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Abstract

The Social Support and Family Health Study: a randomised controlled trial and economic evaluation of two alternative forms of postnatal support for mothers living in disadvantaged inner-city areas

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Objectives: To determine whether increased postnatal support could influence maternal and child health outcomes.

Design: This was a randomised controlled trial comparing maternal and child health outcomes for women offered either of the support interventions with those for control women receiving standard services only. Outcome data were collected through questionnaires distributed 12 and 18 months postrandomisation. Process data were also collected. There was also an integral economic evaluation.

Setting and participants: Women living in deprived enumeration districts in selected London boroughs were eligible for the trial if they gave birth between 1 January and 30 September 1999.

Results: The 731 participants were found to be well matched in terms of socio-economic characteristics and health and support variables (14% of the participants were non-English speaking). Response rates at the two follow-up points were 90% and 82%. At both points there were no differences that could not be attributed to chance on the primary outcomes of maternal depression, child injury or maternal smoking. At the first follow-up, there was reduced use of general practitioners by support health visitor (SHV) children, but increased use of NHS health visitors and social workers by mothers. At the second follow-up, both community group support (CGS) and SHV mothers had less use of midwifery services (fewer were pregnant), and SHV mothers were less worried about their child's health and development. Uptake of the CGS intervention was low: 19%, compared with 94% for the SHV intervention. Satisfaction with the intervention among women in the SHV group was high. Based on the assumptions and conditions of the costing methods, the economic evaluation found no net economic cost or benefit of choosing either of the two interventions.

Conclusions: There was no evidence of impact on the primary outcomes of either intervention. The SHV intervention was popular with women, and was associated with improvement in some of the secondary outcomes. