recorded by intervention and control midwives but it was not possible to obtain information on visit duration from GPs. In-service payments for postnatal care to intervention group GPs were continued for the duration of the trial and were not included in the economic analysis.

Pilot study

A pilot study was undertaken to test the practicalities of implementing redesigned care and the

instruments and methods designed for data collection.

The first general practice where agreement to participate from the GPs, midwifery manager and attached midwives was obtained was asked if they would be prepared also to be used for the pilot study. This practice had two attached midwives and each was randomly allocated, by sealed envelope, to the delivery of redesigned or standard care. Both midwives were given relevant training. Each midwife had her own caseload, which determined the group allocation of the women. Each covered off-duty days of the other midwife and at these visits they continued to provide the care which they, rather than the woman, had been allocated. Midwife contamination was not of major concern in the pilot study, since primary outcomes were not being assessed.

Twenty-one women were recruited over 3 months to the pilot study, 10 to intervention and 11 to standard care. A mean of seven visits, including the postnatal discharge check, were made to women in the redesigned care, with a range of 6–14, and this was similar to that within current care. Various practical difficulties occurred in the pilot phase, in particular, midwives having to write out all the women's details by hand, so printed labels of those details were produced by the study team for the midwives to use in the main study.

The women recruited in the pilot study were also used to pilot the 4- and 12-month questionnaires. These were generally completed without any problem and, with only minor changes in the wording of a few questions, were used for the main study.

Since one of the midwives in the pilot practice was trained to give redesigned care, it was considered necessary in the main trial that this practice be allocated non-randomly, to the intervention group.

Sample size

One imperative was to achieve a reasonably representative spectrum of socio-demographic characteristics and primary care settings to achieve maximum generalisability. Using modelling of these attributes, we estimated that about 40 general practices would be required. Original sample size estimates included inflation factors for three arms and cluster randomisation suggested that the study would have 80% power to detect a two point difference in the PCS of the SF-36 (Type 1 error at 5%). Following trial amendments (to a two-arm trial) and with additional information from practices and midwives at practice allocation, estimation of sample size was checked.

We estimated that there would be around 4000 maternities in 40 practices. With 25% loss to recruitment and follow-up, outcome measures would be available on 3000 women. This sample size would give an 80% power to detect between the groups, a difference in outcome scores of 1.4 points. This calculation is based on the standard normal deviate sample size formula multiplied by a design effect.[76] This design effect can be interpreted as the number of times more subjects that a cluster randomised evaluation should have in order to attain the same power as one in which individuals are randomised. The design effect = $1 + (n - 1) \times$ intra-class correlation (ICC), where n is the average cluster size and the ICC is a measure of the proportion of the variation in outcome that can be attributed to differences between cluster means (the remainder being due to differences between women within clusters). Assumptions used in the calculation were an estimate of 10.42 for the standard deviation for the PCS from data on 1412 women of all ages in the USA,[68] an ICC of 0.01 (reported for a quality of life score for asthma on evaluation of area-wide and organisational interventions),[77] 40 clusters with an average cluster size of 75 and Type 1 error = 0.05. No directly applicable differences in SF-36 scores were available from the literature, but the difference of two points was smaller than that considered likely to represent a clinically meaningful difference in the PCS.

Analysis

The data were entered using FoxPro database version 2.6. The Statistical Package for Social Scientists (SPSS) version 10 was used for univariate analyses. As with calculation of sample size, in analysing cluster randomised data it was necessary to allow for the possibility that outcome measures from individuals within a cluster may not be independent.[76] If the measures were not independent and analysis was performed as if it were individuals who had been randomised, p-values from hypothesis tests would be too low and confidence intervals (CIs) too narrow. For example, factors predisposing to adverse psychological well-being might exist based on geographical location, in this case general practice catchment area. The method we used to take

account of the possible cluster effect was random effects multi-level modelling, which explicitly incorporated the hierarchical nature of the data, and estimated separately the variance attributable to the different levels, in this case the woman and to general practice. We included two levels of variation, individual woman and general practice in the multi-level models, which were analysed using Multi-level Modelling for Windows (MlWin) version 1.1.[78] Odds ratios and 95% CIs were calculated for the categorical outcomes and coefficients for the continuous measures. In presenting the results the multi-level models are the more statistically robust comparison method for study outcomes. Experience with these methods is still limited, however, and to facilitate accessibility of the results to those less familiar with multi-level modelling, the mean scores of cluster means are also presented in tables showing output from multi-level models. These means have not been weighted for cluster size and are referred to as 'unweighted'. Conservative (less powerful) analysis based on the cluster mean is perfectly 'respectable' and is more transparent.

The economic analysis was constrained by there being more than one primary outcome measure specified for the trial and the effectiveness measures were scores that cannot yet be translated into quality-adjusted life-years (QALYs) or other standardised metrics. Hence it was not acceptable to concatenate the costs and effectiveness scores in order to gain an overall measure of cost-effectiveness. The analysis proposed was a cost consequences model, where decision-makers have available the relative effectiveness of the intervention on a variety of outcomes and the comparative costs of the intervention.

All study group comparisons were pre-specified and the analysis was by intention-to-treat.

Chapter 3
Results

Recruitment and baseline details

There were 36 general practices included in the trial, 17 allocated to intervention and 19 to control, from which 2064 women were recruited, 1087 and 977, respectively.

General practice clusters

A randomly selected list of 125 GPs produced 120 general practices to approach for inclusion in the study (five practices were selected twice through two partners). At the same time, the heads of midwifery services in all Trusts in the region that employed the midwives were approached, the result of which was that 31 of the practices could not be recruited. In one Trust the midwifery manager did not want any midwives to take part, and in two others the manager set a limit to the number of midwives, and thus practices, that could be included. Two further practices were excluded by the investigators because the large team midwifery organisational structure in that area predisposed to a high risk of study group contamination. Two single-handed GPs could not be traced and two practices where GPs had agreed later had to withdraw because their health visitors objected. General practice agreement was 51% (43/85) and the overall participation rate was 33% (*Figure 1*).

Following general practice and midwifery manager agreement, the individual midwives attached to practices were approached and all except one agreed to take part. In three practices where the same midwives also gave care to another included practice, each practice pair was included as one cluster.

Study group allocation resulted in 18 general practice clusters in the intervention group and 19 in the control group. Following this allocation process, but before the recruitment of women, the midwife in one of the single-handed general practices allocated to the intervention group went

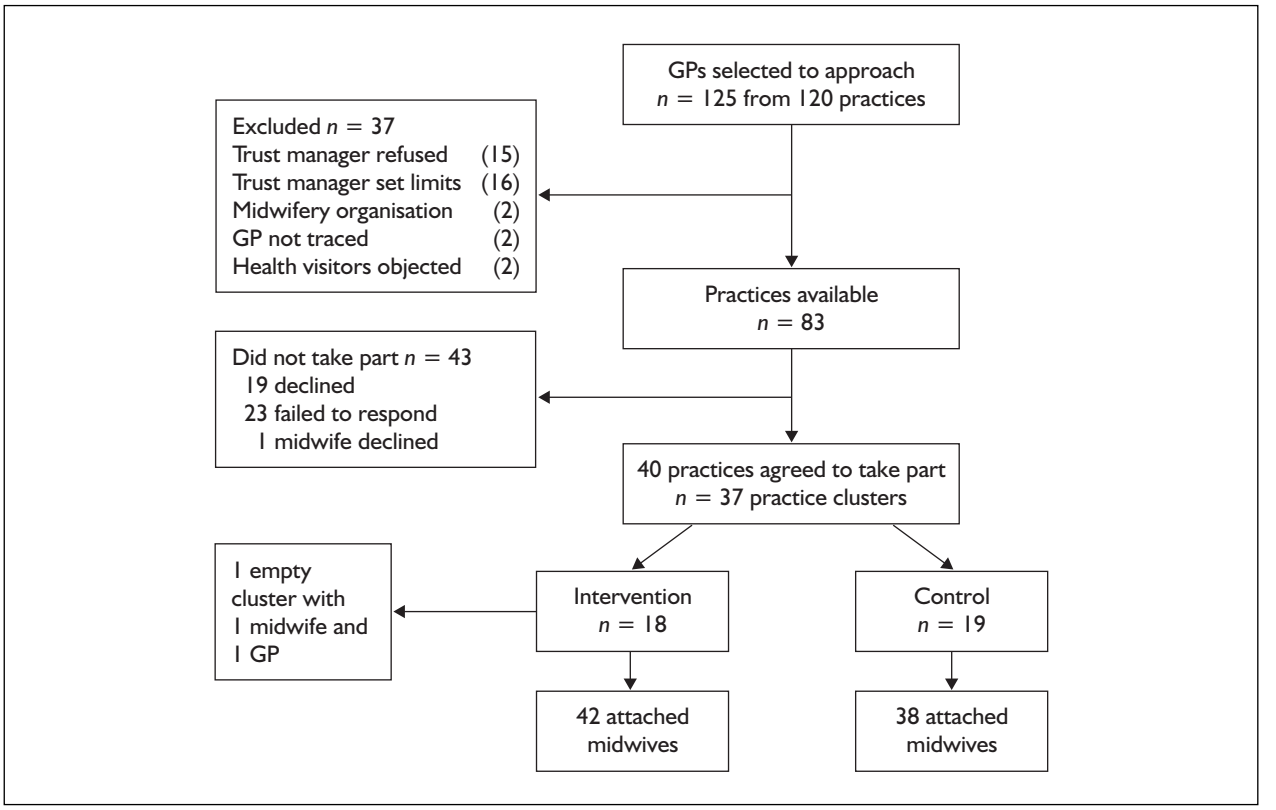

FIGURE 1 *Flow diagram of general practice recruitment*

TABLE 1 *Baseline characteristics of clusters by study group*

	Intervention (n = 17)[a]	Control (n = 19)	Non-recruited practices (n = 83)
GP partners			
1	1	4	18
2–5	6	9	40
≥ 6	10	6	25
Midwives			
1	3	6	
≥ 2	14	13	
Townsend score [mean (SD)]	1.49 (3.9)	1.32 (6.3)	1.20 (3.3)
Midwife qualification score			
Lower	6	12	
Medium	5	4	
Higher	6	3	
Cluster size			
1–50	11	11	
51–100	2	6	
≥ 101	4	2	

[a] The additional 'empty cluster' had one GP, one midwife; a lower qualification score and mean Townsend score including this cluster was 1.37.

on long-term sick leave. The midwifery manager was unable to make a permanent replacement in this practice and cover was to be provided by a variety of midwives from across an area where there were also control practices. The high risk of group contamination therefore necessitated subsequent exclusion of this practice. This left 17 general practice clusters in the intervention group, and 19 in the control group from which midwives proceeded to recruit women.

Over the study period there were 80 attached midwives in these 36 practice clusters, 42 in the intervention group who provided the redesigned postnatal care and 38 in the control group who provided current care. This total included all midwives who provided care during the whole of the intervention period, some who moved before recruitment ended and others who replaced those who moved, although the movement of midwives during the trial was insubstantial.

The characteristics of the clusters are shown in *Table 1*. The number of GP partners ranged from one to 10 and the number of attached midwives during the trial period ranged from one to five, although the maximum at any one time was three. None of the cluster characteristics differed significantly between the study groups. Cluster size in *Table 1* is the number of women recruited, not, as in cluster randomisation, the midwife's estimate of practice caseload.

Women

Over the study period there were 2064 women recruited to the trial, 1087 to the intervention group and 977 to the control group (see *Figure 2*). The respective recruitment rates were estimated at 59 and 57%, respectively, although the exact denominator of all women in the practices who had postnatal care during the recruitment period was difficult to obtain. For several of the clusters only the number of women who had maternity care, rather than postnatal care, was available, so the denominator will include some ineligible women who would have moved before having the postnatal component. The best estimate of eligible women was obtained from a combination of general practice and health authority data.

Figure 2 also shows the flow of follow-up of women to 12 months postpartum. Following recruitment there were 22 women in the intervention and 12 in the control group who were withdrawn by the midwives because they had moved since antenatal recruitment and thus did not have postnatal care. There may have been other recruited women who moved before postnatal care but where the midwife did not notify the study office. These women will be represented among the non-responders. In three cases because the baby died, following discussion with the woman, the midwife asked the researchers to withdraw the women and not follow them up. Baseline information from the obstetric units and from the demographic

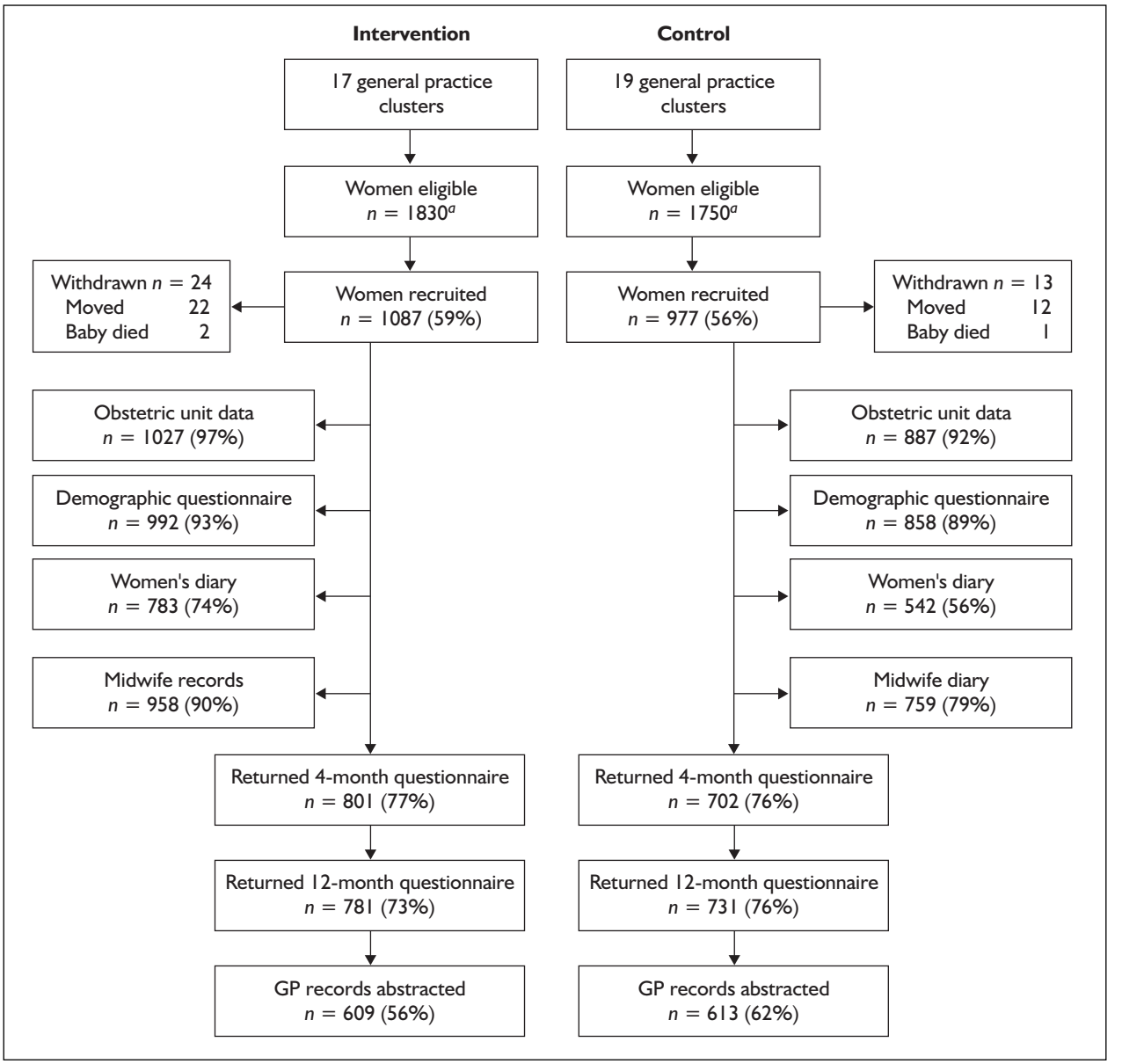

FIGURE 2 *Flow diagram of follow-up of women to 4 months.* [a]*There were 21 women in the intervention group and 39 in the control who for organisational reasons, did not receive a 4-month questionnaire and were excluded from the denominator. They did receive a 12-month questionnaire.*

questionnaire was available for most women in both groups. The home visit diary in which the women were to record all health personnel visits over the first 28 days was returned by a lower proportion of the control group women. One factor likely to have improved return in the intervention group women is that home visits were extended to 28 days, and the midwife may have reminded the woman to return the diary. Follow-up of the women to obtain main trial outcomes at 4 and 12 months were similar in both groups. A slightly higher proportion of GP records were abstracted in the control group.

Baseline characteristics of women

The baseline characteristics of the women in the intervention and control groups are shown in *Table 2*. Multi-level model analyses to examine whether the groups differed more than would be expected given the cluster randomisation showed no significant differences, although there were some proportionate differences. In the main the intervention group had a higher proportion of women in categories that are generally considered to be indicative of worse health outcome, which disfavoured the intervention group. Thus, in the intervention group there were proportionately

TABLE 2 *Baseline characteristics of women by study group*

	Intervention (*n* = 1087)	**Control (*n* = 977)**
Parity		
0	448 (42.2)	435 (46.8)
1	364 (34.3)	324 (34.8)
≥ 2	249 (23.5)	171 (18.4)
Missing	26	47
Maternal age (years)		
≤ 19	61 (5.7)	72 (7.5)
20–24	184 (17.1)	158 (16.4)
25–29	320 (29.8)	329 (34.1)
30–34	337 (31.4)	285 (29.5)
≥ 35	172 (16.0)	122 (12.6)
Missing	13	11
Mode of delivery		
Spontaneous vaginal	693 (66.9)	635 (71.1)
Instrumental	116 (11.2)	107 (12.0)
Section	227 (21.9)	151 (16.9)
Missing	51	84
Perineal trauma[a]		
1st-degree tear	100 (12.8)	114 (16.3)
2nd-degree tear	156 (20.0)	143 (20.5)
3rd/4th-degree tear	4 (0.5)	1 (0.1)
Episiotomy	175 (22.5)	154 (22.0)
Intact	344 (44.2)	287 (41.1)
Missing	30	43
Other adults in house		
0	155 (15.7)	93 (10.9)
1	725 (73.5)	665 (77.8)
≥ 2	106 (10.8)	97 (11.3)
Missing	101	122
Age at completion of full-time education (years)		
≤ 18	686 (69.4)	653 (76.3)
≥ 19	302 (30.6)	203 (23.7)
Missing	99	121
Social support score		
≤ 12	359 (37.6)	307 (37.1)
13–14	273 (28.6)	206 (24.9)
15	323 (33.8)	314 (38.0)
Missing	132	150
Home ownership		
Owned	621 (63.5)	638 (74.9)
Rented	357 (36.5)	214 (25.1)
Missing	109	125
Townsend score		
Most affluent	289 (27.3)	217 (22.9)
Affluent	235 (22.3)	258 (27.2)
Deprived	237 (22.4)	266 (28.1)
Most deprived	297 (28.1)	206 (21.8)
Missing	29	30

[a] Vaginal births only.

more women who were older (≥ 35 years), of higher parity, who had a Caesarean section and were living alone, and fewer women who owned their own home and had the highest social support score. The only baseline difference 'favouring' the intervention was education group – a higher proportion of women had continued in full-time education after the age of 18 years in the intervention group. For Townsend score, although the intervention group had more women in the most affluent quartile, there were also more in the most deprived quartile.

Four-month study outcomes

Response rate at 4 months

There was a nearly identical response rate to the 4-month questionnaire, 77% from women in the intervention group (n = 801) and 76% from those in the control group (n = 702) (*Figure 2*). A second questionnaire and reminder letter were sent to women who did not return the first, and if there was still no reply this was followed by a telephone reminder. Reasons for loss to follow-up are shown in *Table 3*. The women known to have moved and not received a questionnaire are included as non-responders, thus representing the worst-case estimate for response.

Table 4 shows the baseline characteristics of the responders and non-responders. The mode of delivery of these groups was similar but a greater proportion of responders were of lower parity ($p < 0.0001$), older ($p < 0.0001$), from less deprived areas ($p < 0.0001$), lived with another adult ($p < 0.0001$) and lived in non-rented accommodation ($p < 0.0001$). This pattern of response variation is typical of that shown in other studies of postpartum populations.[1,5] The two-fold difference in the proportion of non-responders in rented accommodation would account for some of the loss to follow-up, since those who rent are generally more mobile and thus less likely to have received their questionnaire.

Women's physical and psychological health and well-being at 4 months

The primary study outcomes, women's physical and psychological health, were measured using the PCS and the MCS of the SF-36 and the EPDS. The primary comparison of these is the results of the cluster-adjusted multi-level model analyses, by study group. For additional information, the overall unweighted mean scores of the cluster means for each group and the distributions within each of the study group clusters of the mean outcome scores are also presented.

TABLE 3 *Reasons for loss to follow-up at 4 months postpartum*

	Intervention	Control
Withdrawn because:		
Moved before postnatal care	22	12
Baby died	2	1
No reply (after reminders)	234	212
Not sent questionnaire owing to administrative error	21	39
Known to have left address	7	11
Total	286	275

SF36 – PCS and MCS

The PCS of the SF-36, indicative of physical well-being was not found to differ between study groups at 4 months postpartum (*Table 5*). This lack of effect was not modified by the entry of potential confounding factors into the multi-level model (*Table 6*).

The MCS, indicative of psychological well-being, however, did differ significantly between the study groups, with a score that was 3.03 points higher in the intervention group (*Table 5*). Higher scores indicate better psychological well-being. The distributions of mean MCS score by cluster show that the effect was general and not attributable to a few clusters with extreme changes in scores (*Table 7*). After adjusting for possible confounding factors the difference in MCS between the groups increased to 4.31 points (*Table 6*).

EPDS

The mean EPDS score and the proportion of women who scored 13 or more (indicative of possible depression) were significantly lower in the intervention compared with the control group (*Table 5*). For EPDS, a lower score indicates a lower likelihood of depression. Like MCS, the distributions by cluster showed that the improvement was not an effect resulting from a few clusters exhibiting extreme changes in scores (*Table 8*). Adjustment for other possible confounding factors again resulted in an increased effect of intervention (*Table 6*).

Individual domain scores

The scores of the eight different domains that comprise the SF-36 scale, from which PCS and MCS are constructed, are shown in *Table 9*. These were not the measures pre-specified as primary outcomes but are presented to allow comparisons with other studies that have used individual

TABLE 4 *Maternal and cluster characteristics of responders and non-responders to 4-month questionnaire*

	Responders (n = 1503)	Non-responders (n = 561)
(a) Maternal		
Parity		
0	668 (45.0)	215 (42.3)
1	526 (35.5)	162 (31.9)
≥ 2	289 (19.5)	131 (25.8)
Missing	20	53
Maternal age (years)		
≤ 19	66 (4.4)	67 (12.4)
20–24	209 (13.9)	133 (24.7)
25–29	495 (33.0)	154 (28.6)
30–34	493 (32.8)	129 (23.9)
≥ 35	238 (15.9)	46 (8.2)
Missing	2	22
Mode of delivery		
Spontaneous vaginal delivery	975 (68.1)	353 (70.9)
Instrumental	174 (12.2)	49 (9.8)
Section	282 (19.7)	96 (19.3)
Missing	72	63
Perineal trauma[a]		
1st-degree tear	156 (14.2)	60 (15.6)
2nd-degree tear	239 (21.8)	60 (15.6)
3rd/4th-degree tear	2 (0.2)	3 (0.8)
Episiotomy	272 (24.8)	58 (15.1)
Intact	429 (39.1)	203 (52.9)
Missing	123	81
Other adults in house		
0	168 (11.7)	80 (19.9)
1	1121 (78.0)	269 (66.7)
≥ 2	149 (10.4)	54 (13.4)
Missing	65	158

continued

domains. The particular domains shown to differ significantly between groups in this study were mental health, vitality and role limitation emotional, with social functioning of borderline statistical significance. The mean score for vitality was much lower than for any of the other domains in both groups, and physical functioning was the highest.

Other predictors of health measures at 4 months

Models which adjusted for potential confounders also gave an indication of other independent predictors of the women's physical and psychological health (*Table 6*). Younger age (≤ 19 years) and low social support were consistent predictors of all measures of worse health outcomes: PCS, MCS and EPDS were all worse in these groups. Higher parity (parity 2+) and living in the most deprived localities (Townsend quartile) were both predictive of significantly worse psychological scores and physical health score was in the same direction but not statistically significant. Living alone was associated with lower PCS and worse EPDS, and MCS was in the same direction, although it did not reach statistical significance. Having had a Caesarean section delivery or a perineal laceration were both predictive of worse physical health. An instrumental delivery was associated with worse MCS and a greater risk of an EPDS score indicative of probable depression. The only cluster level variable associated with the physical or psychological health scores was cluster size. Being in a small cluster, where 50 or fewer women had been recruited, was associated with a worse PCS.

Women's opinions about care

The women's opinions of their community postnatal care were secondary study outcomes. These included general assessments and assessments of particular aspects of care and were found to be either significantly more positive in the intervention group or similar in both groups.

TABLE 4 *Maternal and cluster characteristics of responders and non-responders to 4-month questionnaire (cont'd)*

	Responders (*n* = 1503)	Non-responders (*n* = 561)
Age at completion of full-time education		
≤ 18	1034 (71.8)	305 (75.7)
≥ 19	407 (28.2)	98 (24.3)
Missing	62	158
Social support score		
≤ 12	508 (36.3)	158 (41.4)
13–14	378 (27.0)	101 (26.4)
15	514 (36.7)	123 (32.2)
Missing	103	179
Home ownership		
Owned	1062 (74.2)	197 (49.5)
Rented	370 (25.8)	201 (50.5)
Missing	161	163
Townsend quartiles		
Most affluent	412 (28.2)	94 (17.3)
Affluent	387 (26.5)	106 (19.5)
Deprived	363 (24.8)	140 (25.8)
Most deprived	300 (20.5)	203 (37.4)
Missing	41	18
(b) Cluster		
No. of GP partners		
1	86 (5.7)	31 (5.5)
2–5	510 (33.9)	189 (33.7)
≥ 6	907 (60.3)	341 (60.8)
No. of midwives		
1	324 (21.6)	147 (26.2)
≥ 2	1179 (78.4)	414 (73.8)
Midwife qualification score		
Lower	793 (52.8)	279 (49.7)
Medium	330 (22.0)	160 (28.5)
Higher	380 (25.3)	122 (21.7)
Cluster size		
1–50	484 (32.2)	178 (31.7)
51–100	449 (29.9)	169 (30.1)
≥ 101	570 (37.9)	214 (38.1)

[a] Vaginal births only.

Overall satisfaction

This was assessed by the woman's responses to the question 'how satisfied were you overall with the care you had for yourself from the midwives who visited you in the weeks after your baby's birth?'. Women in the intervention group were slightly more likely to be satisfied, but the pre-specified comparison of being satisfied or not did not differ significantly between the study groups (*Table 10*).

Care better than expected

The assessment of how a woman felt her care had been relative to her expectations, better than expectations or not, showed that the intervention group were significantly more likely to rate their care better than they had expected (*Table 10*).

Planning care score

This was based on women's views of the appropriateness of the number of midwife visits, the extent to which they themselves were involved in planning visits and their overall view of whether care was planned. The maximum score was 18, with a median of 16 (range 6–18), hence views were generally positive. A slightly higher score (statistically significant) was found in the intervention group (*Table 10*).

Continuity of care score

This was based on the number of midwives who visited, the extent to which a woman knew who was to make the next visit and the extent to which she felt she had conflicting advice. The maximum

TABLE 5 *Physical and psychological health measures at 4 months by study group*[a]

	PCS	MCS	EPDS	EPDS 13 or more (OR)
Mean of cluster means[b]				
Control	47.84	47.54	8.06	21.25%
Intervention	46.68	50.50	6.40	14.39%
Difference (95% CI)	−1.17 (−2.52 to 0.19)	2.96 (1.16 to 4.77)	−1.66 (−2.49 to −0.83)	−6.85% (−11.99 to −1.71)
p-Value	0.089	0.002	<0.0001	0.010
Multi-level model				
Mean control value	47.57	47.74	8.17	–
Intervention effect size (95% CI)[c]	−0.79 (−1.91 to 0.34)	3.03 (1.53 to 4.52)	−1.92 (−2.55 to −1.29)	0.57 (0.43 to 0.76)
χ^2 (1 df)	1.89	15.77	35.3	15.14
p-Value	0.1692	0.00007	<0.0001	0.0001
ICC	0.00002	0.00534	0.00404	–

[a] For PCS and MCS a higher score is better; for EPDS a lower score is better.
[b] Unweighted.
[c] Effect size for continuous variables is the regression coefficient from the cluster-adjusted multi-level model and transformed for binary variables to an odds ratio.
df, Degrees of freedom; OR, odds ratio.

TABLE 6 *Physical and psychological health measures at 4 months by study group, also adjusting for other variables*

Multi-level model	**Effect size (95% CI)**[a]			
	PCS	**MCS**	**EPDS**	**EPDS 13 or more (OR)**
Study group				
Control	Reference	Reference	Reference	Reference
Intervention	−0.80 (−2.32 to 0.72)	4.31 (2.50 to 6.12)***	−2.68 (−3.46 to −1.89)***	0.47 (0.31 to 0.76)***
Maternal age group (years)				
20–24	Reference	Reference	Reference	Reference
≤ 19	−3.61 (−7.13 to −0.08)*	−4.48 (−8.67 to −0.28)*	1.85 (0.03 to 3.67)*	2.02 (0.89 to 4.59)
25–29	1.36 (−0.62 to 3.34)	−0.42 (−2.78 to 1.95)	−0.38 (−1.40 to 0.64)	0.99 (0.57 to 1.70)
30–34	0.10 (−1.97 to 2.18)	−1.08 (−3.55 to 1.39)	−0.04 (−1.11 to 1.03)	1.28 (0.73 to 2.23)
≥ 35	−0.07 (−2.46 to 2.33)	−2.68 (−5.53 to 0.18)	0.90 (−0.33 to 2.14)	1.88 (1.02 to 3.47)*
Parity				
First child	Reference	Reference	Reference	Reference
Second child	0.61 (−2.03 to 0.79)	−1.29 (−2.97 to 0.39)	0.83 (0.10 to 1.56)*	1.29 (0.88 to 1.90)
Third child +	−1.21 (−3.06 to 0.64)	−4.90 (−7.11 to −2.70)***	1.78 (0.83 to 2.73)***	1.69 (1.05 to 2.70)*

continued

TABLE 6 *Physical and psychological health measures at 4 months by study group, also adjusting for other variables (cont'd)*

Multi-level model	Effect size (95% CI)[a]			
	PCS	**MCS**	**EPDS**	**EPDS 13 or more (OR)**
Other adults in house				
One adult	Reference	Reference	Reference	Reference
No adults	–2.34 (–4.34 to –0.35)*	–1.22 (–3.60 to 1.16)	1.13 (0.10 to 2.16)*	1.85 (1.16 to 2.93)**
Two or more adults	–1.96 (–4.02 to 0.10)	1.29 (–1.17 to 3.74)	–0.01 (–1.07 to 1.04)	1.31 (0.79 to 2.19)
Mode of delivery				
Spontaneous vaginal	Reference	Reference	Reference	Reference
Instrumental vaginal	–0.75 (–3.07 to 1.58)	–2.78 (–5.55 to –0.01)*	0.59 (–0.60 to 1.78)	1.56 (0.85 to 2.87)
Caesarean section	–4.02 (–5.76 to –2.28)***	–1.26 (–3.34 to 0.81)	0.75 (–0.15 to 1.65)	0.99 (0.63 to 1.54)
Townsend score				
Quartile 1 (most affluent)	Reference	Reference	Reference	Reference
Quartile 2 (affluent)	0.87 (–0.76 to 2.49)	–1.08 (–3.02 to 0.86)	0.40 (–0.45 to 1.24)	1.18 (0.75 to 1.85)
Quartile 3 (deprived)	–1.34 (–3.09 to 0.40)	–1.54 (–3.62 to 0.54)	0.87 (–0.03 to 1.77)	1.27 (0.79 to 2.04)
Quartile 4 (most deprived)	0.83 (–1.23 to 2.88)	–2.84 (–5.28 to –0.39)*	1.05 (–0.02 to 2.11)	1.66 (0.98 to 2.82)
Social support score				
Highest	Reference	Reference	Reference	Reference
Medium	–0.67 (–2.18 to 0.84)	–1.04 (–2.84 to 0.76)	0.66 (–0.12 to 1.43)	1.45 (0.95 to 2.20)
Lowest	–1.61 (–3.01 to –0.22)*	–3.11 (–4.77 to –1.45)***	1.53 (0.81 to 2.25)***	2.02 (1.40 to 2.93)***
Cluster size				
>100	Reference	Reference	Reference	Reference
51–100	0.36 (–1.36 to 2.08)	–0.80 (–2.85 to 1.25)	–0.05 (–0.95 to 0.84)	0.91 (0.55 to 1.50)
≤ 50	2.20 (0.46 to 3.95)*	–2.17 (–4.25 to –0.09)*	0.44 (–0.46 to 1.33)	1.13 (0.68 to 1.88)
Mean values for reference group	49.64	52.47	6.26	

[a] Effect size for continuous outcome variables is the regression coefficient from the cluster-adjusted multi-level model transformed for binary outcomes to an odds ratio.
* $p < 0.05$.
** $p < 0.01$.
*** $p < 0.001$.

TABLE 7 *PCS and MCS in individual clusters at 4 months by study group*

Mean PCS[a]		Mean MCS[a]	
Intervention clusters (*n* = 17)	**Control clusters (*n* = 19)**	**Intervention clusters (*n* = 17)**	**Control clusters (*n* = 19)**
50.67	51.79	55.92	53.31
48.86	50.53	53.60	50.76
48.72	49.48	52.64	49.86
48.58	48.93	52.51	49.66
48.18	48.83	52.18	49.60
48.17	48.63	51.65	49.50
48.05	48.61	51.58	49.26
47.68	48.06	50.83	49.08
47.13	47.90	50.61	48.41
46.85	47.89	49.30	47.92
46.68	47.63	48.99	47.47
46.02	47.51	48.56	47.03
45.73	47.17	48.53	46.30
45.38	46.89	48.51	46.12
45.01	46.79	47.78	45.23
44.23	46.34	47.72	44.70
40.57	46.15	47.59	44.17
	45.14		42.89
	44.73		41.98

[a] Cluster mean values ordered in terms of best outcome score.

TABLE 8 *EPDS in individual clusters at 4 months by study group*

Mean EPDS[a]		EPDS 13 or more (%)[a]	
Intervention clusters (*n* = 17)	**Control clusters (*n* = 19)**	**Intervention clusters (*n* = 17)**	**Control clusters (*n* = 19)**
5.08	5.20	0[b]	9.1
5.11	5.75	4.8	10.0
5.18	6.41	7.7	13.7
5.62	6.91	9.6	14.9
5.67	6.94	11.1	15.2
5.76	7.76	11.4	16.3
6.03	7.78	12.1	16.7
6.03	7.79	13.1	18.2
6.37	7.88	13.3	19.4
6.53	7.88	13.3	20.0
6.68	8.27	15.0	21.3
6.77	8.28	15.9	24.1
7.03	8.81	18.2	25.0
7.09	8.91	20.0	25.0
7.47	9.12	20.0	29.6
7.83	9.31	25.8	30.0
8.50	9.63	33.3	30.6
	9.69		31.2
	10.75		33.3

[a] Cluster mean values ordered in terms of best outcome score.
[b] No women in this cluster had a score of ≥ 13.

TABLE 9 *Individual SF-36 domain scores at 4 months by study group*

Multi-level model	Physical functioning	Social functioning	Role limitation physical	Role limitation emotional
Mean control value	88.5	79.3	81.0	74.8
Intervention effect size (95% CI)[a]	–0.56 (–2.67 to 1.54)	2.51 (–0.25 to 5.27)	1.16 (–2.34 to 4.65)	4.29 (0.16 to 8.42)
χ^2	0.273	3.177	0.422	4.138
p-Value	0.601	0.075	0.516	0.042
ICC	0.00627	0.00652	0.00245	0.00452
	Mental health	**Vitality**	**Bodily pain**	**General health**
Mean control value	69.3	51.50	78.76	74.37
Intervention effect size (95% CI)[a]	4.64 (2.57 to 6.71)	3.78 (1.57 to 5.99)	–0.12 (–2.47 to 2.24)	1.44 (–0.54 to 3.42)
χ^2	19.342	11.245	0.009	2.026
p-Value	<0.00001	0.0008	0.924	0.155
ICC	0.00260	0.00000	0.0000	0.0000

[a] Effect size for continuous variables is the regression coefficient from the cluster-adjusted multi-level model.

TABLE 10 *Women's views about care by study group*

Views	Multi-level model: control/intervention effect size[a] (95% CI)	χ^2 (1 df)	*p*-Value
Overall satisfaction	OR 1.09 (0.72 to 1.63)	0.16	0.689
Better than expected	OR 1.35 (1.08 to 1.70)	6.79	0.009
Planning care score (maximum 18, median 10)	0.49 (0.13 to 0.85) Mean control value 15.45	7.02	0.008
Continuity of care score (maximum 14, median 12)	0.21 (–0.11 to 0.52) Mean control value 11.06	1.60	0.206
Maternity discharge score (maximum 11, median 9)	0.19 (–0.11 to 0.50) Mean control value 8.77	1.53	0.216
Talk to midwife about most/all health symptoms	OR 1.52 (1.05 to 2.20)	4.89	0.027
No difficulty in talking to midwife about health symptoms	OR 1.61 (1.07 to 2.41)	5.22	0.022

[a] Effect size for continuous variables is the regression coefficient from the cluster-adjusted multi-level model and transformed for binary variables to an odds ratio.

score was 14, with a median of 12 (range 3–14), so again views generally were positive and no significant difference was found between study groups (*Table 10*).

Maternity discharge check score

The women who said they had a final discharge check then rated their satisfaction with it, the extent to which they had discussed health problems and whether they felt its timing was right. The score had a maximum of 11 and a median of 9 (range 3–11) and no difference was found between the study groups (*Table 10*).

There were problems with this measure, however, as some women seemed to have been unclear about what had comprised their postnatal discharge check. The questionnaire stated 'the next set of questions ask about the final examination (postnatal check) that women have after having a baby', then asked if the woman had had a final postnatal check and, if so, when it was and who she had seen. In the intervention group, 91 women for whom the midwife had completed a check documentation sheet reported not having had a discharge check. This check was undertaken in the woman's home in the intervention group, whereas with current care it is usually done by the GP at the surgery. This finding probably relates to the widespread expectation of the discharge check being by the GP, even though consent to participate in the study required the women to agree to a midwife check. Interpretation of these findings is therefore difficult.

Talking about most health symptoms

The identification and management of the women's health problems were an important component of the redesigned care package, and the proportion of their symptoms that women had felt able to talk to the midwife about differed between study groups. The women in the intervention group were significantly more likely to have felt able to talk about all or most symptoms (*Table 10*).

No difficulty talking about health symptoms

The intervention group women were also significantly more likely to report having no difficulties in talking to the midwife about symptoms (*Table 10*).

Twelve-month study outcomes

Response rate at 12 months

There was a 75% response rate to the 12-month questionnaire, 73% from women in the intervention group (n = 781) and 76% from those in the control group (n = 731) (*Figure 2*). A second questionnaire was sent to non-responders followed by a telephone reminder to those who still failed to respond. At 12 months the GP practices were also contacted to check contact details of non-responders in an attempt to ensure that loss to follow-up did not increase relative to 4 months. Although the overall response level was maintained at 12 months, there was slightly more loss to follow-up among the intervention group. This may be accounted for by the higher proportion of women in the

intervention group who lived in rented accommodation, a group likely to be more mobile (*Table 2*). Reasons for loss to follow-up are shown in *Table 11*. The women known to have moved and not received their questionnaire and those who had said at 4 months that they did not want further follow-up are included as non-responders.

Table 12 compares the baseline characteristics of the responders and non-responders at 12 months. The pattern of response was the same as at 4 months, with more responders of lower parity, older, from less deprived areas, living with another adult and living in non-rented accommodation.

TABLE 11 *Reasons for loss to follow-up at 12 months*

	Intervention	Control
Withdrawn because:		
Moved before postnatal care	22	12
Baby died	2	1
No reply (after reminders)	241	187
Known to have left address	37	33
Did not wish to continue with follow-up	4	11
Total	306	244

TABLE 12 *Maternal and cluster characteristics of responders and non-responders to 12-month questionnaires*

	Responders (n = 1512)	Non-responders (n = 552)
(a) Maternal		
Parity		
0	679 (45.0)	204 (42.4)
1	532 (35.2)	156 (32.4)
≥ 2	299 (19.8)	121 (25.2)
Missing	2	71
Age (years)		
≤ 19	62 (4.1)	71 (13.4)
20–24	213 (14.1)	129 (24.4)
25–29	497 (32.9)	152 (28.7)
30–34	497 (32.9)	125 (23.6)
≥ 35	242 (16.0)	52 (9.8)
Missing	1	23
Mode of delivery		
Spontaneous vaginal delivery	987 (68.3)	341 (70.6)
Instrumental	175 (12.1)	48 (9.9)
Section	284 (19.6)	94 (19.5)
Missing	66	69
Perineal trauma[a]		
1st degree tear	160 (14.5)	56 (14.9)
2nd degree tear	224 (20.2)	75 (20.0)
3rd/4th degree tear	2 (0.2)	3 (0.8)
Episiotomy	272 (24.6)	58 (15.5)
Intact	449 (40.6)	183 (48.8)
Missing	121	83
Other adults in house		
0	165 (11.5)	83 (20.6)
1	1126 (78.2)	264 (65.7)
≥ 2	148 (10.3)	55 (13.7)
Missing	73	150
Age at completion of full-time time education (years)		
≤ 18	1043 (72.3)	296 (73.6)
≥ 19	399 (27.7)	106 (26.4)
Missing	70	150

continued

TABLE 12 *Maternal and cluster characteristics of responders and non-responders to 12-month questionnaires (cont'd)*

	Responders (n = 1512)	Non-responders (n = 552)
Social support score		
≤ 12	498 (35.5)	168 (44.3)
13–14	380 (27.1)	99 (26.1)
15	525 (37.4)	112 (29.6)
Missing	109	173
Home ownership		
Owned	1083 (75.6)	176 (44.3)
Rented	350 (24.4)	221 (55.7)
Missing	79	155
Townsend quartiles		
Most affluent	416 (28.4)	90 (16.7)
Affluent	396 (27.0)	97 (18.0)
Deprived	374 (25.5)	129 (23.9)
Most deprived	279 (19.0)	224 (41.5)
Missing	47	12
(b) Cluster		
No. of GP partners		
1	91 (6.0)	26 (4.7)
2–5	503 (33.3)	196 (35.5)
≥ 6	918 (60.7)	330 (59.8)
No. of midwives		
1	341 (22.6)	130 (23.6)
≥ 2	1171 (77.4)	422 (76.4)
Midwife qualification score		
Lower	803 (53.1)	269 (48.7)
Medium	351 (23.2)	139 (25.2)
Higher	358 (23.7)	144 (26.1)
Cluster size		
1–50	504 (33.3)	158 (28.6)
51–100	468 (31.0)	150 (27.2)
≥ 101	540 (35.7)	244 (44.2)

[a] Vaginal births only – responders (n = 1228), non-responders (n = 458).

Women's physical and psychological health and well-being at 12 months

The measurements of health and well-being used at 4 months postpartum were completed again by the women in their 12-month questionnaire, namely the SF-36 PCS and MCS and the EPDS. Again for each outcome, in addition to presenting the results of the cluster adjusted multi-level model analyses, the unweighted study group means of cluster means and the distributions of the individual cluster means are also given.

SF36 – PCS and MCS

As at 4 months postpartum, PCS at 12 months was not found to differ between study groups, as shown by the cluster mean scores and the multi-level results (*Table 13*). This lack of effect was not modified by entry into the multi-level model of other potential confounding factors. (*Table 14*). As might be expected, since more time from the birth had elapsed, the physical health scores had improved relative to 4 months postpartum in both study groups (see *Tables 5* and *13*).

The comparison of MCS, at 12 months, was again found to differ significantly between study groups, with a score that was 2.74 points higher in the intervention group (*Table 13*). The distributions by cluster showed that this increase was across clusters and not attributable to a few with atypical scores (*Table 15*). After adjusting for possible confounding factors the difference between groups was 3.13 points (*Table 14*). As with PCS, MCS had improved in both groups between 4 and 12 months (see *Tables 5* and *13*). In a multi-level model of 12 month MCS score, the 4 month MCS score was included as a predictor (*Table 16*). The coefficients for the 4-month score indicate that 4-month score

TABLE 13 *Physical and psychological health measures at 12 months postpartum by study group*[a]

	PCS	MCS	EPDS	EPDS 13 or more (OR)
Mean of cluster means[b]				
Control	48.37	48.29	7.60	21.60%
Intervention	48.01	51.15	6.16	12.24%
Difference (95% CI)	–0.37 (–1.88 to 1.15)	2.86 (0.93 to 4.79)	–1.45 (–2.40 to –0.49)	–9.37% (–14.44 to –4.29)
p-Value	0.628	0.005	0.004	0.001
Multi-level model				
Mean control value	48.76	48.46	7.62	1.0
Intervention effect size (95% CI)[c]	–0.24 (–1.37 to 0.89)	2.74 (1.48 to 4.0)	–1.54 (–2.26 to –0.82)	OR 0.46 (0.33 to 0.63)
χ^2 (1 df)	0.17	18.15	17.56	22.29
p-Value	0.6801	0.00002	0.0003	<0.0001
ICC	0.00359	0.00143	0.01297	–

[a] For PCS and MCS a higher score is better; for EPDS a lower score is better.
[b] Unweighted.
[c] Effect size for continuous variables is the regression coefficient from the cluster-adjusted multi-level model and transformed for binary variables to an odds ratio.

TABLE 14 *Physical and psychological health measures at 12 months postpartum by study group, adjusting for other characteristics*

	Effect size (95% CI)[a]			
Multi-level model	**PCS**	**MCS**	**EPDS**	**EPDS 13 or more (OR)**
Study group				
Control	Reference	Reference	Reference	Reference
Intervention	0.09 (–1.29 to 1.47)	3.13 (1.46 to 4.80)***	–1.80 (–2.56 to –1.04)***	0.34 (0.21 to 0.54)***
Maternal age group (years)				
20–24	Reference	Reference	Reference	Reference
≤ 19	–4.41 (–7.81 to –1.00)*	0.46 (–3.65 to 4.57)	0.99 (–0.86 to 2.84)	1.21 (0.49 to 2.96)
25–29	0.62 (–1.24 to 2.47)	1.07 (–1.17 to 3.31)	–0.21 (–1.22 to 0.80)	0.79 (0.46 to 1.36)
30–34	–0.50 (–2.43 to 1.44)	–0.27 (–2.60 to 2.07)	0.27 (–0.78 to 1.32)	0.88 (0.50 to 1.53)
≥ 35	–0.46 (–2.68 to 1.76)	–1.88 (–4.56 to 0.80)	1.03 (–0.18 to 2.24)	1.32 (0.71 to 2.46)
Parity				
0	Reference	Reference	Reference	Reference
1	–0.35 (–1.68 to 0.97)	–1.88 (–3.47 to –0.28)*	1.14 (0.42 to 1.86)**	1.55 (1.03 to 2.33)*
≥ 2	–1.18 (–2.90 to 0.53)	–3.08 (–5.15 to –1.01)**	1.70 (0.76 to 2.63)***	2.44 (1.49 to 4.00)***

continued

TABLE 14 *Physical and psychological health measures at 12 months postpartum by study group, adjusting for other characteristics (cont'd)*

	Effect size (95% CI)[a]			
Multi-level model	**PCS**	**MCS**	**EPDS**	**EPDS 13 or more (OR)**
Other adults in house				
One adult	Reference	Reference	Reference	Reference
No adults	–2.04 (–3.89 to –0.19)*	–0.31 (–2.54 to 1.92)	0.51 (–0.50 to 1.53)	0.87 (0.50 to 1.50)
Two or more adults	–1.89 (–3.87 to 0.09)	1.80 (–0.59 to 4.19)	0.07 (–1.01 to 1.14)	1.07 (0.63 to 1.84)
Mode of delivery				
Normal delivery	Reference	Reference	Reference	Reference
Instrumental delivery	0.45 (–1.73 to 2.63)	–2.70 (–5.33 to –0.07)*	0.59 (–0.59 to 1.76)	1.07 (0.56 to 2.03)
Caesarean section	–2.03 (–3.64 to –0.42)*	–2.32 (–4.26 to –0.38)*	1.43 (0.56 to 2.30)**	1.46 (0.93 to 2.29)
Townsend quartiles				
Quartile 1 (most affluent)	Reference	Reference	Reference	Reference
Quartile 2 (affluent)	–0.20 (–1.70 to 1.30)	–0.80 (–2.60 to 1.01)	0.56 (–0.26 to 1.38)	1.17 (0.72 to 1.89)
Quartile 3 (deprived)	–2.22 (–3.85 to –0.59)**	–1.38 (–3.35 to 0.60)	1.42 (0.53 to 2.31)	1.65 (1.01 to 2.68)*
Quartile 4 (most deprived)	–0.44 (–2.38 to 1.49)	0.62 (–1.72 to 2.95)	0.59 (–0.47 to 1.64)	1.04 (0.58 to 1.88)
Social support score				
Most support	Reference	Reference	Reference	Reference
Medium support	–0.57 (–1.96 to 0.82)	–2.60 (–4.27 to –0.92)**	1.16 (0.40 to 1.92)	1.31 (0.86 to 2.00)
Least support	–0.94 (–2.24 to 0.35)	–2.77 (–4.34 to –1.21)***	1.26 (0.56 to 1.96)	1.46 (1.00 to 2.15)
Home ownership				
Owned	Reference	Reference	Reference	Reference
Rented	1.64 (–3.17 to –0.11)*	–1.31 (–3.16 to 0.54)	0.86 (0.03 to 1.70)*	1.63 (1.07 to 2.49)*
Mean values for reference group	51.20	53.07	3.70	

[a] Effect size for continuous outcome variables is the regression coefficient from the cluster-adjusted multi-level model transformed for binary outcomes to an odds ratio.
* $p < 0.05$.
** $p < 0.01$.
*** $p < 0.001$.

TABLE 15 *PCS and MCS in individual clusters at 12 months by study group*

Mean PCS[a]		Mean MCS[a]	
Intervention clusters (*n* = 17)	**Control clusters (*n* = 19)**	**Intervention clusters (*n* = 17)**	**Control clusters (*n* = 19)**
51.27	50.83	57.63	51.53
50.84	50.67	56.49	51.52
50.10	50.07	55.52	51.01
49.98	50.06	52.10	50.99
49.55	49.98	51.88	50.31
48.97	49.86	51.83	49.66
48.79	49.65	51.55	48.95
48.72	49.37	51.33	48.95
48.49	49.04	51.20	48.94
47.74	48.64	50.43	48.93
47.28	48.43	50.41	48.22
47.26	48.29	50.17	47.88
46.92	48.24	49.57	47.74
46.80	48.04	49.42	47.24
46.75	47.71	48.71	46.78
44.85	46.58	47.09	46.36
41.79	46.01	44.21	45.28
	45.77		44.43
	41.79		42.77

[a] Cluster mean values ordered in terms of best outcome score.

is a very strong predictor of 12-month score. The size of the intervention effects, even after adjusting for 4-month score, suggest further beneficial effect of the intervention, not simply residual longer term benefit from the earlier effect.

EPDS

The mean EPDS score and the proportion of women with a score of 13 or more were both significantly lower (better) in the intervention compared with control group (*Table 13*). This improvement was across clusters (*Table 17*) and, as at 4 months, adjustment for possible confounders increased the effect size (*Table 14*). Between 4 and 12 months the mean EPDS scores had improved in both groups, but the proportion with a score of 13 or more had reduced only in the intervention group (see *Tables 5* and *13*). As for MCS, in the multi-level model of 12-month EPDS score ≥ 13 which included the 4-month scores as a predictor, study group still showed a significant effect, although not quite for mean score.

Individual domain scores

The mean SF-36 individual domain scores at 12 months are given in *Table 18*. Most of these scores were higher than at 4 months but there was least change over time for vitality and general health. As at 4 months, mean scores for mental health, role limitation emotional and vitality were significantly greater in the intervention group, but at 12 months the mean score for general health was also better.

Women's reported morbidity

Women's morbidity reported at 12 months postpartum in the postal questionnaire was a secondary study outcome. The morbidities specified were based on those covered in the symptom checklist. *Table 19* shows the cluster-adjusted odds ratios of whether each of the specified health problems was present at 12 months postpartum, as reported by the women. To indicate how common the various symptoms were among the women at this stage, the crude numbers are also presented. Depression, fatigue and haemorrhoids were significantly less likely to be reported as present at 12 months postpartum in the intervention group relative to controls, whereas for the other morbidities there were no significant differences. The more immediate postpartum problems, relating to Caesarean section wounds, breastfeeding, uterine infection and heavy vaginal bleeding, which were assessed based on whether they had been present at all following the birth, did not differ between study groups (*Table 20*).

Other secondary outcomes

Other secondary outcomes were additional indicators of good midwife or GP postnatal practices.

TABLE 16 *Physical and psychological health measures at 12 months by study group, adjusting for 4-month scores*

	Effect size (95% CI)[a]			
Multi-level model	**PCS**	**MCS**	**EPDS**	**EPDS 13 or more**
Study group				
Control	Reference	Reference	Reference	Reference
Intervention	0.38 (–0.54 to 1.29)	1.24 (0.18 to 2.29)	–0.44 (–0.90 to 0.009)	OR 0.46 (0.33 to 0.66)
4-month score	0.56 (0.52 to 0.60)	0.55 (0.51 to 0.60)	0.67 (0.63 to 0.71)	OR 15.70 (11.01 to 22.39)
Mean values for reference group	21.99	21.74	2.29	–

[a] Effect size for continuous outcome variables is the regression coefficient from the cluster-adjusted multi-level model.

TABLE 17 *EPDS in individual clusters at 12 months by study group*

Mean EPDS[a]		EPDS 13 or more (%)[a]	
Intervention clusters (*n* = 17)	**Control clusters (*n* = 19)**	**Intervention clusters (*n* = 17)**	**Control clusters (*n* = 19)**
3.10	5.76	0[b]	11.1
3.35	6.20	0[b]	12.5
5.02	6.44	5.9	15.2
5.23	6.61	7.1	15.6
5.48	6.63	7.4	16.7
5.78	6.70	7.6	17.4
5.79	6.78	8.5	17.6
5.82	6.81	9.7	20.0
6.01	7.00	10.7	20.5
6.33	7.50	12.1	21.4
6.43	7.51	12.2	22.2
6.55	7.56	12.7	22.2
7.21	8.22	15.1	24.6
7.31	8.50	17.6	25.0
7.32	8.76	23.1	26.1
8.67	9.03	25.0	27.6
9.25	9.06	33.3	31.2
	9.30		31.2
	10.06		32.2

[a] Cluster mean values ordered in terms of best outcome score.
[b] No women in these clusters had a score of 13 or more.

Breastfeeding continuation

Since the intervention tested in this trial was community based, there was no possibility of an effect on the uptake of breast feeding. Continuation of breastfeeding, however, could have been affected and was evaluated. A higher proportion of women in the intervention group than controls reported having commenced breastfeeding, although the difference was not statistically significant. Of the 523 intervention women (68.9%) who started breastfeeding, 214 (41.8%) were still feeding at 4 months and 60 (11.7%) at 12 months, compared with 175 (38.3%) and 44 (9.6%), respectively, of the 460 (64.3%) controls who had commenced feeding. The cluster-adjusted model, however, showed no statistically significant differences between study groups in terms of either the odds of breastfeeding continuation to 4 or to 12 months or in the mean number of days of feeding (*Table 21*).

Contraception

Discussion of contraception is traditionally covered by GPs. To ensure that this was covered by the intervention midwives, there was space to record that contraception had been discussed with the woman (and, if required, referral advised) at the first home visit and again at the 10–12-week discharge check. This discussion was recorded on almost all of the first home visit and the discharge check sheets returned to the study office (see later). The data from the GP records (see later, *Table 48*) showed, as expected, that contraception was much more likely to be a topic of a GP consultation for control than intervention group women when postnatal care consultations were included (i.e. 0–365 days). Consulting with the GP in the first year about contraception outside of postnatal care, however, did not differ between the groups [odds ratio (OR) 0.93, 95% CI 0.67 to 1.28]. Significantly more women consulted about a subsequent pregnancy in the control group (OR 0.60, 95% CI 0.37 to 0.99), supporting the likelihood that contraceptive advice had been adequately provided for the intervention group women.

Immunisation of baby

Since the intervention group women were not seen by the GP routinely for their postnatal care, this might have affected opportunistic immunisation uptake for the infant. Information on immunisation completeness, recorded from GP notes, showed that all immunisations due by 12 months were complete for 98% of infants in both study groups (*Table 22*). A cluster adjusted multi-level analysis was not considered necessary.

TABLE 18 *Individual SF-36 domain values at 12 months by study group*

Multi-level model	Physical functioning	Social functioning	Role limitation physical	Role limitation emotional
Mean control value	91.19	83.39	84.92	78.79
Intervention effect size (95% CI)[a]	–0.19 (–2.25 to 1.86)	1.70 (–0.62 to 4.02)	0.07 (–2.14 to 3.69)	5.28 (1.94 to 8.62)
χ^2	0.034	2.055	0.271	9.600
p-Value	0.854	0.152	0.602	0.002
ICC	0.01365	0.00273	<0.0001	<0.0001
	Mental health	**Vitality**	**Bodily pain**	**General health**
Mean control value	70.25	51.99	80.31	73.85
Intervention effect size (95% CI)[a]	3.72 (1.48 to 5.95)	4.43 (2.27 to 6.60)	1.21 (–1.38 to 3.81)	2.30 (0.30 to 4.29)
χ^2	10.638	16.161	0.836	5.093
p-Value	0.001	0.00006	0.361	0.024
ICC	0.00877	<0.0001	0.00480	<0.0001

[a] Effect size for continuous outcome variables is the regression coefficient from the cluster-adjusted multi-level model.

TABLE 19 *Reported morbidities present at 12 months postpartum by study group*

	Intervention (*n* = 781)	Control (*n* = 731)	Multi-level model: control/intervention effect size[a] OR (95% CI)
Backache	249	250	0.92 (0.41 to 2.07)
Headache	187	203	0.94 (0.72 to 1.22)
Depression	110	141	0.71 (0.54 to 0.94)
Fatigue	193	221	0.75 (0.60 to 0.94)
Dyspareunia	56	43	1.27 (0.76 to 2.10)
Stress incontinence	124	126	0.90 (0.68 to 1.19)
Haemorrhoids	85	112	0.67 (0.50 to 0.91)
Constipation	43	59	0.68 (0.42 to 1.08)
Bowel control problems	35	28	1.18 (0.71 to 1.96)
Perineal pain	73	93	0.92 (0.46 to 1.90)

[a] Effect size for continuous variables is the regression coefficient from the cluster-adjusted multi-level model and transformed for binary variables to an odds ratio.

TABLE 20 *Reported short-term morbidities occurring after the birth by study group*

	Intervention (*n* = 781)	Control (*n* = 731)	Multi-level model: control/intervention effect size[a] OR (95% CI)
Caesarean section wound problems	52	35	1.08 (0.62 to 1.88)[b]
Breastfeeding problems	236	216	0.95 (0.72 to 1.27)[c]
Heavy vaginal bleeding	138	161	0.70 (0.48 to 1.01)
Uterine infection	30	36	0.77 (0.47 to 1.27)

[a] Effect size for continuous variables is the regression coefficient from the cluster-adjusted multi-level model and transformed for binary variables to an odds ratio.
[b] Among Caesarean section deliveries.
[c] Among women who ever breastfed.

TABLE 21 *Breast feeding continuation by study group*

	Breastfeeding duration (days)
Mean of cluster means[a]	
Control	140.13
Intervention	140.40
Difference (95% CI)	–0.26 (–23.12 to 22.59)
p-Value	
Multi-level model	
Mean control value	137.84
Intervention effect size (95% CI)[b]	7.17 (–14.66 to 28.99)
χ^2	0.41
p-Value	0.522
ICC	0.02636
Still feeding at 4 months	
OR (95% CI)	1.05 (0.75 to 1.48)
Still feeding at 12 months	
OR (95% CI)	1.25 (0.83 to 1.88)

[a] Unweighted.
[b] Effect size for continuous variables is the regression coefficient from the cluster-adjusted multi-level model.

TABLE 22 *Immunisation of the infant recorded in GP notes by study group*

	Intervention (*n* = 608)	Control (*n* = 613)
Complete	592	590
Incomplete	9	8
Refused/did not answer	2	3
Missing	5	12

Views of health professionals

Questionnaires to assess the health professionals' views about care were sent to the midwives and GPs at the end of the intervention period. Although modification to health visitor care was not part of the intervention, since this professional group is also involved in providing care for postnatal women, the health visitors attached to the trial practices were also sent a questionnaire to ascertain their views. Response rates for the various groups are shown in *Table 23*. These were similar between the study groups. We had expected a higher response rate for the midwives,

TABLE 23 *Response rates of health professional groups*

No. in group	Questionnaires returned:	
	No. (%)	No. of clusters
Midwives		
Intervention: *n* = 42	31 (73.8)	15
Control: *n* = 38	28 (73.7)	16
GPs		
Intervention: *n* = 97	63 (65.0)	17
Control: *n* = 77	58 (75.3)	17
Health visitors		
Intervention: *n* = 31	26 (83.9)	15
Control: *n* = 27	24 (88.9)	16

TABLE 24 *Age and years qualified of midwives by study group*

	Intervention: midwives = 31 clusters = 15 No. (%)	Control: midwives = 28[a] clusters = 16 No. (%)
Age (years)		
26–35	8 (25.8)	3 (11.1)
36–45	19 (61.9)	16 (59.3)
46–55	4 (12.9)	7 (25.9)
56–65	–	1 (3.7)
Years qualified		
<10	7 (22.6)	7 (25.9)
10–15	14 (45.2)	10 (37.0)
16–20	7 (22.6)	5 (17.9)
>20	3 (9.7)	6 (22.2)

[a] One control group midwife did not answer.

but we only had work addresses and several midwives had retired or moved out of the local area, and so could not be traced and did not receive a questionnaire. Not all of the trial clusters were represented among the health professionals who returned questionnaires (*Table 23*).

In comparing the health professionals' views by study group, in order to take account of possible inter-relationships between those in the same cluster, the mean cluster scores for each of the variables were calculated and the tests of statistical significance were based on the means of these for each study group. Because of small numbers, the multi-level model analysis used in the other study group comparisons was not meaningful. Crude numbers are also given in the tables.

Midwives

The age groups of the midwives and their years since qualifying are shown in *Table 24*. In seeking information from the midwives, those in the intervention group were asked about the redesigned care and the control midwives about current care. Their satisfaction with the organisation of postnatal care generally, and their satisfaction with the specific roles of the three professional groups midwives, GPs and health visitors, involved in its provision were shown to differ significantly between the study groups. Although dissatisfied responses were rare in both groups, the intervention midwives were likely to be more satisfied than controls, especially in relation to their own role (*Table 25*). Whether the midwives felt that the postnatal care service was able to deliver care that was appropriate to women's individual needs also differed: more of the intervention midwives considered that the redesigned care was appropriate than did the control midwives in relation to standard care (*Table 25*). Whether postnatal care makes the most appropriate use of the skills and time of midwives produced similarly positive responses in both groups (*Table 26*), as did their views

TABLE 25 *Midwives' views about postnatal care by study group*

Satisfaction scores for	Intervention: midwives = 31 clusters = 15 No. (%)	Control: midwives = 28 clusters = 16 No. (%)	*p*-Value[a]
Organisation of postnatal care			
Very satisfied (4)	17 (54.8)	3 (10.7)	
Satisfied (3)	13 (41.9)	21 (73.0)	
Neither satisfied/dissatisfied (2)	1 (3.2)	2 (7.1)	
Fairly dissatisfied (1)	–	2 (7.1)	
Mean of cluster means (SD)	3.58 (0.44)	2.95 (0.39)	<0.001
Role of midwife			
Very satisfied (4)	23 (74.2)	7 (25.0)	
Fairly satisfied (3)	7 (22.6)	21 (75.0)	
Neither satisfied/dissatisfied (2)	1 (3.2)	–	
Mean of cluster means (SD)	3.73 (0.38)	3.26 (0.38)	0.002
Role of GP			
Very satisfied (4)	9 (29.0)	1 (3.6)	
Fairly satisfied (3)	11 (35.5)	7 (25.0)	
Neither satisfied/dissatisfied (2)	7 (22.6)	9 (32.2)	
Fairly dissatisfied (1)	3 (9.7)	7 (25.0)	
Dissatisfied (0)	1 (3.2)	4 (14.3)	
Mean of cluster means (SD)	2.78 (0.93)	1.64 (0.87)	0.002
Role of health visitor			
Very satisfied (4)	12 (38.7)	3 (10.7)	
Fairly satisfied (3)	11 (35.5)	19 (67.9)	
Neither satisfied/dissatisfied (2)	6 (19.4)	3 (10.7)	
Fairly dissatisfied (1)	–	3 (10.7)	
Dissatisfied (0)	2 (6.5)	–	
Mean of cluster means (SD)	2.99 (0.97)	2.80 (0.70)	0.545
Organisation of postnatal care allows care appropriate to individual needs			
Yes, in most cases (2)	29 (93.5)	15 (53.6)	
Yes, in some cases (1)	2 (6.5)	11 (39.3)	
No (0)	–	2 (7.1)	
Mean of cluster means (SD)	1.94 (0.15)	1.45 (0.46)	<0.001

[a] Based on comparison of the mean score of all the cluster means in each study group. Scores were calculated from the figures in parentheses.

about the extent to which there was opportunity to discuss postnatal concerns of the women when necessary with the GP or the health visitor (*Table 27*).

In addition to the various assessments of midwife views about care, some information on their perceptions of their own practice during the trial period was obtained. Practice in relation to when they generally undertook the various observations and examinations is shown in *Table 28*. For uterine palpation, observation of the lochia and examination of the legs, more control midwives reported performing these at most of their home visits, whereas more intervention midwives said they did them when necessary, although these differences were not statistically significant. At which visits the midwives generally performed the various other observations was similar across the groups (*Table 28*). The midwives' perceptions of whether they gave a similar number of visits to most women were similar between the groups and the average number of visits that these midwives reported giving is shown on *Table 29*.

Information that was specific to the redesigned care or specific to standard care, was separately obtained from the two groups of midwives. **Intervention midwives** were asked if they had had any difficulties with the various specified aspects of the redesigned care, with an open-ended section included where they could note difficulties with any other aspects (*Table 30*). Difficulties with any of the aspects were rare, except for undertaking the discharge check at 10–12 weeks, which over one-third reported finding difficult. Unfortunately, however, the wording of the question did not

TABLE 26 *Views of whether postnatal care makes appropriate use of midwife skills and time by study group*

	Intervention: midwives = 31 clusters = 15 No. (%)	Control: midwives = 28 clusters = 16 No. (%)	*p*-Value[a]
Skills (score)			
Yes (1)	30 (96.8)	25 (89.3)	
No (0)	1 (3.2)	2 (7.1)	
Don't know (excluded)	–	1 (3.6)	
Mean of cluster means (SD)	0.98 (0.09)	0.92 (0.26)	0.391
Time (score)			
Yes (1)	25 (80.6)	24 (85.7)	
No (0)	2 (6.5)	1 (3.6)	
Don't know (excluded)	4 (12.9)	3 (10.7)	
Mean of cluster means (SD)	0.93 (0.18)	0.93 (0.26)	1.00

[a] Based on comparison of the mean score of all the cluster means in each study group. Scores were calculated from the figures in parentheses.

TABLE 27 *Midwives' views of whether they have opportunity to discuss postnatal concerns of women with other health professionals by study group*

	Intervention: midwives = 31 clusters = 15 No. (%)	Control: midwives = 28 clusters = 16 No. (%)	*p*-Value[a]
With GP (score)			
Almost always (3)	24 (77.4).	26 (92.9)	
Sometimes (2)	5 (16.1)	1 (3.6)	
Rarely (1)	1 (3.2)	–	
Never (0)	–	–	
Don't know (excluded)	1 (3.2)	1 (3.6)	
Mean cluster of means (SD)	2.62 (0.78)	2.97 (0.13)	0.09
With health visitor (score)			
Almost always (3)	27 (87.1)	24 (85.7)	
Sometimes (2)	2 (6.5)	3 (10.7)	
Rarely (1)	–	–	
Never (0)	1 (3.2)	–	
Don't know (excluded)	1 (3.2)	1 (3.6)	
Mean cluster of means (SD)	2.88 (0.29)	2.92 (0.20)	0.58

[a] Based on comparison of the mean score of all the cluster means in each study group. Scores were calculated from the figures in parentheses.

distinguish between a difficulty in them undertaking the check (rather than the GP) or in undertaking it at 10–12 weeks. The midwives' responses to whether they had found the guidelines to be helpful were equally divided between having found them very helpful or just helpful: only three midwives had found them unhelpful, all for different reasons (*Table 31*). Almost all of the intervention midwives said that they would like to continue to provide the redesigned care, only two not wanting to (both for reasons relating to the final check) and two more unsure. Reasons for these responses, elicited using an open-ended format, were varied (*Table 32*). Views on whether the midwives felt the redesigned care had increased their workload varied: 12 (38.7%) thought it had not, 16 (51.6%) thought it had a little and 3 (9.7%) thought it had a lot. Finally, the midwives' views on whether it had benefited women's health showed that most thought it had: 15 (48.4%) thought it had benefited health a lot and 10 (32.3%) a little. There were four (12.9%) who felt there was no additional benefit and two (6.5%) who were unsure.

TABLE 28 *Examination/observation: reported practices of midwives by study group*

Examination (score)[a]	Intervention: midwives = 31 clusters = 15 No. (%)	Control: midwives = 28 clusters = 16 No. (%)	*p*-Value[b]
Abdominal palpation			
When necessary (2)	15 (50.0)	10 (35.7)	
First visit only (1)	6 (20.0)	–	
At most visits (0)	9 (30.0)	18 (64.9)	
Mean of cluster means (SD)	1.26 (0.69)	0.75 (0.83)	0.079
Lochia			
When necessary (2)	15 (50.0)	7 (25.0)	
First visit only (1)	3 (10.0)	–	
At most visits (0)	12 (40.0)	21 (75.0)	
Mean of cluster means (SD)	1.05 (0.82)	0.52 (0.80)	0.085
Perineum			
When necessary (2)	19 (63.3)	22 (78.6)	
First visit only (1)	4 (13.3)	–	
At most visits (0)	7 (23.3)	6 (21.4)	
Mean of cluster means (SD)	1.46 (0.67)	1.54 (0.75)	0.770
Breast			
When necessary (2)	28 (93.3)	26 (92.9)	
First visit only (1)	1 (3.3)	–	
At most visits (0)	1 (3.3)	2 (7.1)	
Mean of cluster means (SD)	1.89 (0.29)	1.81 (0.54)	0.625
Legs			
When necessary (2)	21 (70.0)	13 (48.2)	
First visit only (1)	4 (13.3)	–	
At most visits (0)	5 (16.7)	14 (51.8)	
Mean of cluster means (SD)	1.52 (0.65)	1.02 (0.86)	0.087
Temperature			
When necessary (2)	28 (93.3)	26 (92.9)	
First visit only (1)	2 (6.7)	1 (3.6)	
At most visits (0)	–	1 (3.6)	
Mean of cluster means (SD)	1.94 (0.15)	1.91 (0.27)	0.681
Blood pressure			
When necessary (2)	26 (86.7)	23 (82.1)	
First visit only (1)	4 (13.3)	4 (14.3)	
At most visits (0)	–	–	
Mean of cluster means (SD)	1.87 (0.22)	1.88 (0.29)	0.950

[a] One intervention midwife did not answer any of this set of questions and one control midwife did not answer for leg examination.

[b] Based on comparison of the mean score of all the cluster means in each study group. Scores were calculated from the figures in parentheses.

TABLE 29 *Midwife-reported visit frequency patterns by study group*

	Intervention: midwives = 31 clusters = 15 No. (%)	Control: midwives = 28 clusters = 16 No. (%)
Give similar No. of visits to women	16 (51.6)	11 (39.3)
If similar what is average No.	*n* = 16	*n* = 11
≤ 4	1	1
5	6	2
6	5	5
7	3	1
≥ 8	2	2

TABLE 30 *Difficulties with aspects of redesigned care among intervention midwives*

Had difficulties with:	**Intervention midwives: *n* = 31 No. (%)**
Changing visit frequency	4 (12.9)
Using guidelines	4 (12.9)
Visiting up to 28 days	1 (3.2)
Changing content of visits	2 (6.5)
Accepting main responsibility for postnatal care	1 (3.2)
Undertaking check at 10–12 weeks	12 (38.7)
Liaising with GPs	3 (9.7)
Liaising with health visitors	2 (6.5)
Other:	
Giving family planning advice	1
Arranging the later visit	1
Remembering to record visit duration	1
Difficulties only until familiar	1

TABLE 31 *Views about helpfulness of guidelines among intervention midwives*

	Intervention midwives: *n* = 31 No. (%)
Found guidelines	
Very helpful	14 (45.2)
Helpful	14 (45.2)
Unhelpful	3 (9.7)
Very unhelpful	–
Reasons if unhelpful[a]	
Practice already in line with guideline advice	1
Guidelines only told me what already knew	1
Other health problems (e.g. thrombosis) needed including	1
Would be helpful to students or new midwives	1

[a] Could give more than one reason.

Control midwives were asked if they routinely question the mother about any particular health problems and, if so, which are they. Two-thirds (67.9%) said they did routinely ask about something: urinary problems, followed by bowel and psychological problems, were the ones most commonly assessed (*Table 33*). Just over one-third of control midwives said there were local policies or guidelines available to help plan postnatal care: guidance on selective visiting was mentioned by six of the midwives. Routine discharge of women by the control midwives generally still followed the traditional pattern, with most of them discharging women by day 14, with only six midwives routinely visiting after this (*Table 34*).

GPs

The questionnaire designed for GPs was purposely brief to facilitate an acceptable response rate, which was achieved (*Table 23*). The demographic characteristics of the groups are shown in *Table 35*. Since the GPs were not the main focus of intervention care, unlike the midwives, they were not asked to answer the questions with reference to care during the trial period, but about postnatal care generally. With the exception of one question about consultations with women recruited to the trial, the questions to GPs in both groups were the same. The GP levels of satisfaction with the current roles of the three professional groups involved in postnatal care were shown to be similar in the study groups (*Table 36*). Satisfaction with the role of the GP was generally lower than the satisfaction that the midwives had reported with their postnatal role. Over three-quarters of the GPs, however, felt that the current organisation and content of community postnatal care is appropriate to the individual needs of women; this again was similar in both groups (intervention 44/61, 72.1%; control 45/58, 77.6%). The extent to which the GPs felt there was opportunity to discuss any postnatal

TABLE 32 *Views about continuing with redesigned care among intervention midwives*

	Intervention midwives: *n* = 31 No. (%)
Would like to continue	27 (87.1)
Reasons[a]	
Enabled midwives to concentrate on women as individuals	9
Enjoyable to see women over a longer period	6
Increased continuity of care	3
Enjoyed responsibility to detect and deal with problems	3
Allowed mothers to take more control of own health	3
Could spend quality time with women	3
Mothers open and trusting of midwives	3
Enjoyed flexibility of visits	2
Care satisfied both mother and midwife	2
Visits only undertaken when required	2
Yes, but need to ensure cooperation of GPs and health visitors	2
Better use of time	1
Could give extra support when wanted	1
Liked doing the postnatal check	1
Made more confident about selective visiting	1
Yes, but too much paperwork	1
Would like to continue without 10–12-week check	1
Would not like to continue	2 (6.5)
Reasons[a]	
Had to chase women up to do 10–12-week check	1
Not relevant for midwife to see woman at 10–12 weeks	2
Unsure about continuing	2 (6.5)

[a] Could give more than one reason.

TABLE 33 *Routine questioning about any particular health problems among control midwives*

	Control midwives: *n* = 28 No. (%)
Ask routinely	19 (67.9)
Problems asked about	
Urinary problems	12
Bowel problems	7
Psychological problems	6
Backache	3
How woman feels generally	3
How is woman coping with baby and family	2
They have any pain	2
Trouble sleeping	1
Problems with feeding	1
Breast problems	1
Dizziness	1
Explain symptoms of DVT[a]	1
Don't ask routinely, only if notice something	1

DVT, deep vein thrombosis.

concerns of women with the midwives or health visitors was also generally positive and similar in both groups (*Table 37*).

Views on whether GPs should, or should not, routinely see all postnatal women, and their reasons for this (open-ended responses) were

TABLE 34 *Postnatal day of average routine discharge among control midwives*

By day	Control midwives: *n* = 28 No. (%)
10	4 (14.3)
11–12	5 (17.9)
13–14	8 (28.6)
15–16	2 (7.1)
17–20	1 (3.6)
Later	3 (10.7)
Don't know	5 (17.9)

TABLE 35 *Demographic characteristics of GPs by study group*

	Intervention: GPs = 63 clusters = 17 No. (%)	Control: GPs = 58 clusters = 17 No. (%)
Age (years)		
25–35	13 (22.4)	14 (24.6)
36–45	23 (39.7)	22 (38.6)
46–55	18 (31.0)	16 (28.1)
56–65	4 (6.9)	5 (8.8)
Missing	5	1
Male	35 (58.3)	36 (63.2)
Female	25 (41.7)	21 (36.8)
Missing	3	1
Full-time	47 (79.7)	43 (76.8)
Part-time	12 (20.3)	13 (23.2)
Missing	4	2
DRCOG	32 (55.2)	33 (57.9)
Missing	5	1

DRCOG, Diploma of the Royal College of Obstetricians and Gynaecologists.

similar between groups, with an almost equal proportion of GPs holding both views (*Table 38*). The various examinations or tests that the GPs said they routinely include in the 6–8-week discharge check were similar between groups (*Table 39*).

The intervention group GPs were asked whether during the trial period they had continued to make routine home visits and undertake the 6–8-week postnatal check. From these reports (*Table 40*), around half had generally continued to do both. The control group GPs were asked about their routine postnatal care. There were 36 (62.1%) who said they routinely make postnatal home visits, most (21) usually only one visit, and all (except one GP who did not answer this) offered a 6–8-week check.

Health visitors

No change to health visitor activity was specified in the intervention group, but the questionnaires were sent to the health visitors attached to the trial practices and responses from 31 practices were received. *Table 41* shows the demographic characteristics. The health visitors' level of satisfaction with the roles of the three professional groups involved in postnatal care did not differ between the intervention and control practice clusters, nor did their views on whether postnatal care is appropriate to individual health needs (*Table 42*). The extent to which they felt there was opportunity to discuss postnatal concerns with GPs and midwives was also similar across intervention and control groups (*Table 43*). Information about the health visitors' usual postnatal practice in the period is shown in *Table 44*.

Although health visitor care was not part of the intervention, it may have been modified by it. In the women's 28-day home visit diaries and in the 4-month questionnaires, information on the number of visits by the health visitor was recorded

TABLE 36 *GPs' views about postnatal care by study group*

Satisfaction scores with roles of	Intervention: GPs = 63 clusters = 17 No. (%)	Control: GPs = 58 clusters = 17 No. (%)	*p*-Value[a]
GPs			
Very satisfied (4)	18 (30.5)	15 (25.9)	
Fairly satisfied (3)	23 (39.0)	27 (46.6)	
Neither satisfied nor dissatisfied (2)	12 (20.3)	10 (17.2)	
Fairly dissatisfied (1)	5 (8.5)	6 (10.3)	
Very dissatisfied (0)	1 (1.7)	–	
Don't know (excluded)	4		
Mean of cluster means (SD)	3.05 (0.72)	3.04 (0.62)	0.979
Midwife			
Very satisfied (4)	26 (44.1)	29 (50.0)	
Fairly satisfied (3)	26 (44.1)	22 (37.9)	
Neither satisfied nor dissatisfied (2)	7 (11.9)	5 (8.6)	
Fairly dissatisfied (1)	–	2 (3.4)	
Very dissatisfied (0)	–	–	
Don't know (excluded)	4		
Mean of cluster means (SD)	3.38 (0.45)	3.45 (0.39)	0.661
Health visitor			
Very satisfied (4)	24 (40.7)	21 (36.8)	
Fairly satisfied (3)	31 (52.5)	27 (47.4)	
Neither satisfied nor dissatisfied (2)	4 (6.8)	7 (12.3)	
Fairly dissatisfied (1)	–	2 (3.5)	
Very dissatisfied (0)	–	–	
Don't know (excluded)	4	1	
Mean of cluster means (SD)	3.37 (0.39)	3.25 (0.55)	0.457

[a] Based on comparison of the mean scores of all the cluster means in each study group. Scores were calculated from the figures in parentheses.

TABLE 37 *GPs' views of whether they have opportunity to discuss postnatal concerns of women with other health professionals by study group*

	Intervention: GPs = 63 clusters = 17 No. (%)	Control: GPs = 58 clusters = 17 No. (%)	*p*-Value[a]
With midwife (score)			
Almost always (3)	41 (70.7)	45 (77.6)	
Sometimes (2)	8 (13.8)	11 (19.0)	
Rarely (1)	2 (3.4)	1 (1.7)	
Almost never (0)	7 (12.1)	1 (1.7)	
Missing (excluded)	5	–	
Mean of cluster means (SD)	2.46 (0.76)	2.73 (0.36)	0.188
With health visitor (score)			
Almost always (3)	41 (69.5)	44 (75.9)	
Sometimes (2)	16 (27.1)	8 (13.8)	
Rarely (1)	2 (3.4)	4 (6.9)	
Almost never (0)	–	2 (3.4)	
Missing (excluded)	4	–	
Mean of cluster means (SD)	2.62 (0.37)	2.63 (0.57)	0.934

[a] Based on comparison of the mean scores of all the cluster means in each study group. Scores were calculated from the figures in parentheses.

TABLE 38 *GPs' views on whether they should routinely see postnatal women and reasons by study group*

Reasons why GPs should routinely see postnatal women			
Intervention (*n* = 32)		**Control (*n* = 31)**	
Good for relationship with family/woman	21	Good for relationship with family/woman	15
To give advice on contraception	7	To give advice on contraception	2
To provide continuity of care	6	To provide continuity of care	8
To detect PND	4	To detect PND	2
To provide support for mother	4	Opportunity to discuss any problems	5
GPs should see but at surgery	2	For 6-week check	3
		To counsel about delivery	3
		To assess health of woman	2
Reasons why GPs should not routinely see postnatal women			
Intervention (*n* = 28)		**Control (*n* = 27)**	
Midwives have necessary skills	8	Midwives have necessary skills	1
Not medically necessary	7	Not medically necessary	3
Midwives/health visitors will refer if necessary	5	Midwives/health visitors will refer if necessary	12
Not cost-effective/inappropriate resource usage	6	GP is available if required	11
GPs don't have time/workload problems	7		

TABLE 39 *Observations/examinations that GPs routinely include in 6–8-week check by study group*

	Intervention: GPs = 63[a] clusters = 17 No. (%)	**Control: GPs = 58 clusters = 17 No. (%)**
Blood pressure	46 (74.2)	46 (79.3)
Abdominal examination	35 (56.5)	32 (56.1)
Weight	27 (43.5)	22 (37.9)
Vaginal	20 (32.3)	13 (22.4)
Urine	19 (30.6)	15 (25.9)
Blood sample	7 (11.3)	5 (8.6)

[a] One intervention GP did not answer these questions.

TABLE 40 *Postnatal practice of intervention group GPs during trial period*

GP completed	**(*n* = 63)**
Home visits	
Almost always	25 (43.1)
Sometimes	10 (17.2)
Rarely	5 (8.6)
Almost never	18 (31.0)
Missing	5
6–8-week check	
Almost always	29 (53.7)
Sometimes	8 (14.8)
Rarely	5 (9.3)
Almost never	12 (22.2)
Missing	9

TABLE 41 *Demographic characteristics of health visitors (HVs) attached to study practices*

	Intervention: HVs = 26 clusters = 15 No. (%)	**Control: HVs = 24 clusters = 16 No. (%)**
Age (years)		
26–35	2 (8.0)	6 (25.0)
36–45	11 (44.0)	8 (33.3)
46–55	9 (36.0)	10 (41.7)
56–65	3 (12.0)	–
Missing	1	–
Years qualified		
<10	6 (23.1)	13 (54.2)
10–15	13 (50.0)	2 (8.3)
15–20	3 (11.5)	5 (20.8)
>20	4 (15.4)	4 (16.7)
Qualified as midwife	11 (42.3)	7 (29.2)

TABLE 42 *Health visitors' views about postnatal care in intervention and control practices*

Satisfaction scores with roles of	Intervention: HVs = 26 clusters = 15 No. (%)	Control: HVs = 24 clusters = 16 No. (%)	*p*-Value[a]
Health visitor	10 (38.5)	9 (37.5)	
Very satisfied (4)	16 (61.5)	13 (54.2)	
Fairly satisfied (3)	–	2 (8.3)	
Don't know (excluded)			
Mean of cluster means (SD)	3.24 (0.42)	3.39 (0.45)	0.884
GPs			
Very satisfied (4)	5 (19.2)	7 (30.4)	
Fairly satisfied (3)	11 (42.3)	12 (52.2)	
Neither satisfied nor dissatisfied (2)	8 (30.8)	3 (13.0)	
Fairly dissatisfied (1)	2 (7.7)	1 (4.3)	
Don't know (excluded)	–	1	
Mean of cluster means (SD)	2.78 (0.62)	3.16 (0.72)	0.131
Midwife			
Very satisfied (4)	7 (26.9)	7 (30.4)	
Fairly satisfied (3)	16 (61.5)	15 (65.2)	
Neither satisfied nor dissatisfied (2)	2 (7.7)	–	
Fairly dissatisfied (1)	1 (3.8)	1 (4.3)	
Don't know (excluded)		1	
Mean of cluster means (SD)	3.12 (0.54)	3.21 (0.55)	0.624
Organisation of postnatal care allows care appropriate to individual needs			
Yes, in most cases (2)	20 (76.9)	15 (62.5)	
Yes, in some cases (1)	2 (7.7)	8 (33.3)	
No (0)	4 (15.4)	1 (4.2)	
Mean of cluster means (SD)	1.63 (0.58)	1.63 (0.50)	0.966

[a] Based on comparison of the mean scores of all the cluster means in each study group. Scores were calculated from the figures in parentheses.

alongside that of the other health professionals. In the women's diaries, which covered only the first 28 days, the mean number of health visitor visits did not differ between groups (*Table 45*). From the 4-month questionnaires, however, over the longer period the number of visits were greater in the intervention group, although not statistically significant (*Table 45*).

TABLE 43 *Health visitors' views of whether they have opportunity to discuss postnatal concerns of women with other health professionals in intervention and control practices*

	Intervention: clusters =15 HVs = 26 No. (%)	Control: clusters = 16 HVs = 24 No. (%)	*p*-Value[a]
With GP (score)			
Almost always (3)	22 (84.6)	18 (75.0)	
Sometimes (2)	4 (15.4)	6 (25.0)	
Mean of cluster means (SD)	2.86 (0.29)	2.77 (0.40)	0.483
With midwife (score)			
Almost always (3)	19 (79.2)	18 (78.3)	
Sometimes (2)	2 (8.3)	4 (17.4)	
Rarely (1)	3 (12.5)	1 (4.3)	
Don't know (excluded)	2	1	
Mean of cluster means (SD)	2.69 (0.63)	2.77 (0.48)	0.702

[a] Based on comparison of the mean score of all the cluster means in each study group. Scores were calculated from the figures in parentheses.

TABLE 44 *Aspects of health visitor care in intervention and control practices*

	Intervention: HVs = 26 clusters = 15 No. (%)	Control: HVs = 24 clusters = 16 No. (%)
No. of days postpartum make first visit		
Soon after 10–14 days	26 (100)	24 (100)
First home visit after midwife discharge		
Always	10 (38.5)	5 (20.8)
Sometimes	10 (38.5)	14 (58.3)
No	6 (23.0)	5 (20.8)
Are postnatal roles of HV and midwife complementary		
Mostly	12 (50.0)	8 (34.8)
Sometimes	8 (33.3)	13 (56.5)
Not at all	4 (16.7)	2 (8.7)
Don't know	2	1
Is there any HV/midwife care duplication in own practice		
Often	3 (12.0)	1 (4.2)
Sometimes	9 (36.0)	15 (62.5)
Not at all	13 (52.0)	8 (33.3)
Don't know	1	–

TABLE 45 *Health visitor visits from women's diaries and 4-month questionnaires by study group*

	Women's diary	Four-month questionnaire
Mean of cluster means[a]		
Control	1.91	2.71
Intervention	1.70	3.34
Difference (95% CI)	–0.21 (–0.56 to 0.15)	0.63 (–0.13 to 1.38)
p-Value	0.247	0.100
Multi-level model		
Mean control value	1.89	2.56
Intervention effect size (95% CI)[b]	–0.20 (–0.53 to 0.14)	0.66 (–0.05 to 1.37)
χ^2	1.341	3.349
p-Value	0.247	0.067
ICC	0.136809	0.190266

[a] Unweighted.
[b] Effect size for continuous variables is the regression coefficient from the cluster-adjusted multi-level model.

TABLE 46 *Collection and reasons for non-collection of health service usage data from GP records*

	Intervention	Control
Returned 12-month questionnaire	781	731
Woman refused access	84	63
Notes not available – left practice	83	53
Completed mother records	609	613
Completed baby records	608	613
Percentage of 12-month responders	78.0	83.8
Percentage of total recruited	56.0	62.0

Health service usage

A secondary outcome of the study was whether the redesigned model of postnatal care had any effect on wider health service usage. *Table 46* shows the loss to follow-up for GP practice data used to examine this. About 10% of the women who

TABLE 47 *GP consultations of mother during first postpartum year by study group*

	GP consultations		
	All	**Excluding postnatal care**	**Excl postnatal care and/or within 42 days**
Mean of cluster means[a]			
Control	7.32	5.72	4.84
Intervention	6.19	5.20	4.39
Difference (95% CI)	–1.13 (–1.87 to –0.39)	–0.52 (–1.15 to 0.12)	–0.45 (–1.02 to 0.12)
p-Value	0.004	0.106	0.119
Multi-level model			
Mean control value	7.49	5.93	5.09
Intervention effect size (95% CI)[b]	–1.33 (–1.94 to –0.72)	–0.72 (–1.24 to –0.20)	–0.68 (–1.10 to –0.26)
χ^2	18.05	7.34	9.91
p-Value	0.00002	0.0067	0.0016
ICC	0.01370	0.00471	0.00000

[a] Unweighted.
[b] Effect size is the regression coefficient from the cluster-adjusted multi-level model.

returned their 12-month questionnaire did not sign the consent form for their GP records to be abstracted, and in a similar proportion consent was given but the general practice notes were unavailable. For practical reasons each GP practice was visited to obtain these data about twice during the trial period and most of the cases of unavailable notes were for women who had moved out of the practice between giving consent and this data abstraction visit. The proportion of notes that were unavailable differed between groups, 10.6% of the intervention group who had returned a 12-month questionnaire compared with 7.3% among controls. This may be explained by the greater proportion of intervention group women living in rented accommodation, generally a more mobile group.

GP consultation rates for mother

The cluster-adjusted model to compare rates of GP consultations, both in total and those outside of postnatal care (*Table 47*), showed that the intervention group women had made significantly fewer visits to the GP during the first postpartum year than those in the control group. For total consultations during the year, the difference was 1.33 fewer visits. Excluding all GP visits that were recorded in the practice notes as being for postnatal care (i.e. GP home visits and the maternity discharge check), the difference between the groups was reduced to 0.72 visits, but remained statistically significant. Some GPs may have had a consultation with a woman during the postnatal period but omitted to record in the notes that the woman was postnatal. An even more cautious estimate of the GP consultation rate outside of postnatal care was therefore made by excluding all visits within the first 42 days, in addition to those recorded as postnatal in the notes. This analysis reduced the overall mean number of consultations a little, but the level of difference between the groups remained similar, with 0.68 fewer visits per woman in the intervention group.

Topics of GP consultations for mother

The topics covered in all GP consultations during the 12 months were also recorded. At some consultations more than one topic was covered and up to five topics per consultation were recorded. The cluster adjusted results for each of these are shown in *Table 48*. For each consultation topic, the odds of making a visit about that topic at some time during the period according to group are shown, in addition to the mean number of visits. This information is given for (a) topics consulted about in the whole of the first year, (b) those covered within a consultation that was not recorded as postnatal and (c) also excluding those consultations within the first 42 days.

The topics that showed significant differences in consultation rates between the study groups were perineal pain/dyspareunia, bowel problems, contraception, gynaecological symptoms, general problems and subsequent pregnancy. For all these topics GP consultations were significantly more common in the control compared with the intervention group (*Table 48*). The patterns over time differed for some of these problems. For perineal pain and contraception, the excess consultations among the control women were

TABLE 48 *GP consultations according to topic during the first postpartum year by study group*

Multi-level model	Abnormal bleeding	Perineal pain/dyspareunia	Abdominal wound	Breast feeding problems	Urinary problems
0–365 days					
Mean control value	0.44	0.39	0.19	0.41	0.19
Intervention effect size (95% CI)[a]	–0.04 (–0.18 to 0.11)	–0.17 (–0.27 to –0.06)	0.00 (–0.10 to 0.10)	0.05 (–0.09 to 0.19)	–0.03 (–0.10 to 0.04)
χ^2	0.24	9.55	0.00	0.47	0.93
p-Value	0.6242	0.002	1.0000	0.493	0.3349
ICC	0.0205	0.0095	0.0125	0.0402	0.0030
OR (95% CI)	0.86 (0.58 to 1.27)	0.46 (0.32 to 0.68)	1.35 (0.83 to 2.23)	1.28 (0.86 to1.91)	0.99 (0.65 to 1.49)
0–365 days excluding postnatal care					
Mean control value	0.34	0.21	0.12	0.22	0.15
Intervention effect size (95% CI)[a]	–0.01 (–0.11 to 0.10)	–0.05 (–0.12 to 0.03)	–0.03 (–0.09 to 0.04)	0.06 (–0.02 to 0.13)	–0.01 (–0.67 to 0.06)
χ^2	0.01	1.55	0.64	2.36	0.06
p-Value	0.9203	0.2131	0.4237	0.1245	0.8065
ICC	0.0041	0.0000	0.0037	0.0000	0.0000
OR (95% CI)	1.02 (0.74 to 1.39)	0.74 (0.52 to 1.05)	1.29 (0.69 to 2.42)	1.30 (0.91 to 1.85)	1.24 (0.84 to 1.83)
43–365 days excluding postnatal care					
Mean control value	0.26	0.14	0.02	0.13	0.11
Intervention effect size (95% CI)[a]	0.002 (–0.08 to 0.09)	–0.01 (–0.07 to 0.05)	0.01 (–0.01 to 0.03)	0.03 (–0.03 to 0.08)	0.00 (–0.06 to 0.06)
χ^2	0.002	0.183	0.78	1.05	0.00
p-Value	0.9643	0.6688	0.3771	0.3055	1.0000
ICC	0.0000	0.0000	0.0000	0.0000	0.0047
OR (95% CI)	1.19 (0.86 to 1.65)	0.86 (0.57 to 1.30)	1.50 (0.58 to 4.43)	1.19 (0.83 to 1.71)	1.20 (0.74 to 1.95)

continued

TABLE 48 *GP consultations according to topic during the first postpartum year by study group (cont'd)*

Multi-level model	Bowel problems	Depression	Fatigue	Backache	Headache
0–365 days					
Mean control value	0.36	0.59	0.21	0.30	0.17
Intervention effect size (95% CI)[a]	–0.14 (–0.23 to –0.04)	–0.06 (–0.26 to 0.14)	–0.04 (–0.10 to 0.18)	–0.06 (–0.16 to 0.04)	–0.02 (–0.08 to 0.04)
χ^2	7.94	0.33	1.77	1.31	0.46
p-Value	0.0048	0.5657	0.1834	0.2524	0.4976
ICC	0.0050	0.0021	0.0000	0.0000	0.0000
OR (95 %CI)	0.67 (0.48 to 0.94)	0.95 (0.69 to 1.31)	0.86 (0.60 to 1.23)	1.03 (0.71 to 1.49)	1.01 (0.70 to 1.46)
0–365 days excluding postnatal care					
Mean control value	0.29	0.55	0.17	0.28	0.16
Intervention effect size (95% CI)[a]	–0.11 (–0.19 to –0.02)	–0.04 (–0.23 to 0.16)	–0.01 (–0.07 to 0.04)	–0.06 (–0.15 to 0.04)	–0.01 (–0.07 to 0.04)
χ^2	6.19	0.13	0.22	0.32	0.23
p-Value	0.0128	0.7184	0.639	0.5716	0.6315
ICC	0.0040	0.0015	0.0000	0.0000	0.0000
OR (95% CI)	0.76 (0.54 to 1.09)	1.00 (0.74 to 1.36)	1.03 (0.73 to 1.45)	1.06 (0.72 to 1.56)	1.03 (0.70 to 1.49)
43–365 days excluding postnatal care					
Mean control value	0.21	0.50	0.16	0.25	0.15
Intervention effect size (95% CI)[a]	–0.08 (–0.14 to –0.01)	–0.04 (–0.22 to 0.14)	–0.03 (–0.08 to 0.02)	–0.07 (–0.16 to 0.02)	–0.02 (–0.08 to 0.03)
χ^2	5.00	0.18	1.14	2.14	0.76
p-Value	0.0253	0.6714	0.2857	0.1435	0.3833
ICC	0.0000	0.0021	0.0000	0.0000	0.0000
OR (95% CI)	0.75 (0.50 to 1.15)	1.08 (0.79 to 1.48)	0.95 (0.67 to 1.36)	1.03 (0.72 to 1.48)	0.97 (0.66 to 1.42)

continued

TABLE 48 *GP consultations according to topic during the first postpartum year by study group (cont'd)*

Multi-level model	Contraception	Gynaecological problems	Subsequent pregnancy	Other musculo-skeletal problems	Other psychological problems
0–365 days					
Mean control value	2.13	1.17	0.21	0.40	0.46
Intervention effect size (95% CI)[a]	–0.39 (–0.70 to –0.08)	–0.25 (–0.42 to –0.08)	–0.06 (–0.17 to 0.04)	–0.01 (–0.13 to 0.11)	0.004 (–0.15 to 0.16)
χ^2	6.24	8.16	1.33	0.02	0.003
p-Value	0.0125	0.0043	0.2488	0.8875	0.9563
ICC	0.0556	0.0097	0.0000	0.0000	0.0051
OR (95 %CI)	0.25 (0.15 to 0.44)	0.58 (0.43 to 0.77)	0.59 (0.36 to 0.97)	1.09 (0.80 to 1.49)	0.98 (0.70 to 1.37)
0–365 days excluding postnatal care					
Mean control value	1.27	0.98	0.21	0.38	0.42
Intervention effect size (95% CI)[a]	0.04 (–0.22 to 0.30)	–0.16 (–0.32 to 0.004)	–0.06 (–0.17 to 0.04)	0.004 (–0.11 to 0.12)	0.01 (–0.14 to 0.16)
χ^2	0.11	3.66	1.35	0.004	0.03
p-Value	0.7401	0.0557	0.2453	0.9496	0.8625
ICC	0.0390	0.0078	0.0000	0.0000	0.0033
OR (95% CI)	0.98 (0.69 to 1.39)	0.72 (0.55 to 0.94)	0.60 (0.37 to 0.99)	1.10 (0.81 to 1.50)	1.00 (0.72 to 1.38)
43–365 days excluding postnatal care					
Mean control value	1.10	0.87	0.21	0.36	0.39
Intervention effect size (95% CI)[a]	–0.01 (–0.22 to 0.21)	–0.14 (–0.30 to 0.01)	–0.06 (–0.17 to 0.04)	–0.003 (–0.11 to 0.11)	0.01 (–0.13 to 0.15)
χ^2	0.004	3.27	1.35	0.002	0.02
p-Value	0.9496	0.0706	0.2453	0.9643	0.8875
ICC	0.0271	0.0099	0.0000	0.0000	0.0044
OR (95% CI)	0.93 (0.67 to 1.28)	0.75 (0.57 to 0.98)	0.60 (0.37 to 0.99)	1.06 (0.76 to 1.47)	1.01 (0.70 to 1.45)

continued

TABLE 48 *GP consultations according to topic during the first postpartum year by study group (cont'd)*

Multi-level model	Gastrointestinal problems	Respiratory problems	Skin problems	Cardiovascular problems	Other problems
0–365 days					
Mean control value	0.24	0.90	0.62	0.22	1.15
Intervention effect size (95% CI)[a]	–0.05 (–0.13 to 0.02)	–0.05 (–0.21 to 0.10)	–0.09 (–0.23 to 0.05)	–0.04 (–0.15 to 0.08)	–0.15 (–0.38 to 0.07)
χ^2	1.95	0.45	1.44	0.39	1.84
p-Value	0.1626	0.5023	0.2301	0.5323	0.1750
ICC	0.0000	0.0000	0.0021	0.0010	0.0124
OR (95 %CI)	0.86 (0.61 to 1.20)	0.87 (0.69 to 1.11)	0.83 (0.64 to 1.08)	1.07 (0.59 to 1.97)	0.75 (0.56 to 1.02)
0–365 days excluding postnatal care					
Mean control value	0.23	0.88	0.60	0.19	1.05
Intervention effect size (95% CI)[a]	–0.05 (–0.12 to 0.02)	–0.04 (–0.20 to 0.11)	–0.09 (–0.22 to 0.05)	–0.03 (–0.14 to 0.08)	–0.16 (–0.35 to 0.04)
χ^2	1.77	0.29	1.49	0.32	2.45
p-Value	0.1834	0.5902	0.2222	0.5716	0.1175
ICC	0.0000	0.0000	0.0030	0.0000	0.0069
OR (95% CI)	0.85 (0.61 to 1.20)	0.90 (0.72 to 1.13)	0.84 (0.64 to 1.10)	1.00 (0.56 to 1.78)	0.71 (0.53 to 0.95)
43–365 days excluding postnatal care					
Mean control value	0.22	0.80	0.55	0.14	0.91
Intervention effect size (95% CI)[a]	–0.05 (–0.12 to 0.02)	–0.02 (–0.17 to 0.13)	–0.10 (–0.24 to 0.04)	–0.02 (–0.10 to 0.06)	–0.17 (–0.36 to 0.03)
χ^2	1.75	0.07	2.07	0.30	2.84
p-Value	0.1859	0.7913	0.1502	0.5839	0.0919
ICC	0.0000	0.0000	0.004	0.0000	0.0092
OR (95% CI)	0.82 (0.56 to 1.19)	0.90 (0.72 to 1.13)	0.76 (0.57 to 1.01)	1.13 (0.61 to 2.08)	0.64 (0.48 to 0.87)

[a] Effect size is the regression coefficient from the cluster-adjusted multi-level model.

accounted for by these topics being covered by the GP in postnatal care visits, with no differences once postnatal consultations had been excluded. For consultations about bowel and gynaecological symptoms, however, the excess among control women persisted even when all postnatal-labelled consultations in addition to those in the first 42 days were excluded, although for gynaecological symptoms the difference was of borderline statistical significance. For the other non-specified conditions (general problems) the difference between study groups was not quite statistically significant but outside of postnatal care the difference was more pronounced. The odds of consulting about a subsequent pregnancy were significantly greater in the control group, although the mean number of consultations for this was not significantly different.

TABLE 49 *GP prescriptions by study group*

Mean of cluster means[a]	
Control	6.38
Intervention	5.62
Difference (95% CI)	–0.75 (–1.64 to 0.13)
p-Value	0.093
Multi-level model	
Mean control value	6.47
Intervention effect size (95% CI)[b]	–0.86 (–1.59 to –0.13)
χ^2	5.349
p-Value	0.0207
ICC	0.02772

[a] Unweighted.
[b] Effect size is the regression coefficient from the cluster-adjusted multi-level model.

GP prescriptions

The mean number of conditions for which a prescription was issued by GPs to women in the study groups was significantly different, with more issued to women in the control group (*Table 49*).

Secondary care referrals for mother

Information on referrals to secondary health service care were also obtained from the GP records. The particular specialty type to which the referral was made was recorded, but the numbers were generally very small for each of these. In order to make a meaningful comparison, they were categorised into the three main types, medical, surgical and professions allied to medicine (PAMs). Referral to PAMs included all such groups working within secondary care, for example, physiotherapists, psychologists, counsellors, chiropodists and dieticians. Most of the secondary care referrals were made by the GP, but referrals made from one secondary care specialist to another, such as an orthopaedic surgeon referring to a neurologist, or a psychiatrist referring to a counsellor, are also included. The comparisons between study groups are given in *Table 50*, and are expressed in terms of the mean numbers of referrals to each of the speciality groups, and also the odds of a woman being referred to one or more specialist in that group (the former takes account of women who were referred to more than one speciality within the group, e.g. psychiatrist and neurologist, during the 12 months, whereas the latter gives the odds of having a referral at all to that specialist group). There was no difference between study groups in referrals to medical or surgical specialties, but the intervention group women had significantly more

TABLE 50 *Secondary care referrals to specialty groups by study group*

	Medical specialty	Surgical specialty	PAM
Mean of cluster means[a]			
Control	0.15	0.15	0.08
Intervention	0.12	0.16	0.12
Difference (95% CI)	–0.03 (–0.09 to 0.02)	0.01 (–0.07 to 0.08)	0.04 (–0.004 to 0.09)
p-Value	0.210	0.847	0.074
Multi-level model			
Mean control value	0.16	0.13	0.09
Intervention effect size (95% CI)[b]	–0.02 (–0.07 to 0.04)	0.02 (–0.03 to 0.08)	0.05 (0.01 to 0.10)
χ^2	0.296	0.828	5.193
p-Value	0.5864	0.3629	0.0227
ICC	0.00524	0.01290	0.00877
OR (95% CI)	0.84 (0.56 to 1.25)	1.12 (0.73 to 1.72)	1.61 (1.03 to 2.50)

[a] Unweighted.
[b] Effect size is the regression coefficient from the cluster-adjusted multi-level model and transformed for binary variables to an odds ratio.

referrals to PAMs. These comparisons are based on small numbers, however, the PAM referrals being 0.05 (95% CI 0.01 to 0.10) of a referral more per woman in the intervention group. The OR of being referred to a PAM was 1.60 (95% CI 1.03 to 2.49) for the intervention group.

Some practices have access to a variety of PAMs working within primary care. The use of these was also abstracted from the GP records, and showed that the odds of having a referral to a PAM in primary care in the control group was significantly greater than in the intervention group, although this difference was not statistically significant (*Table 51*).

Since obstetrics and gynaecology were likely to be the most common referral specialty, this group was categorised separately, but no difference was found between the study groups: OR 1.07 (95% CI 0.69 to 1.65) for intervention versus control.

TABLE 51 *PAM consultations within primary care by study group*

	PAMs in primary care
Mean of cluster means[a]	
Control	0.24
Intervention	0.22
Difference (95% CI)	–0.02 (–0.16 to 0.11)
p-Value	0.711
Multi-level model	
Mean control value	0.24
Intervention effect size (95% CI)[b]	–0.05 (–0.14 to 0.04)
χ^2	1.103
p-Value	0.2936
ICC	0.01733
OR (95% CI)	0.63 (0.41 to 0.96)

[a] Unweighted.
[b] Effect size is the regression coefficient from the cluster-adjusted multi-level model and transformed for binary variables to an odds ratio.

Health service usage for baby

The information collected on the baby from the GP records comprised the total number of consultations with the GP throughout the first year and the total number of consultations within, rather than referrals to, secondary care. Since infant effects were not the main focus of the intervention, reasons for GP consultations and details about type of the secondary care contacts were not recorded. *Table 52* shows that there was a slight intervention group excess of both GP and secondary care consultations for the baby, and for the secondary care referrals this difference was statistically significant.

Economic analysis

The economic analysis specified in the original proposal was a cost consequences model, where commissioners have available both the relative costs, benefits and disbenefits of both intervention and control care, since the study outcomes were multi-dimensional and did not lend themselves to aggregation. The new model would be considered more cost-effective than current care if outcomes

TABLE 52 *GP and secondary care consultations for the baby during the year by study group*

	GP	Secondary care
Mean of cluster means[a]		
Control	7.38	0.79
Intervention	7.64	0.99
Difference (95% CI)	0.26 (–0.70 to 1.22)	0.20 (–0.15 to 0.56)
p-Value	0.582	0.258
Multi-level model		
Mean control value	7.67	0.82
Intervention effect size (95% CI)[b]	0.23 (–0.49 to 0.94)	0.27 (0.007 to 0.53)
χ^2	0.386	4.065
p-Value	0.534	0.0438
ICC	0.00998	0.01605
OR (95% CI)	N/A[c]	1.37 (0.93 to 2.03)

[a] Unweighted.
[b] Effect size is the regression coefficient from the cluster-adjusted multi-level model and transformed for binary variables to an odds ratio.
[c] All babies had at least one GP consultation.

were higher (equivalent) and costs were the same (lower). Were the costs of intervention care to exceed those of current care and yet effectiveness was also higher, a financing constraint would need to be imposed. Costs were estimated from the perspective of the NHS.

Costing

Costs being evaluated can be divided into primary care and secondary care costs. Other related costs were also considered for possible inclusion in the analysis.

The primary care costs were incurred through midwife visits to the woman in her home, GP visits to the woman in her home, GP consultations the woman had at the practice surgery, drug prescriptions, investigations and referrals to PAMs within the practice.

The secondary care costs were incurred through outpatient appointments at a hospital specialty consultant clinic, outpatient investigations, minor surgical procedures, day-case 'inpatient' days, non-day-case 'inpatient' days and major surgical procedures.

Healthcare usage for the mother was the focus of the cost-effectiveness analysis. Care of the infant was not changed and only minimal information was collected on the baby. Costs incurred by the mothers themselves were not included in this inquiry. Also, since no change in the behaviour of health visitors was planned as part of the intervention, they were not asked to record their contacts with the women, and so these costs were not included.

To calculate the costs across both primary and secondary care, the time per consultation is multiplied by a time-price; this price is based on salary payments and is up-rated for overheads, equipment and materials and for transport across visits (*Table 53*). The prices for these services are based on national data, and the same price is applied across the intervention and the control arms.[75] Costs were accrued for each woman for the 12 months following her delivery with almost all deliveries during the period 1998–9. Prices for 1999 were used. Present value discounting was not applied as all relevant costs were incurred within 1 year, and simultaneously for the intervention and control groups.

Midwife visits

Data on the number of midwife visits were available from midwife records and from women's 28-day diaries, for which there were differential return rates. The intervention midwives returned

TABLE 53 *Unit costs used in costs comparison*

Unit costs for	Derivation of unit cost [Schema][a]	Unit cost (£)
Primary care costs		
Per midwife minute	39.23/60 [8.1]	0.65
Per midwife visit	Duration × 39.23/60 + 1.06 [8.1, 8.7a]	
Per midwife non-visit	5 minutes × 39.23/60 + 1.06 [8.1, 8.7a]	4.33
Per midwife discharge visit	[8.7b]	22.00
Per GP home visit	[8.7b]	49.00
Per GP consultation	[8.7b)	22.00
Per prescription	[8.7b]	12.00
Per referral or investigation within Primary Care Team	[7.1]	20.00
Secondary care costs		
Per inpatient days for major surgery	[6.1]	301.00
Per day-case days for major surgery	[6.1]	301.00
Per outpatient appointment for minor surgery	[6.1]	54.00
Per inpatient days for minor surgery	[6.1]	301.00
Per day-case days for minor surgery	[6.1]	301.00
Per outpatient appointments for mainstream specialities	15 minutes × 2.4 [13.4]	36.00
Per inpatient days for mainstream specialities	[6.1]	222.00
Per day-case days for mainstream specialities	[6.1]	222.00
Per outpatient appointments for PAMs	30 minutes × 0.58 [11.1]	17.40
Per inpatient days for PAMs	[6.1]	222.00
Per day-case days for PAMs	[6.1]	222.00
Per 'did not attend' appointments	10 minutes × 0.58 [11.1]	12.00

[a] These unit cost figures are taken from Netten and colleagues.[75] The number in parenthesis refers to the Schema in Netten and colleagues.[75] 1998 prices.

TABLE 54 *Midwife home visits by study group*

	Source of information	
	Midwife records	**Women's diaries**
Mean of cluster means[a]		
Control	4.07	5.99
Intervention	6.00	5.82
Difference (95% CI)	1.92 (1.04 to 2.80)	–0.17 (–0.89 to 0.54)
p-Value	<0.0001	0.627
Multi-level model		
Mean control value	4.34	5.98
Intervention effect size (95% CI)[b]	1.67 (0.95 to 2.39)	–0.14 (–0.79 to 0.51)
χ^2	20.774	0.651
p-Value	<0.0001	0.420
ICC	0.21418	0.19082

[a] Unweighted.
[b] Effect size is the regression coefficient from the cluster-adjusted multi-level model.

records of their home visits for 958 (90%) of the women in the group, but records on home visits from control midwives were returned for only 759 (79%) of the women (*Figure 2*). Intervention group midwives also recorded attempted visits – where the midwife visited the home and the mother was out – but control midwives did not. The information from women's 28-day visit diaries also showed a differential response rate, being returned by 783 (74%) of the intervention women and by 542 (56%) of controls (*Figure 2*).

The frequency of midwife postnatal home visits as recorded by the midwives and by the women was found to differ (*Table 54*). As recorded by midwives, the mean number of visits to women was significantly greater in the intervention than the control group (6.0 versus 4.3). The mean number of midwife visits recorded by the women in their diaries however, was the same in both groups (6.0), and was similar to the number recorded by the intervention midwives.

The duration of the home visits was recorded only in the midwife records and the mean duration in the intervention group was found to be greater than for controls by 11 minutes for the first visit and by 5 minutes for subsequent visits (*Table 55*). Using the midwives' and women's information, two calculations of overall postnatal visit duration could be made. Based on the number of midwife-recorded visits, the mean total duration of all home visits was 78 minutes greater in the intervention group (*Table 55*, Total duration estimation A). Based on the number of visits recorded by the women, however, by multiplying the visit number by the visit duration means (recorded by midwives) for the study group, the difference between groups was 31 minutes (*Table 55*, Total duration estimation B).

GP visits

The mean number of GP home visits recorded by the women in their 28-day visit diaries showed a reduction in visit rate of 0.31 per woman in the intervention group relative to controls, which was of borderline statistical significance (*Table 56*). In the data collected from the general practice records, the place of consultation was recorded, and also the reason for the consultation, which allowed consultations that took place in the woman's home for postnatal care to be identified from this data source. The estimated reduction in GP postnatal visit rate relative to controls based on these data was 0.17, which was not statistically significant. The proportion of intervention women who were recorded as having at least one visit was 45%, compared with 58% of controls. For completeness, the responses from the 4-month questionnaire's GP visit frequency question are also shown. In these data the reduction per woman was 0.18 visits (not significant) in the intervention group (*Table 56*). We have no information on how many of the intervention GP home visits were the result of midwife request, and thus non-routine and in accordance with the trial protocol.

Postnatal discharge check

The midwife postnatal discharge consultation, which took place at 10–12 weeks postpartum, represented an additional contact and was not included in the midwife visit totals described earlier. A record of the postnatal discharge consultation by the intervention group midwives

TABLE 55 *Duration of midwife home visits by study group*

	First visit	Subsequent visits	Total duration estimation A	Total duration estimation B
Mean of cluster means[a]				
Control	30.59	25.29	108.34	156.79
Intervention	41.31	30.22	192.27	186.91
Difference (95% CI)	10.71 (4.46 to 16.97)	4.93 (0.53 to 9.33)	83.92 (59.85 to 108.00)	30.12 (10.18 to 50.06)
p-Value	0.0014	0.029	<0.0001	0.004
Multi-level model				
Mean control value	30.20	24.59	114.95	156.43
Intervention effect size (95% CI)[b]	11.20 (5.17 to 17.23)	5.23 (1.14 to 9.31)	77.80 (54.49 to 98.12)	30.98 (12.64 to 49.31)
χ^2	13.266	6.294	56.309	10.956
p-Value	0.0003	0.0121	<0.0001	0.0009
ICC	0.32995	0.45254	0.21865	0.18440

[a] Unweighted.
[b] Effect size is the regression coefficient from the cluster-adjusted multi-level model.

TABLE 56 *GP postnatal home visits by study group*

	Source of information		
	Women's diaries	Four-month questionnaire	GP records
Mean of cluster means[a]			
Control	0.88	0.78	0.72
Intervention	0.57	0.60	0.54
Difference (95% CI)	–0.31 (–0.67 to 0.04)	–0.18 (–0.51 to 0.14)	–0.18 (–0.46 to 0.10)
p-Value	0.084	0.258	0.200
Multi-level model			
Mean control value	0.88	0.78	0.72
Intervention effect size (95% CI)[b]	–0.31 (–0.65 to 0.03)	–0.18 (–0.49 to 0.12)	–0.17 (–0.44 to 0.09)
χ^2	3.165	1.365	1.66
p-Value	0.075	0.243	0.1976
ICC	0.392687	0.364286	0.2988

[a] Unweighted.
[b] Effect size is the regression coefficient from the cluster-adjusted multi-level model.

TABLE 57 *GP records of postnatal check by study group*

	Postnatal check
Mean of cluster means[a]	
Control	0.87
Intervention	0.44
Difference (95% CI)	–0.42 (–0.56 to 0.30)
p-Value	<0.0001
Multi-level model	
Mean control value	0.88
Intervention effect size (95% CI)[b]	–0.45 (–0.57 to –0.33)
χ^2	55.144
p-Value	<0.0001
ICC	0.14689
OR (95% CI)	0.10 (0.06 to 0.19)

[a] Unweighted.
[b] Effect size is the regression coefficient from the cluster-adjusted multi-level model and transformed for binary variables to an odds ratio.

was available for 909 women. The duration of this consultation was not recorded and the costing analysis used 30 minutes for all cases. Referral to the GP was recorded for 268 (29%) of the intervention women at this consultation.

In the control group, the postnatal check was undertaken by the GP and the data source for this was the GP practice records. There were 88% of control women who were recorded as having this from their GP. From the same data source, 39% of the intervention women were recorded as having a GP check. The cluster-adjusted OR of this was 0.1 (*Table 57*). Within the intervention group it was not possible to determine how many of the women recorded as having a GP postnatal check were those referred to the GP by the midwife.

GP consultations

The data on GP consultations other than home visits were collected from the practice records (*Table 56*). The comparison of rates of consultation with the GP has already been shown in the section 'Health service usage' (p. 47). For these and the remaining items included in the costs comparison, the figures for control and intervention are summarised in *Table 58*. For transparency, only means of cluster means have been shown, but the cost calculations used multi-level techniques.

Unit costs

The unit costs for each component of the workload were calculated, based on a common framework (*Table 53*). For midwives' time, costs estimates are adapted from those for district nurses by Netten and colleagues[75] (their Schema 8.1, 8.7a). Per year, wages/salaries, salary on-costs and (capital) overheads total £27,957 per midwife. Based on 1575 hours per year and a contact time proportion of 45.2%, the average cost per hour of

TABLE 58 *Workload estimates and data items used in costs comparisons by study group*

	Control		Intervention	
	Mean[a]	SE	Mean[a]	SE
Midwife home visits				
Source: midwife records	4.07	0.32	6.00	0.28
Source: women's diaries	5.99	0.23	5.82	0.26
Source: midwife records (postnatal check)			0.77	0.05
GP home visits as part of postnatal care				
Source: women's diaries	0.88	0.15	0.57	0.09
Source: practice data	0.72	0.11	0.54	0.09
GP postnatal check	0.87	0.02	0.44	0.06
GP consultations (excluding postnatal check and home visits for postnatal care)	5.72	0.22	5.20	0.22
With prescription	6.38	0.27	5.62	0.35
With referral to PAMs in practice	0.24	0.04	0.22	0.05
Hospital medical specialty outpatient appointments	0.45	0.06	0.42	0.07
Hospital appointment with PAM referral	0.40	0.09	0.99	0.13
Hospital appointment with minor surgery	0.06	0.02	0.09	0.02
Inpatient days: surgical	0.16	0.07	0.05	0.04
Inpatient days: non-surgical	0.48	0.06	0.41	0.08

[a] Mean of cluster means (unweighted).

face-to-face contact is £39.23. For each visit, travel costs of £1.06 per visit are added. The cost per maternity is therefore calculated as £39.23 times hours of care, plus £1.06 times the number of visits.

Unit costs per GP consultation were estimated with an average time for a consultation multiplied by the contact cost of £114 per hour.[75] Questioning of participating general practices suggested that although some do book a 'double' appointment for a postnatal check, the majority do not. Therefore, postnatal checks at the GP surgery were costed as an average consultation. Where GPs consulted the mother in the home, additional transport costs were included in the unit cost estimate. For the unit costs of other health professionals, similar unit cost formulae were applied (as detailed in *Table 53*). Finally, for outpatient appointments in secondary care, day-case and inpatient stays, unit costs were estimated from Netten and colleagues.[75] To derive total costs per maternity, workload amounts were multiplied by unit costs.

Total costs

Baseline costing matrices were generated for both the crude data (matrix a), and having replaced some of the missing data from an alternative source (matrix b). In matrix a (*Table 59*), midwife home visit frequency and duration were taken from the midwife diaries, GP home visit frequency and consultations from the GP records, and secondary care referral data, as for all the models, from the GP records. Complete data from both sources were available for 1042 cases. In this model, the mean intervention costs per woman over the whole year (unweighted mean of cluster means) were lower than for the control care: £469.64 versus £541.52 per woman. *Table 60* shows the cluster means and the number of cases from which they were generated in each cluster. In one of the clusters no data were included and in another cluster complete data were available for only one woman, who had a high total cost. Being cluster randomised, the failure of the midwife to return records, especially for smaller clusters, leaves potential for the comparison to be systematically weighted by this level of incompleteness of the data. When modelled in MlWin, the direction of effect was reversed, with intervention costs on average exceeding those in the control group by £29.50 per woman (*Table 59*). None of these differences were statistically significant.

In the next costs matrix, b (*Table 61*), where available, data on midwife home visit frequency from women's diaries were used for cases where the midwife records were not available. Group-specific means of first and subsequent visits duration were applied to estimate midwives' time. Replacement of these missing values increased the number of women for whom total costs could be generated to 1102, and the cluster means are shown in *Table 62*. The number of women with complete data remains small for some clusters, but all clusters have some data. Only one case was added to the control cluster that previously had complete data for only one woman with a very high cost, but the cluster mean fell substantially. Comparing total costs using this dataset still shows the mean intervention group costs to be lower than the control group, by £10.15, a non-significant difference. In the cluster-adjusted multi-level model, the intervention group cost estimate exceeded that of the control group by £26.90, again a non-significant difference.

Sensitivity analysis

Under-recording by control midwives was anticipated as a potential problem and the data described above suggest that this probably occurred. The sensitivity of the balance of costs to midwife activity was therefore tested by deriving the midwifery visit frequency from an alternative source – the women's 28-day diaries.

In costs matrix c, the data from the women's diaries were used for visit frequency of midwives and GPs (*Table 63*). Duration estimates were those from the midwife diaries, with group-specific means applied and the remainder of costed variable estimates from GP records. In this matrix, the intervention mean cost per woman was £27.37 less than for the control group. Although not statistically significant, the direction of effect was the same for the means of cluster means (£51.60 less) and the multi-level model effects, unlike the previous two costing matrices. The cluster means are shown in *Table 64*. The total number of women with complete 28-day diaries and GP records was 899, but complete data were available for some women in all clusters. The differential return rate for women's diaries is reflected in the relatively higher numbers of intervention group women included in this analysis (485 versus 414). Based on the multi-level models across the various costing matrices, the intervention care could cost as little as £82 more or £78 less.

Cost-effectiveness

The cost consequences analysis establishes that the costs of the intervention and control care were broadly equivalent. In terms of effectiveness, there

TABLE 59 *Matrix a: costs (£) per woman by study group*[a]

	Total costs	Postnatal care costs
Mean of cluster means[b]		
Control (n = 485 in 18 clusters)	541.5	125.5
Intervention (n = 557 in 17 clusters)	469.9	190.1
Difference (95% CI)	–71.6 (–180.6 to 323.7)	64.4 (37.1 to 91.6)
p-Value	0.57	<0.001
Multi-level model		
Mean control value (reference)	449.8	129.1
Intervention effect size (95% CI)[c]	30.4 (–22.2 to 81.9)	61.4 (35.7 to 87.0)
χ^2 (1 df)	1.25	21.982
p-Value	0.2572	<0.0001
ICC	0.007072	0.306789

[a] Data sources: midwife records and GP records.
[b] Unweighted.
[c] Effect size is the regression coefficient from the cluster-adjusted multi-level model.

TABLE 60 *Means of total costs (£) by cluster for costs matrix a*[a]

Intervention clusters n = 17		Control clusters n = 19	
Mean per cluster	No. of women per cluster	Mean per cluster	No. of women per cluster
428.97	4	466.28	42
483.44	97	466.57	38
492.84	18	2527.39	1
305.64	9	520.12	33
519.48	63	436.91	20
645.01	52	449.45	9
546.02	25	360.16	14
354.55	15	376.68	22
419.27	49	262.45	1
382.37	44	416.62	28
653.40	11	380.46	65
455.32	23	510.02	19
414.59	5	440.65	42
594.73	20	494.74	64
482.07	20	422.64	41
369.85	19	265.39	7
441.41	83	543.67	23
		407.21	16

[a] Data sources: midwife records and GP records.

was no difference in physical well-being scores, satisfaction with care was at least as good in the intervention group, and the main effect was improved psychological well-being. Taking these findings together, intervention care – which was more effective for the same cost – is *ipso facto* more cost-effective. The implications for resource allocations from the intervention care could be illustrated as cost per unit of MCS, or as cost per unit reduction of EPDS, but these are not readily meaningful or comparable. As the intervention effects for MCS and EPDS were coherent, we have therefore based the illustration on the numbers of women in each arm who, at 12 months, had an EPDS score of ⩾13, regarded as indicative of probable depression.

The OR of EPDS ⩾13 in the intervention group relative to the control group was 0.46 (95% CI 0.33 to 0.63). In the control group the mean rate of EPDS ⩾13 was 21.6% (mean of cluster means – unweighted). Based on the study data, of 1000

TABLE 61 *Costs matrix b: costs (£) per woman by study group*[a]

	Total costs	Postnatal care costs
Mean of cluster means[b]		
Control (n = 540 in 19 clusters)	478.79	134.36
Intervention (n = 562 in 17 clusters)	468.64	189.90
Difference (95% CI)	–10.2 (–143.7 to 123.4)	55.5 (29.5 to 81.6)
p-Value	0.880	<0.001
Multi-level model		
Mean control value	451.85	133.97
Intervention effect size (95% CI)[c]	26.9 (–24.7 to 78.5)	56.2 (31.4 to 81.0)
χ^2 (1 df)	1.0143	19.795
p-Value	0.3071	<0.0001
ICC	0.008148	0.299406

[a] Data sources: midwife records, women's diaries for missing midwife records and GP records otherwise.
[b] Unweighted.
[c] Effect size is the regression coefficient from the cluster-adjusted multi-level model.

TABLE 62 *Means of total costs (£) by cluster for costs matrix b*[a]

Intervention clusters n = 17		Control clusters n = 19	
Mean per cluster	**No. of women per cluster**	**Mean per cluster**	**No. of women per cluster**
428.97	4	463.27	45
483.44	97	507.95	43
492.01	19	354.69	4
293.27	10	1475.51	2
519.48	63	516.05	43
645.01	52	436.91	20
546.02	25	428.83	10
354.55	15	360.92	15
419.27	49	376.14	24
382.24	45	214.83	2
653.40	11	416.62	28
455.32	23	381.29	68
414.59	5	510.02	19
594.73	20	446.93	45
475.24	21	493.98	65
369.85	19	426.71	58
439.55	84	337.52	9
		543.67	23
		405.19	17

[a] Data sources: midwife records, women's diaries for missing midwife records and GP records otherwise.

women one would expect 216 to have an EPDS score of ⩾13 at 12 months postpartum, but with new care this number would be reduced by a factor of 0.46, to 99 women. Assuming the worst-case scenario, intervention care costs £81.90 per woman more. Therefore, to prevent these 117 cases of probable depression would cost an extra £81,900 for intervention care to the 1000 women – £700 per case of probable depression prevented. Assuming that the costs are equivalent (or under the best-case scenario £78.30 less per woman for the intervention care), there would in fact be substantially lower postpartum depression with no change (or at best a reduction) in the resources devoted to NHS care costs.

Postnatal care costs

The elements of standard community services provided to postpartum women were viewed in this study as a package of postnatal care. The key

TABLE 63 *Costs matrix c: costs (£) per woman by study group*[a]

	Total costs	Postnatal care costs
Mean of cluster means[b]		
Control (n = 414 in 19 clusters)	508.57	161.27
Intervention (n = 485 in 17 clusters)	456.97	151.94
Difference (95% CI)	–51.6 (–188.3 to 85.11)	–9.3 (–28.4 to 9.7)
p-Value	0.448	0.327
Multi-level model		
Mean control value	487.68	160.16
Intervention effect size (95% CI)[c]	–27.37 (–78.3 to 23.6)	–7.5 (–23.3 to 8.2)
χ^2 (1 df)	1.079	0.880
p-Value	0.2989	0.3482
ICC	<0.000001	0.226240

[a] Data sources: women's 28-day diaries for midwife and GP home visit frequency, GP records otherwise.
[b] Unweighted.
[c] Effect size is the regression coefficient from the cluster-adjusted multi-level model.

TABLE 64 *Means of total costs (£) by cluster for costs matrix c*[a]

Intervention clusters n = 17		Control clusters n = 19	
Mean per cluster	**No. of women per cluster**	**Mean per cluster**	**No. of women per cluster**
380.54	3	600.58	34
473.70	85	533.90	32
411.46	14	368.19	4
306.16	10	1519.27	2
505.02	58	560.88	39
539.64	47	421.63	17
564.30	22	526.97	9
397.49	13	375.11	12
402.44	48	397.39	20
392.82	40	167.22	1
637.59	9	413.71	19
462.16	21	404.50	53
379.42	5	528.92	12
599.81	15	483.03	36
450.03	15	517.68	55
468.63	12	428.41	38
397.29	68	407.40	6
		575.37	17
		432.77	8

[a] Data sources: women's 28-day diaries for midwife and GP home visit frequency, GP records otherwise.

elements of this were the midwife home visits, GP home visits and the postnatal check. Postnatal care, so defined, does not denote the whole of NHS care provision, as the normal GP service is still available to these women, in addition to the health visiting services. Comparison of the costs of postnatal care for each study group cannot be truly regarded as the comparative cost of the intervention, but has been included as a guide to how professional NHS resource use differed between groups in the immediate postnatal period.

For models a, b and c, the costs of postnatal care as defined above are presented in *Tables 59*, *61* and *63*, respectively. The relative excess suggested for intervention group midwife time if midwife diaries are used as the source of data is reflected in the significantly higher estimate of mean cost of postnatal care per woman in the intervention group in costs models a and b (*Tables 59* and *61*). Even accepting excess duration estimates from these diaries, however, if women's 28-day diary estimates of visit frequency are used, postnatal care costs in both groups differ little (*Table 63*).

TABLE 65 *Breakdown of costs (£) in matrices by study group*

	Mean of cluster means[a]	
	Control (SD)	**Intervention (SD)**
Matrix A		
Midwife time	74.12 (27.59)	157.16 (40.65)
GP time	288.79 (38.64)	247.19 (56.47)
Secondary care	85.63 (78.67)	74.88 (52.64)
Matrix B		
Midwife time	80.79 (23.12)	157.17 (40.68)
GP time	288.79 (38.64)	247.19 (56.47)
Secondary care	85.63 (78.67)	74.88 (52.64)
Matrix C		
Midwife time	106.33 (17.48)	145.56 (24.27)
GP time	275.08 (62.19)	241.98 (59.66)
Secondary care	85.63 (78.67)	74.88 (52.64)

[a] Unweighted.

In breaking down the total NHS costs accrued, GP time formed the highest proportion of the total since, relative to midwives, these costs extend throughout the year (*Table 65*). Secondary care costs, similar in both arms, constituted the smallest element of overall costs for the year.

Training costs

Within the trial, in order to avoid a differential Hawthorne effect, care was taken to devote equal attention in terms of training and support to intervention and control midwives. This amounted typically to one full day of training in groups of about 15, routine meetings with a research midwife every 2 months and telephone availability and *ad hoc* meetings as required, although the latter were rare. Since these costs were similar for both groups and training was delivered by team members, they have not been included in the costs comparison. In any case, as an estimate of what would be required to train midwives to deliver redesigned care as standard, they would be misleading, since training and support in the trial also related to various trial-specific requirements, such as data collection.

It is difficult to project accurately how training would be rolled out within individual NHS. Trusts, were this intervention to be implemented as standard. It would be naive to expect to achieve the changes in care that we believe have resulted in the trial effect shown on women's psychological health, without reasonable investment in the training and support of midwives. This level of investment may vary according to factors such as skill mix and training allocation budgets of individual Trusts, but the training could form part of the midwives' post-registration training requirements, as it did in the study.

Implementation of redesigned care

The redesigned postnatal care tested in this trial comprised a wide-ranging set of care modifications, so it was important to obtain information to consider the extent to which the various components were actually implemented. The documentation recorded by the intervention group midwives on each visit made to the women included items of information that could be used for this purpose.

Proportion of visits completed by intervention midwives

At the first home visit the intervention midwife took a study pack, which included a first visit sheet and numerous subsequent visit sheets, and left this in the woman's home. It was not possible, therefore, for a non-intervention midwife to have completed a first visit documentation sheet, but in cases where the intervention midwife or midwives were unavailable, they could have completed a subsequent one. There was space on each of these documentation sheets for the midwife to note if she was a non-trial or a control midwife, although the latter was planned not to occur. Of the 5046 subsequent visit sheets returned to the trial office, 400 (7.9%) were completed by a non-trial midwife and 74 (1.5%) by a control midwife. For first home visits, we know that a

TABLE 66 *Symptoms identified among intervention group from immediate symptom checklist*

	Total with completed first visit records *n* = 939 No. (%)
Symptoms identified	
Breast problems	223 (23.7)
Bowel problems (constipation/haemorrhoids)	191 (20.3)
Perineal pain	144 (15.4)
Voiding difficulties	113 (12.0)
Bleeding problems	86 (9.2)
No. of symptoms identified	
None	554 (59.0)
One	218 (23.2)
Two	75 (8.0)
More	92 (9.8)

completed documentation sheet was returned to the study office for 939 intervention women (88%). For the remainder we do not know which women had their first visit from an intervention midwife who forgot to return the completed documentation, and which had their first visit from a non-trial midwife.

Identification of health needs

The identification of health needs was an important component of the intervention and to ensure this was done systematically, rather than the usual reliance on clinical judgement, midwives were asked to administer the set of screening tools. The first was a **brief symptom checklist** at the first home visit to ascertain the presence of more immediate symptoms (*Table 66*). Among the 939 women for whom completed first home visit documentation was returned to the study office, one or more symptoms were identified in 385 of them (41.0%).

At about 10 and 28 days, then again at the 10–12-week discharge check, the midwives were asked to administer the full **symptom checklist**. Completed 10- and 28-day checklist records were returned to the study office for 944 intervention group women (89%), and at 10–12 weeks for 909 women (86%). The particular symptoms identified at the various times are shown in *Table 67*. At 10 days, 62.5% of the women (n = 590) had at least one symptom identified; at 28 days it was 53.9% (n = 509) and at 10–12 weeks it was 52.1% (n = 474).

TABLE 67 *Symptoms identified among intervention group by checklists*

	Total with completed records at 10 days *n* = 944 No. (%)	**Total with completed records at 28 days *n* = 944 No. (%)**	**Total with completed records at 10–12 weeks *n* = 909 No. (%)**
Symptoms identified			
Backache	224 (23.7)	186 (19.7)	220 (24.2)
Fatigue	223 (23.6)	192 (20.3)	139 (15.3)
Headache	164 (17.4)	140 (14.8)	119 (13.1)
Bowel problems	143 (15.1)	107 (11.3)	94 (10.3)
Breast problems	126 (13.3)	70 (7.4)	44 (4.8)
Perineal pain and dyspareunia	108 (11.4)	41 (4.3)	57 (6.3)
Urinary problems	74 (7.8)	50 (5.3)	40 (4.4)
Depression	67 (7.1)	71 (7.5)	89 (9.8)
Abnormal bleeding	62 (6.6)	32 (3.4)	43 (4.7)
Wound problems	46 (4.9)	33 (3.5)	13 (1.4)
No. of symptoms identified			
None	354 (37.5)	435 (46.1)	435 (47.9)
One	234 (24.8)	258 (27.3)	256 (28.2)
Two	189 (20.0)	143 (15.1)	109 (12.0)
Three	167 (17.7)	108 (11.4)	109 (12.0)

The **EPDS** was also used as a screening tool at 28 days (not validated for earlier use) and at 10–12 weeks. (In a few practices where health visitors were already routinely administering the EPDS, the midwives were asked to liaise with them to avoid each completing an EPDS at a similar time for a woman.) A 28-day EPDS was completed and returned to the study office for 820 of the intervention group women (77.1%) and a 10–12-week EPDS for 752 (70.7%) women. The mean EPDS score at 28 days was 7.0 [standard deviation (SD) 4.5], with 122 women (14.9%) scoring 12 or more (the level at which health professional action is considered necessary). At 10–12 weeks the mean EPDS score was lower, at 4.9 (SD 4.2), with 54 women (7.2%) scoring 12 or more.

Management of identified health needs

Once symptoms had been identified, either by the screening tools or by clinical judgement or maternal report, a set of 10 evidence-based guidelines was provided to assist the midwives in their management. A record of whether a guideline had been used, and which one(s), was made on each home visit documentation sheet, which showed that midwives were frequently recording guideline use. At the first home visit (completed sheets returned for 939 women) midwives recorded at least one guideline used for 300 of the women (31.9%), with guidelines used a total of 485 times. For subsequent visits, the 5046 completed documentation sheets that were returned related to 945 women and, among these, there were 566 women (59.9%) for whom the midwife had used at least one guideline at some time. Guidelines were used a total of 2035 times. The proportion of women who had the particular guidelines used for them at any visit (first or subsequent) is shown in *Table 68*. The guideline used for most women was on backache, and that used the least was on urinary problems. *Table 68* also shows the extent to which women who had a particular guideline used once had it used again for them: most guidelines tended to be recorded as used only once for a woman. The 10–12-week check documentation was much briefer than for the earlier home visits and did not include a record of guideline use, so that the above figures do not include the guidelines used at the discharge check. A comparison of *Tables 67* and *68* shows that the extent to which different guidelines were used was relatively consistent with the extent to which the symptoms were identified by the checklists.

Provision of flexible, tailored care

The rationale for the use of screening tools and guidelines was to facilitate planned care tailored to individual needs, rather than routine care. Various items recorded in the documentation provided some indication of whether this occurred.

Care plans based on need were to be made by the midwife and agreed with the woman at the first home visit, modified later as required. Almost three-quarters of the women (697/939; 74.2%) had a care plan recorded at this visit in which the midwife described what was planned. At subsequent visits there was also a section on the documentation sheet in which to describe the care plan, although it was given less prominence (smaller space allocated), and fewer (1289/5046; 25.5%) of these recorded care plan information. At each subsequent home visit a **reason for the visit** was also requested. The midwives were asked to record whether the visit was made as part of an agreed care plan, at the mother's request, at the midwife's suggestion or for routine purposes (options were not mutually exclusive), and 59% of the visits (2958/5046) were recorded as being part

TABLE 68 *Number of women who had particular guidelines used at any home visit*

	Total with completed records *n* = 945	
Guideline	**No. (%)**	**No. (% of women where used)**
Backache	246 (26.0)	101 (41.1)
Breastfeeding issues	235 (24.9)	116 (49.4)
Headache	181 (19.2)	47 (26.0)
Bowel problems	180 (19.0)	50 (27.8)
Fatigue	157 (16.6)	38 (24.2)
Abnormal bleeding	142 (15.0)	35 (24.6)
Perineal pain and dyspareunia	149 (15.8)	62 (43.7)
Depression	90 (9.5)	23 (25.6)
Abdominal wound problems	80 (8.5)	37 (46.3)
Urinary problems	78 (8.3)	22 (28.2)

TABLE 69 *Observations and examinations recorded at subsequent home visits*

Recorded observation/ examination of	Total visits recorded *n* = 5046 No. (%)
Breast	2392 (47.4)
Lochia	2355 (46.7)
Abdomen (palpation)	2109 (41.8)
Legs	1901 (37.7)
Perineum	1597 (31.6)
Blood pressure	415 (8.2)
Temperature	282 (5.6)

TABLE 70 *Postnatal day of last recorded home visit*

Last visit recorded at day	Total with completed records *n* = 945 No. (%)
≤ 14	115 (12.2)
15–19	48 (5.1)
20–24	69 (7.3)
25–27	89 (9.4)
28	254 (26.9)
29–31	117 (12.4)
32–41	82 (8.7)
≥ 42	171 (18.1)

of the agreed care plan. Other reasons were much less commonly recorded: 6.3% at the midwife's suggestion (n = 319), 5.8% at the mother's request (n = 294) and 9.6% as routine (n = 484).

The date of the next planned visit was to be recorded at each visit. Of 939 first home visit sheets, 790 (84.1%) recorded this, as did 3411 of the 5046 (67.6%) subsequent visit sheets. When the next planned visit was to be the 10–12-week check, some midwives might not have completed this section, because a special appointment postcard was supplied for the midwives to post out later giving the date for the final check, since there were usually several weeks between the check and the previous visit.

Tailored care should lead to **reduced routine observations and examinations**. At the first visit the midwives were asked to perform baseline observations and these were almost always recorded. At subsequent visits the midwives were asked only to complete an observation or examination if they judged it to be required and to state why it was required. The proportion of observations/examinations recorded at subsequent visits was substantially reduced from the first visit, but they were still fairly often completed (see *Table 69*). Reasons for requiring them, however, were generally not given.

Extended midwife-led care

Midwife home visits were planned to take place over a longer period, up to about day 28, and the postnatal day of each visit made was to be recorded. *Table 70* gives the distribution of when the women had their last visit (excluding the final check, showing that most (713/945; 75.2%) did have a late visit. Some women (12%), however, still only had midwife visits over the traditional 14-day period. At the other extreme, a fairly high proportion (18%) had had their last visit extended to much later than in the intervention protocol, to day 42 or after. The postnatal discharge check was to be completed by the midwife at 10–12 weeks and records of these were returned for 909 women (85.5%).

GPs in the intervention practices were not required to make routine home visits and, although there were fewer visits made than for the controls from the GP records, there were still 45% (275/609) who had a visit. Information on which of these GP visits were at the midwife's request was not collected, but it is likely that many were not. At the 10–12-week postnatal check 29% of the women (268/909) were recorded as having been referred to the GP by the midwife. Information on whether the GP had completed a postnatal check was obtained from the GP records, and among the intervention women for whom these data were available, 39% (237/609) were recorded as having had one. Which of these women were the midwife referrals is not known, but the comparable proportions described above suggest that at least some women had a GP check in addition to one from the midwife.

Chapter 4
Discussion

Health outcomes

This study has shown that the model of redesigned community postnatal care, developed and tested in the trial, was associated with positive psychological health outcomes in the women at 4 months postpartum. These were still present at 12 months postpartum, although the physical health measure did not differ at 4 and 12 months. Both measures of psychological health, the SF-36 MCS and the EPDS (mean value and proportion with score suggestive of depression) showed benefits. At 12 months the scores in both groups had improved, but the differences between groups remained; they were of slightly smaller magnitude for mean MCS and EPDS, but the difference in the score indicative of probable depression had not reduced compared with that at 4 months. The results showed consistency with the women's reported morbidity at 12 months, with significantly less depression present at this time among the intervention group. Fatigue, which is often a feature of depression, was also reported less often.

The results are consistent with the findings of a trial of midwife-managed compared with shared maternity care, that was provided for women who had no adverse characteristics at antenatal booking, undertaken in Glasgow.[79,80] As in our study, the intervention was provided as an alternative to standard care and was midwife-led, with obstetric input only when required and based on individual needs. The midwife-managed care covered the whole antenatal, intrapartum and postnatal period, with a named midwife who aimed to provide the majority of planned care. Unlike our intervention, it was not specifically focused on postnatal care and was not routinely extended past the usual 10–14-day postnatal period. There were no specific protocols or evidence-based guidelines, but the postnatal care followed the same principle as care generally for that unit (which presumably the controls also had), which was to plan a programme of individualised postnatal care with the aim of ensuring continuity, choice and control for women. The main study outcomes were obstetric interventions,[80] but the women were followed up at 7 weeks postpartum, when maternal health was evaluated.[79] The improvement found in the EPDS scores of the women was of a similar magnitude to those in our study. The researchers had used the EPDS without the item on self-harm, so the score was out of 27 rather than the usual 30: the mean score was 8.1 in the midwife-managed and 9.0 in the shared care groups (difference –0.9, 95% CI –1.6 to –0.2), and the proportions with a score of $\geqslant$13 were 16.7 and 23.2%, respectively (difference –6.5, 95% CI –12.1 to –0.9%). The women in the midwife-managed group were also more likely to feel that their postnatal care had prepared them better in relation to their physical health problems, their emotional problems and in looking after themselves.

Our results are also consistent with the findings of an earlier RCT of supportive midwife care for women at high risk of low birthweight,[60] described in Chapter 1. This intervention, which was mainly provided during pregnancy, with only one brief postnatal visit, was given in addition to routine midwife care. The minimum package offered, three antenatal visits and two further brief or telephone visits, had high uptake (70%), and there was greater support available for those who required it. The main study outcome was birthweight, and the postnatal health outcomes were secondary. They were obtained by a questionnaire at 6 weeks postpartum and showed better general health, less depression and a greater feeling of control over life reported by the supported women. Follow-up of this trial population, at 1 year,[81] and again at 7 years, found that the women who had been in the midwife social support group still reported better general health and satisfaction with life, in addition to there being persisting advantages in the health and development of the children.[82] The authors concluded that results confirm "the importance of providing supportive care within the routine maternity services, not only as a means to improve women's pregnancy experiences but in order to promote their and their children's health and development".[82]

Additional support during labour has been the subject of numerous intervention studies,[83] mainly evaluating intrapartum outcomes, but in one of these trials women's psychological health at 6 weeks postpartum was also examined.[62] The labour

support was lay, not given by a health professional, but the results showed increased self-esteem scores and reduced anxiety scores and depression scores at 6 weeks postpartum among the women who had the additional support. The Pitt Depression Inventory was used to assess depression and the mean scores at 6 weeks were 23.27 [standard error (SE) 1.28] among controls, compared with 10.40 (SE 0.77) among the supported mothers ($p < 0.001$).

Several other well-conducted RCTs, specifically testing postnatal interventions aimed at improving women's physical and/or psychological health, have been published since this study began, but have not demonstrated benefit. All these interventions were delivered in the postnatal period, but varied substantially in their content and were generally less wide-ranging than the present study, mainly focusing on a specific aspect of postnatal care. In Victoria, Australia, Gunn and colleagues[53] completed a RCT to investigate the effects on maternal health and well-being of an early postpartum visit to a GP, at 1 week after hospital discharge, compared with the traditional 6-week check. Only the timing of the intervention was changed, not the content of the check, and GPs were not given detailed instructions on what they should do at it. Women who delivered live, term infants in a rural and a metropolitan hospital over a defined period were included, with a 67% recruitment rate and an average response to follow-up at 3 and 6 months of 67%. Uptake of the early check (76.4%) was slightly lower than the 6-week check (88.4%). No significant differences were found between groups in any of the SF-36 individual domain scores, in mean EPDS or in the proportion with a score of ⩾13, at either 3 or 6 months. The authors concluded that "to make clinically important improvements more is required than an early postnatal review. The next step is to trial carefully planned evidence based postnatal educational interventions aimed at health professionals and women" (p. 996), which is essentially what we have tested in the present study.

Morrell and colleagues[84] in Sheffield, completed a RCT to examine the costs and benefits of postnatal support workers on women's health, which was funded from the same NHS health technology assessment research priority area as the current study. The intervention in the Sheffield trial consisted of trained lay support workers offering up to 10, 3-hour home visits in the first 28 days, to provide practical and emotional support to help rest and recovery. Uptake of these visits among the women who had agreed to take part in the trial was incomplete: only 15% of the 311 women allocated to the support workers group had the full 10 visits and 12% declined all visits; 54% had six or more.[84] The activity on which the most time was spent during visits was housework (mean duration per visit 53.9 minutes) and the particular activity most often cited as having occurred at each visit was bottle feeding. The primary study outcome was the general health perception domain of the SF-36, but neither this nor the secondary outcomes (mean EPDS, Duke Functional Social Support Score, breastfeeding rates) were found to differ between study groups at 6 weeks or at 6 months postpartum. Women's satisfaction with the postnatal support workers, however, was higher than for all other services received.

A trial of additional postnatal support offered to women, either an invitation to attend a local postnatal support group or a postnatal support booklet through the post, or both, used similar outcome measures to the studies described above. Again women's views about the support were positive, but uptake of the support group was low and no effect was shown on their physical or mental health.[85]

Supportive interventions specifically aimed at preventing PND in women who were assessed antenatally as at higher risk have produced conflicting results.[86–88] Stamp and colleagues,[88] in a RCT in Australia, categorised 58% of the antenatal population screened as more vulnerable and invited them to take part in the trial. The intervention, conducted by a midwife-educator, comprised two antenatal and one postnatal classes specifically aimed at how to prevent PND, with partners also invited. Uptake of the classes, however, was low, at 31% overall. The EPDS was used to measure depression at 6 weeks, 12 weeks and 6 months and no differences between groups were found.

More recently, a group in Leicester,[86] tested the hypothesis that increased antenatal psychosocial support could prevent postnatal depression. They screened 1300 primiparous women at antenatal classes using a modified General Health Questionnaire (GHQ-D), 400 of whom screened positive; 209 consented, of whom 106 were randomised to routine antenatal care and 103 to the additional support. The intervention comprised six 2-hour antenatal classes for the woman and her partner, delivered by nurses and occupational therapists. The content was based on a review of the social support intervention

literature.[89] Again uptake was low, with only 45% attending sufficient sessions to be likely to produce benefit, and no differences were found in depression between the groups at 3 months postpartum, as measured by the GHQ-D, the EPDS or the Schedules for Clinical Assessment in Neuropsychiatry (SCAN ICD 10).

The third trial with the objective of preventing PND in those at higher risk did show a positive effect at 3 months postpartum among the first-time mothers who had the psychosocial intervention.[87] Based on their expected date of delivery, the women categorised as more vulnerable on screening were allocated to the intervention ($n = 47$) or control group ($n = 52$). The intervention was extensive and comprised 11 contact sessions delivered by a psychologist and health visitors, five antenatal and six postnatal. First-time and second-time mothers attended separate groups, which included parity-relevant materials. Among first-time mothers, a significant reduction in the median EPDS score (3 versus 8, $p < 0.005$) was found in the intervention group. Using the Present State Examination, 19% were diagnosed as being 'cases' of depression or 'borderline', compared with 39% of controls. Almost all (18) of the 21 first-time mothers had attended at least one of the sessions, with an average attendance of seven. No difference in depression was found for second-time mothers. The results of this trial, however, must be interpreted with caution as allocation to study group was non-randomised and the numbers of first-time mothers in each group (21 versus 24) were small.

The improvement found in psychological health in our trial could be due to the redesigned care preventing women from developing psychological problems, perhaps through being more supportive, or to its effectiveness in detecting psychological problems as early as possible and allowing for their successful treatment. Our data do not provide evidence to separate these possible effects, although both mechanisms are plausible. The protocol in our intervention included repeated opportunities, additional to those in usual care, for the midwives to assess the women's psychological health, through asking about depression (and fatigue) in the 10- and 28-day and 10–12-week checklists, and through using the EPDS as screening tool on the last two occasions. The set of management guidelines which all the midwives were provided with, included one on 'depression and other psychological morbidity', but midwives were not advised themselves to deliver any treatment. The health visitor management of women with depression (or a high risk of being depressed) varies between districts, with some health visitors routinely using EPDS screening and some trained to deliver psychological counselling. The midwives in the intervention group were advised to liaise with the health visitors and/or refer women who had high EPDS scores or reported feeling depressed to the GP for diagnosis and treatment, all according to their local treatment policy. It is possible, of course, that midwife discussion with the woman on identifying a high EPDS score or when a woman reported depression might have been therapeutic in itself. The intervention, however, incorporated no specified change in the treatment of depression, but rather maximised the likelihood that it be identified.

Once identified, there are effective treatments available for PND, although based on evidence of small trials in postnatal populations. Antidepressants have been shown to be effective,[26] although many postpartum women are not keen to have drug therapy, especially if they are breastfeeding. Trials have also shown that psychological counselling, including non-directive counselling delivered by a health visitor,[27] and cognitive behaviour therapy delivered by a psychologist,[26] are both effective in resolving symptoms. Although in our study there was less psychological morbidity in the intervention group, as measured by the MCS and the EPDS and reported by the women, the GP consultation rates during the year after birth for depression, for fatigue or for other psychological problems were similar in the two study groups. This might be taken as an indication that a greater proportion of the intervention women who had developed emotional health problems did receive treatment for them or it may be that the psychological morbidity influenced by the intervention was among women less likely to attend for medical care.

The PCS score showed no difference between the study groups at 4 or 12 months, suggesting that the redesigned care incurred no benefit on women's physical health. For women's reported morbidity at 12 months postpartum, however, the direction of difference for most health problems favoured the intervention group, although the only physical problem that showed a significant difference between groups was haemorrhoids, with borderline reductions for heavy vaginal bleeding and constipation compared with controls. The frequency of consultations with a woman's GP

could be taken as another indicator of morbidity. The overall rate of GP consultations within the whole of the first postpartum year, even after excluding those labelled as 'postnatal', as well as all those occurring in the first 6 weeks, was significantly lower for the intervention group. The consultation categories of perineal pain, gynaecological problems and a group labelled 'other problems' were the particular ones to show a significant reduction in the intervention group. It may be that this SF-36 single composite measure of physical health is not a sensitive enough indicator of postpartum physical health.

Even if there were a complete lack of difference in physical health, however, it is still plausible that the psychological health effects of the intervention might have been mediated through the management of physical health problems. Some postpartum women report that physical health problems do affect aspects of their lives,[2] and a relationship between postpartum physical symptoms and depression has been demonstrated.[29] Women with certain common post-childbirth symptoms, such as stress incontinence, however, frequently do not report a pervasive effect on their lives.[2] Context is an important factor in the impact of physical symptoms and it may that with the competing childcare demands, even moderate physical symptoms may not feature in an overall physical health measure among postpartum women. The range of problems experienced might also mean that preventive or treatment interventions need to be targeted at particular physical postpartum problems to produce a measurable effect. In addition, although some physical problems, such as haemorrhoids, can be successfully treated, many of the common ones, such as incontinence, backache or dyspareunia, are much less amenable to immediate or complete resolution. Supportive discussion and reassurance about them, however, especially from a knowledgeable individual, could result in women feeling less concerned about them, thus benefiting their emotional well-being.[15]

The EPDS was designed specifically for use in postpartum women, but the other primary study outcome measure, the SF-36, was general population based. The implications of the 3-point difference in MCS that we found, or the effects that it might translate into, are not, therefore, as readily meaningful. Moreover, with a scale that has a mean of 50, the size of the demonstrated effect might not seem substantial. However, the SF-36 has been used in numerous studies of particular disease states and similar size MCS differences have been shown among patients (compared with non-patients) with such conditions as chronic lung disease, rheumatoid arthritis and vision impairment.[68] In addition, in the multi-level models undertaken to consider the effects of adjustment for possible confounders on outcomes, the effect of having a low (relative to high) level of social support was associated with a similar size MCS effect (3.11 points). Social support is well documented in the literature as an important predictor of maternal psychological health or well-being.[25,90]

Implementation of redesigned care

As discussed above, most of the postpartum interventions evaluated in trials that did not show benefits to health were provided as additions to routine care, and had relatively low uptake by the women. The intervention in our trial, as a revision of routine NHS care, was delivered as standard to all women in the group, and therefore compliance depended on the care providers, rather than the women.

Completed home visit records were returned by intervention midwives for almost 90% of the women. On these a space was included to note whether the midwife who visited was an intervention, non-trial or control midwife, so that we know that only 8% of visits were completed by a non-trial midwife and 1.5% by a control midwife. It is gratifying that so many of the women did receive their care from the intervention midwives and that control contamination was so low, given the efforts taken to avoid this. For the 11% of women with no visit records, some may be missing because the midwife forgot to return them to the study office, but for others it will be because they had none or only partial intervention care. We know that in two of the intervention clusters there was long-term midwife sickness during the trial, such that not all the women received the prescribed intervention care.

The midwives who provided the intervention care were the usual midwives attached to the recruited general practices, and not volunteers or employed on the research project, and it was theoretically possible that in their visits they continued to give usual care, or at least some aspects of it. Information collected to examine the extent to which the redesigned care was implemented, however, indicated that midwife compliance with the content was high. We know that the symptom

checklists were used in just under 90% of women, numerous health problems were identified and the proportions of women recorded with the various problems were generally consistent with literature prevalences.[1,3,5] EPDS screening records were less complete, returned for 77% of the women at 28 days and 71% at 10–12 weeks. This may have been because in practices where health visitors were routinely using the EPDS at the same times, the midwives were asked to liaise with them so as not to duplicate the test. We asked them to encourage health visitors to make a record of the midwife score, but where they would not agree to this, the midwives were advised to record the health visitor score. This did allow, however, more scope for there being a failure in EPDS recording being passed on to the study office, even though it may have been completed and acted upon.

The evidence-based guidelines were frequently used to manage identified symptoms, with 60% of women having at least one used for them. It tended to be that women usually had the same guideline recorded only once, although exceptions to this were for the guidelines on backache, breastfeeding and perineal pain/dyspareunia. It is probable that knowledge obtained from the guideline on its first use is likely to have informed later visits if the problem was still present, without the midwife having specifically to refer to it.

In general, therefore, the available evidence suggests high midwife compliance in using the new aspects of the redesigned care protocol, but compliance with reducing routine observations and examinations was not so high. In almost one-half of all visits, breasts, lochia and abdomen were still being examined, and legs and perineum in about one-third. Although the midwives were asked to record for each of the examinations they performed why it was required, this section of the record was rarely completed. Nevertheless, there was some reduction in frequency of routine observations compared with control midwives. In the midwife questionnaires at the end of the trial, more of the control than intervention midwives said that they usually performed abdominal, lochia and leg observations at **most** visits, although this difference was not statistically significant. The reported usual frequency of perineum, breast, temperature and blood pressure observations, however, was similar between the midwife groups.

Extending midwife care over a longer period was successfully achieved and over three-quarters of the women had their last visit at around day 28 or later. Only four of the 28 control midwives (in their post-trial questionnaire) said that they routinely visit after 14–16 days. A record of the midwife maternity discharge check at 10–12 weeks was available for 86% of the intervention women, but this was the aspect of the redesigned care with which intervention midwives reported having had most difficulty. Difficulties in either the timing of the check, which was a visit to the home so much later than in usual care, or in them doing the check rather than the GP are possible. These were not separately specified in the questionnaire, so it is not known which was the most prevalent, although in the midwife contact meetings during the trial, and also on the day in which feedback of study results were given to the midwives who took part, both of these difficulties were mentioned. The 10–12-week check records were available for 86% of the intervention women and in 29% of cases a midwife referral to the GP was recorded.

Compliance with the intervention care for GPs amounted to them relinquishing routine care, but this was incomplete. Among the intervention women, 45% were recorded in practice notes as receiving at least one GP home visit, although this was still fewer than the 58% among controls. We do not know how many of the intervention GP visits were non-routine at the midwife's request, but it is implausible that they could all have been. Also, 39% (compared with 88% of controls) were recorded as having a GP postnatal discharge check, whereas only 29% had been referred by the midwife as needing GP input for this. It had been arranged with the relevant local and national bodies that for the duration of the trial, postnatal payment of GPs was not dependent on them providing routine care themselves, but several GPs, when agreeing to take part in the trial, said they still wanted to make some home visits, mainly because they valued it as maintaining contact with the woman and family. A few GPs had also said they still wanted to continue with the final check.

The evidence then supports the general adoption of the new elements of the care implementation by midwives, but discouraging GPs from visiting women routinely was less successful. Some of this imperfect compliance could be predicted as noted above, and in other instances GPs may have continued to visit through routine practice being difficult to change, because they were still receiving in-service payments, lack of confidence in midwives or other local issues. It is not possible, therefore, to assert that there was no additional effect to intervention care from GP visits or that implementation as standard could occur without sensitivity to and evaluation of the local situation.

Protocol- and guideline-based care

Although often used interchangeably, current understanding is that guidelines differ from protocols as defined by the Institute of Medicine (1990) as "systematically developed statements to assist practitioner decisions about appropriate health care for specific clinical circumstances". An equally accepted definition for protocol-based care was not found but the tenor is more around rules for care in specific clinical situations, which in the case of this intervention comprised symptom checklists and screening tools and certain prescribed visit times (28-days and 10–12-week checks). Derivation of the midwife management guidelines used in this study followed closely the principles arising from the best evidence on deriving scientifically valid guidelines.[54,57] The guidelines were disseminated within an educational intervention and, whilst academic detailing was not undertaken specifically, regular contact in their clinical situation was maintained by members of the study team who helped derive the guidelines. The measure of success achieved in this trial in implementing the guidelines for care can be attributed to adherence to the principles known to be associated with the greater likelihood of success in changing clinical practice.

In proposing a strategy to increase midwives' awareness of research and to overcome barriers to undertaking and using research, Milne and Hundley[91] suggest that the key is empowering midwives through knowledge and skills, thereby creating confidence to effect change. Doubt about the effectiveness of guidelines in changing practice is greater in relation to doctors' behaviour than for nurses. A Cochrane review of guidelines in PAMs[92] concluded that findings from 18 studies provided some evidence that guideline-driven care can be effective in changing both the process and outcome of care. All but one study involved nurses, although most were not midwives.

Women's opinions about care

According to the measures constructed for this study, women's views about their community postnatal care were generally positive. Their overall satisfaction with care did not differ between study groups, although the intervention women assessed their care as significantly better relative to their expectations. Satisfaction was generally high, however, making discernment of difference less likely. In the Glasgow trial of midwife-managed care, a satisfaction score was used, and although this was significantly higher for intervention women than for controls for community postnatal care, the score was positively skewed in both groups, which was not the case for the antenatal and hospital postnatal care satisfaction scores.[80] Similarly, in an Australian trial to evaluate satisfaction with team midwife care versus standard care, differences in women's satisfaction were noticeable for antenatal care, less noticeable for intrapartum care and least noticeable for postpartum care.[93]

Discussing health problems with the midwife was an important component of our redesigned care and for both measures of this, the intervention group women were significantly more positive, although again positive views were generally high in both groups. Planning of care was also significantly more highly rated for the redesigned care, but the women's ratings of continuity of care and final discharge check did not differ. There did seem to be a problem of perception, however, for the assessment of the final discharge check, which in standard care is completed in the GP surgery or occasionally at the maternity unit. Since in the intervention group it was done by the midwives in the home, some women did not answer that they had had the check, and hence did not go on to rate it.

Health professionals' views about care

The views of the health professionals about care was sought at the end of the trial period and differences in midwife views between study groups were found, although it had been difficult to word the questions to be appropriate to the two groups while producing comparable indicators of satisfaction. As for the women, dissatisfaction with the delivery of community postnatal care was uncommon. Nevertheless, the intervention midwives were more satisfied with their own role, and also with those of the GP and health visitor in the redesigned care, than were control midwives about usual care. The intervention midwives were also more likely to feel that the care they had delivered was appropriate to women's individual needs. Views on whether postnatal care makes appropriate use of the time and skills of the various professional groups, however, was similar, even though this had been seen by the investigators as comprising an important advantage of the redesigned care. Although the

two midwife groups were questioned specifically about the care they gave during the trial, GPs and health visitors were asked about their usual postnatal care and no intervention/control differences were found for either of these professional groups. The GPs' views on whether they should routinely see postnatal women showed an almost equal division of viewpoints in each study group. The most commonly mentioned reason why they should continue was that it was a good opportunity to maintain the relationship with the woman and family, which was compatible with what some of the intervention GPs had said on agreeing to take part in the trial

Validity

The case for randomisation by cluster in this trial was clear, and appropriate sample size calculations were used. In the practical enactment of any trial, however, some estimations will change. Recruitment and follow-up rates were lower than planned, but the intra-cluster correlation coefficient was overestimated in the sample size calculation. The net result was that the trial parameters allowed estimation of the effect size for the main outcome which was larger than the minimum effect size that the study was powered to detect.

Appropriate statistical techniques for a cluster randomised trial were used to undertake the analysis. In effect, for the main outcome measures the proportion of variance attributable to cluster was small, represented by the small intra-cluster correlation coefficients.

Issues relating to the validity of results need to be considered in any randomised trial, and those that have a cluster design have special potential problems.[76] The random distribution of clusters to study group should avoid allocation bias, but randomisation may still leave appreciable imbalances between intervention groups, especially when the number of randomised 'units' is small, as tends to be the case in cluster randomised trials. With 36 clusters this trial was moderately sized, but it is possible that by chance, the midwife characteristics might have varied between groups. The measures used, midwife qualification level and number of years since qualifying, did not support this, and although more direct estimation methods, such as psychometric testing would have been more robust, these were not feasible.

The single most important problem associated with cluster randomised trials is 'recruitment bias';[76] where individuals have to be recruited, and as in this case, the staff recruiting patients are aware of the difference of care between arms, they may form a view that the intervention care is better. This may mean that they try harder to recruit women, so that for example, more women with a tendency to be resistant to inclusion may consent to take part in the intervention arm, resulting in imbalances. It is not possible to know whether this may have occurred but the similar recruitment rates between study groups makes it less likely. The imbalances between arms in the women's baseline characteristics were mostly small and by chance, in the main, seemed to 'favour' the control group in terms of disposing to a good outcome (see *Table 2*). Thus, even if this does reflect recruitment bias, it is in the direction that would decrease, rather than increase, the likelihood that it could account for the positive mental health outcomes in the intervention group. Further, in the models with 'adjustment' for possible confounders, the effect sizes for MCS and EPDS increased.

There are other areas where there could be a potential for bias. A possible differential Hawthorne effect, with intervention midwives more enthusiastic in their care (and also their recruitment), was recognised at the design stage of the study and various measures were taken to minimise this. Equal attention was given to midwives in both groups, in the regular meetings and newsletters and the midwife training stressed the importance of control group members within trials.

Loss to follow-up of women in the study was just over 20% at both 4 and 12 months postpartum and non-responders differed in their socio-demographic but not their main obstetric characteristics, which is a similar pattern to other postpartum studies.[1,5] However, we feel this is unlikely to have greatly biased the comparisons of study outcomes since the rate and pattern of response were similar in each arm. The only significant differences in follow-up rates between study groups were for the midwife records and the mothers' 28-day diaries, where the intervention return rate was greater, and for the GP record data, with a greater follow-up for control women. These may have introduced bias in the economic analysis, as discussed later, but could not have done so for the effectiveness outcomes.

The intervention women completed the EPDS within the redesigned care package twice as a screening tool, prior to its use as a study outcome

measure. With some scales a 'practice' effect can occur with repeated use, although this is not documented for the EPDS. We examined our data set to see if there was any evidence of a consistent reduction in the intervention group scores, but could find none. In general, the EPDS pattern among intervention women was that the mean score at 10–12 weeks (4.89, SD 4.3) was lower than at 28 days (6.99, SD 4.5), then increased again at 4 months, although not back to the earliest score (6.23, SD 5.4). For the women (n = 97) where we only had a 28-day and a 4 month score, the pattern was consistent with this (7.16, SD 4.8 and 6.42, SD 6.2, respectively), as it was for the women (n = 165) where we only had 28-day and 10–12-week scores (7.77, SD 4.8 and 5.43, SD 4.8, respectively). This does not seem to show evidence of any practice effect. Moreover, the positive EPDS effect was in line with the other mental health measure, which was used for the first time in both groups at 4 months.

Generalisability

This was a pragmatic trial, with care delivered by the standard community midwifery personnel. It was undertaken throughout the West Midlands, rather than in a small area, and included inner-city, town and more rural populations. Type of general practice was also varied. As such, it should be even more readily applicable to routine practice than where the interventions have been undertaken by professionals specially employed on the project, or by those who have volunteered, as in the trial of midwife-managed care in Glasgow.[79] If the professionals delivering care were special in some way, routine practice may not be able to replicate their effects. Generalisability of the results in this trial therefore should be as good as they could be. In any trial situation however, enthusiasm is likely to be greater because of the Hawthorne effect, of staff being given more attention than usual. Although the measures to minimise a differential Hawthorne effect between midwife groups makes it more likely that the **relative** effect was a real one, the size of the effect may not be replicated in a non-trial situation. If adopted as standard care, some form of further evaluation would be required.

Loss to follow-up in the study, although similar between groups and thus not a major source of outcome bias, may still affect generalisability. The women who were non-responders differed in several of their socio-demographic characteristics that indicate a likelihood of worse health outcome and so the psychological health benefit for them may not be the same. The estimated recruitment rate to the study was good, and similar in both groups, but again it is possible that the women who were not recruited may differ. In particular, we are uncertain of applicability among all ethnic groups. In the West Midlands there is a substantial minority of women of South Asian origin as well as African-Caribbean women, all of whom were eligible for the trial. Unfortunately, ethnic group was omitted from the baseline questionnaire and was only included at 12 months. At this time, although 8% of the women who responded were from ethnic minority groups, the proportion of Asian women (2%) was much lower than the proportion generally found within the region. We do not know, however, how much of this was accounted for by the lower recruitment of Asian women by midwives, perhaps because of language difficulties in obtaining properly informed consent, and how much was greater non-response by the women. Further research among ethnic minority groups is required

Cost-effectiveness analysis

In considering whether to adopt the model as standard practice, its cost-effectiveness is a major factor. The cost consequences analysis establishes that overall costs differed little between groups, with intervention care costing at a maximum £81.90 more per woman to deliver, but possibly representing a saving of £78.30 per woman, depending on assumptions used. The use of intervention care is probably resource neutral, when the perspective of the NHS is used. It is necessary to recognise, however, that overall resource neutrality does not imply that there would be no resource transfers between groups of health professionals: such transfers between health professionals can be politically sensitive and practically difficult to obtain.

We recognised at the design stage that midwifery postnatal workload was difficult to measure among control midwives without changing the care they gave and, therefore, it would be difficult to obtain equally valid measures from both groups. The data collected by the midwives suggested 1.7 fewer visits per woman in the control group (4.3 versus 6.0), but we had expected under-recording by control midwives. Although the response rate for women's diaries among controls was lower, these showed the same midwife visit rates in both study groups (6.0) and were consistent with the published rate of 6.6 for England.[47] The balance

of evidence therefore suggests that the number of visits probably did not differ much, apart from completion of the maternity discharge consultation, which was an additional visit.

Visit duration was only recorded by midwives and was, on average, 11 minutes longer for the first and 5 minutes for subsequent visits in the intervention group. At least some of this may be accounted for by the much more comprehensive documentation required in the intervention arm, especially for the first visit. Midwife familiarity with this is likely to reduce duration and there were some items that were recorded for the trial that would be unnecessary if care was standard.

As described earlier, every effort was made to discourage routine home visits by GPs in the intervention practices. Although GP home visit frequency was lower than for controls, the difference was not as substantial as we had hoped and it is unlikely to have been accounted for by non-routine GP visits. In addition to remuneration of intervention practices not being affected during the trial period, there were other issues identified by GPs in the design phase as additional critical outcomes of their home visits (contraception needs, immunisation requirements of the baby and the need to register the baby at a practice) and documentation to record that these had been covered by the midwives was completed and copied to the practices At least a proportion of the continued GP contact will have happened because, in the usual system of remuneration, practices often have strict procedures set up to ensure that the visits are scheduled and documented, which may have over-ridden the trial protocol. Alternatively, the continued payment may have resulted in some GPs feeling a 'moral' imperative to continue to visit. If intervention GPs in the trial had stopped providing routine home visits and discharge check, the relative costs of intervention/control care would have been improved, although we cannot exclude the possibility of some small disbenefit on effectiveness.

Assessing the costs of healthcare technologies in clinical trials and uncertainty in cost comparisons are already the subject of HTA monographs.[94,95] We have adhered where possible to established principles, and although the study was powered around effectiveness outcomes, the 95% CIs for cost comparisons in the analysis were at most in the order of £80 in either direction. This margin of error in deriving costs is, at least in part, attributable to the need for complete data from a variety of sources. As described, there was a differential rate of return of midwife records and, owing to data protection issues that came to the fore during the study, GP records were only accessed for women who responded to the 12-month questionnaire and gave their consent to this.

The comparative cost of delivering postnatal care between groups was close when the women's estimates of visit frequency were used. The extra intervention costs (for longer visits and the postnatal check) were balanced in this matrix by the slightly lower rates of GP home visits and few GP postnatal checks. Based on the data suggesting a more sizeable difference in midwife visit frequency, the intervention would appear to shift the burden of resource use. More intensive resource use in the immediate postnatal period was required, but the subsequent reduced demands on the health service during the year after delivery in the intervention group meant that even in this matrix the overall costs were equivalent. It was not considered appropriate to undertake further analyses to test the sensitivity of the results to the differential in costing estimates, but the results were tested for sensitivity to the variables most likely to influence the balance between groups.[96]

These data can be compared with other evidence although, as others have noted,[97,98] economic evaluations of postnatal care are few or brief. Rowley and colleagues[99] compared team care by midwives against routine care including antenatal, intrapartum and postnatal care, and showed that midwife team care was at a lower cost by around 4.5%. Ratcliffe and colleagues[100] compared antenatal obstetrician-led shared care with GP/midwife-managed care and found the latter to be of lower cost. York and colleagues reported costs in a group of high-risk childbearing women who received clinical nurse specialist follow-up care.[101] The intervention was a substantial cost saving, because of lower re-hospitalisation rates. Most pertinent to the present study is the work reported by Young and colleagues,[102] who estimated the costs of midwife-managed maternity care compared with shared care in the Glasgow trial described earlier,[80] and separately distinguished the antenatal, intrapartum and postpartum costs. They found that, although costs of antenatal and intrapartum care did not differ between arms, the midwife-managed postnatal care cost (median/mean £470.84/496.83) was significantly higher than the shared care (£352.03/397.10). Postnatal care included hospital and community costs. The midwife-managed care resulted in higher costs because it required higher grades of midwife, care was delivered through

home visits and hospitals (rather than GP surgeries), hospital postnatal care was in small, dedicated wards and the caseload of the midwife-managed programme was lower.

Costs to the women were not included in our study. The variation in costs between each study group incurred by the mothers, however, is likely to be small, although costs in the intervention group may perhaps be lower because of the flexibility of visiting and not needing to go to the surgery for the postnatal check. The costs of developing the guidelines were absorbed within the trial research costs and these have now been published. Training costs and ongoing support are likely to have prompted the success of implementation but, for reasons described earlier, these were not included in the cost-effectiveness analysis. Without underestimating the initial expenditure required to implement intervention care, the additional cost per woman that this represents seems more than justified. Attempts to deliver the redesigned care on a wider basis, however, would need to recognise these as critical components of the plan. If intervention care were delivered as standard, its relative cost-effectiveness may change: either costs for the inputs may rise/fall or effectiveness may change.

The in-service payments to GPs for their postnatal services were not included in the trial costs since these payments were continued to practices delivering both forms of care for the duration of the study. We could have modelled this as a saving to the NHS, either for all of the women in the intervention arm, or for those women only who were not visited by their GP and did not appear to have been referred by the midwife to their GP. To have done so would have favoured the intervention in terms of costs to the NHS, but the issue is more complex than this would suggest. Politically, it may seem only just that transfer of all, or part, of the in-service payments should be made to the midwife. This would be resource neutral in terms of cost comparison between study groups, and might represent a means of funding the implementation costs and increased midwife effort required. These payments, however, constitute part of a complex system of remuneration to GPs for their services to the NHS and there is little doubt that the financial loss induced were these payments to have been ceased would have been unacceptable to the general practices involved in the study.

Most postnatal care is delivered by the midwife and indeed it forms a substantial part of her workload. There will have been opportunity costs, which we were not able to measure – things the midwife was unable to do as a result of using her time to do the postnatal check, while GP time was freed for other activities. Intervention care intuitively represents a more appropriate use of professional skill. In addition to training costs, there may well be a need to recognise the increased effort of the midwives, if standard care were to be changed towards the intervention model. The outcomes in women's health alone would in any case justify additional costs that may be less than the highest potential estimates from this study, which are based on the maximum margin of error. If, as is likely, there are benefits to children attributable to the mothers' improved psychological well-being, there could be little doubt that the intervention is cost-effective.

Relevance of findings to NHS

The potential to improve psychological health among the 750,000 or so women who give birth each year in the UK means that the results of this study are highly relevant to the NHS. Depression in the postpartum period can have a substantial impact, not only on the woman but also on her infant and family. The redesign of postnatal care in the intervention that was tested in this trial showed that it reflected an improvement in women's postnatal psychological health and reduced probable depression relative to current postnatal care, as delivered in the control group. However, there are various issues to consider in terms of the implications for NHS healthcare. We have already noted that, although the trial was designed with generalisability in mind, it is usually the case that outside the trial situation, for example without the motivational influence of the care deliverers being 'studied', the size of effect tends not to be as great.

In terms of midwife care, the small increase in time taken over the postnatal home visits, especially the first, may well lessen as midwives became more familiar with the redesigned care changes. If midwives were able to limit further their use of routine examinations and observations to that intended in the protocol, this should certainly reduce time, although something more is probably needed to give midwives confidence in this aspect of care. Nevertheless, as a result of the midwives undertaking the postnatal discharge check instead of GPs, the redesigned care package did represent more effort on their part. This may

comprise a barrier to be overcome if the redesigned care were to be adopted as standard. Our experience in discussing the trial results and its implications with individual midwives who took part and with managers was very positive, but the midwifery service may well look to some additional resourcing or a redistribution of NHS resources if they were to take over aspects of care formerly undertaken by GPs.

Change to GP postnatal practice was attenuated in the trial, relative to that intended in the redesigned care protocol. This may have been affected by the continuation during the trial of the GP postnatal care in-service payments, leading some still to feel a 'moral' imperative to make some visits, or there may be a reluctance on the part of GPs to relinquish routine postnatal care totally. Since these attenuated changes were in practices who agreed to take part in the study, GP change outside the trial situation may be harder to effect. The trial findings, however, indicate a benefit to the NHS GP services since there was a significant reduction in GP consultations throughout the year after birth, among the women who had intervention care relative to controls.

Possible implications of the redesigned care model for health visitors, the other main professional group involved with postnatal women, would also require further consideration, in terms of both the time overlap and the identification of postnatal depression. The extension of routine midwife care to 28 days covers the time when the health visitor usually makes first contact with the woman. Although health visitor care was not amended as part of the intervention, some health visitors did feel challenged by the extension of midwifery contact. Information collected from the women on visits of all health professionals indicated that health visitors did seem to make their first visit later to women in the intervention group. In some areas health visitors undertake routine EPDS screening and offer treatment for PND. In the trial the midwives were asked, in using the EPDS, to liaise with the health visitor to ensure no duplication. Treatment of depression was not part of the midwife role in the redesigned care, so there was no overlap in this.

Standard NHS implementation of the redesigned care package is therefore likely to require consideration of organisational issues and negotiation, especially around the overlap of professional roles and resources. There is a potential to integrate care to the advantage of the women and their babies, however, and the evidence produced by this trial indicates that the gains to the psychological health of women in the year after birth could be substantial.

Conclusions

- Women's psychological health measured by MCS and EPDS was improved, including a reduction in probable depression, among the women in the practices allocated to the redesigned postnatal care arm.
- The psychological health scores by 12 months were better overall than at 4 months, but the intervention group improvement relative to controls was maintained.
- Morbidity reported by women as present at 12 months postpartum was consistent with these findings, with less depression and fatigue in the intervention group.
- Women's physical health measured by SF-36 PCS at 4 and 12 months did not differ between study groups and, except for haemorrhoids, nor did the physical health problems reported by the women at 12 months.
- Women's opinions about the various aspects of redesigned care were either more positive than for standard care or did not differ. Overall satisfaction with community postnatal care did not differ.
- Contraceptive advice and infant immunisation uptake were maintained.
- Breastfeeding continuation showed no significant difference between study groups.
- Midwives attached to intervention practices were able to implement the care and were more satisfied with their own postnatal role, with those of the GP and health visitor, and with the organisation of the redesigned care, than were control practice midwives about current care.
- GP consultation rates during the first year were significantly reduced in the intervention group compared with controls, and secondary care referrals to medical and surgical specialties and to obstetricians and gynaecologists did not differ. There were significantly more secondary referrals to PAMs in the intervention group but referrals to PAMs within primary care were greater among controls.
- With the inclusion of the postnatal discharge check, more time was spent by midwives in delivering the redesigned care, and less time was spent by GPs, but the overall costs of providing NHS care throughout the first 12 months did not differ substantially between trial groups.

Recommendations for research

Identification of postnatal depression through screening

The benefits of the intervention care were to women's psychological health and, although we do not know which particular aspects of care might have had this effect, one possible mechanism is through the identification of PND by screening tools, thus maximising the likelihood of the women receiving effective treatment. This would merit separate testing.

Effects on the children

Adverse effects on the development of children, up to age 5 years, of women who have PND have been documented. It would be important, therefore, to consider whether fewer adverse longer term effects might be demonstrated among the children of the women who had the intervention care relative to the controls, consistent with their improvement in psychological health.

Reduction of physical morbidity

The primary assessment of women's physical morbidity, the SF-36 PCS, did not differ between groups at either 4 or 12 months postpartum, although there were significantly fewer GP consultations during the first year in the intervention group. Further research, testing interventions to reduce physical morbidity, is required, including studies to validate measures of physical health in postpartum women. It may be that to treat physical health problems effectively and produce measurable differences in postpartum physical outcomes, interventions specific to individual symptoms may be necessary.

Ethnic minority groups

This study included only a few women of South Asian origin, disproportionate to the population within the region and the UK. We do not know, therefore, whether the redesigned care would have the same benefits among this group of women. Further research is required to investigate appropriate postnatal care for ethnic minority groups.

Implications for health care

In the authors' opinion, the evidence of this trial suggests that adoption of the redesigned community postnatal care as standard would be justified. To achieve this, appropriate training and guidance are crucial and there should also be evaluation of effects outside of the trial setting. Midwife implementation of new aspects of the intervention protocol was high, but reducing routine examinations and observations was less complete, and GPs did not fully relinquish routine care. Although it is possible that over a longer period more complete change might occur in these aspects, this may be sensitive to local issues and should be monitored. Finally, since the multifaceted model of care tested in this trial was implemented as a package, it is not possible to know if any of the elements might be more effective than others and policy makers must be aware that incorporating only part of it is unlikely to have the same effect.

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Evidence-based guidelines

The evidence-based guidelines developed for midwife use in the trial were peer-reviewed by national experts who are listed below, and we would like to express our appreciation to them for this.

Endometritis and abnormal bleeding:
Dr Sally Marchant RN RM ADM Diploma in Research Studies PhD. Senior Lecturer in Midwifery, Institute of Health and Community Studies, Bournemouth University.

Perineal pain and dyspareunia:
Mrs Christine Kettle SRN SCM DipMS. Midwifery Research Fellow, North Staffordshire Hospital Centre NHS Trust.

Professor Richard Johanson MA BSc MBBchir MRCOG MD. North Staffordshire Hospital Centre NHS Trust/Keele University.

Caesarean wound care and pain relief:
Mrs Pauline M Hobbs SRN BSc. Infection Control Nurse Specialist, Department of Microbiology, Birmingham Women's Hospital NHS Trust.

Dr Richard H George MBChB FRCPath. Consultant Microbiologist, Department of Microbiology, Birmingham Women's Hospital NHS Trust.

Breastfeeding issues:
Professor Mary Renfrew BSc RGN SCM RN PhD. Professor of Midwifery Studies, Mother and Infant Research Unit, University of Leeds.

Mrs Christine Carson SRN SCM PGDip MSc. National Infant Feeding Adviser, Department of Health.

Urinary problems:
Professor Linda Cardozo MD FRCOG. Professor of Urogynaecology, Department of Obstetrics, Kings College Hospital, London.

Ms Nina Bridges SRP MCSP. Physiotherapy Manager, Department of Physiotherapy, Birmingham Women's Hospital NHS Trust.

Bowel problems:
Professor Michael Keighley MS FRCS. Barling Professor of Surgery, Head of Department of Surgery, University of Birmingham.

Mr Abdul Sultan MB ChB MRCOG MD. Consultant Obstetrician and Gynaecologist, Mayday Hospital, Surrey.

Depression and other psychological morbidity:
Professor John Cox DM FRCPsych. Professor of Psychiatry, Department of Psychiatry, University of Keele and President, The Royal College of Psychiatry, London.

Mrs Gail Chapman RM MPhil. Research Midwife, Academic Department of Obstetrics and Gynaecology, North Staffordshire Hospital NHS Trust.

Backache:
Dr Martin Wilkinson MMedSci FRCGP Lecturer, Department of Primary Care and General Practice, University of Birmingham.

Ms Ros Davies MCSP SRP. Senior Physiotherapist, Department of Physiotherapy, Birmingham Women's Hospital NHS Trust.

Headache:
Dr Griselda Cooper MB ChB FRCA. Senior Lecturer in Anaesthetics, University of Birmingham.

Mr Andrew Shennan MBBS MRCOG MD. Senior Lecturer in Maternal and Fetal Health, Fetal Health Research Group, Kings College, University of London.

Contribution of authors

Christine MacArthur (CM) and Heather Winter (HW), together with Debra Bick (DeB) conceived the study. These authors, with the help of Richard Lilford (RiL), Christine Henderson (CH) and Harry Gee (HG), wrote the original grant proposal and were members of the trial management group. Data collection tools and training models were designed by CM, DeB, Robert Lancashire (RoL), HW, Helena Knowles (HK) and CH. The guidelines were prepared by DeB, CM, HK and HW. Trial implementation was largely undertaken by DeB and HK, overseen by CM, HW and the trial management group. Analysis was undertaken by CM, HW, RoL and David Braunholtz (DaB) and the findings interpreted by them, with DeB and RiL. Economic analysis was undertaken by Clive Belfield (CB), with HW and RoL, and CB was also a member of the trial management group. The report was drafted by CM and HW; all authors contributed to the final text.

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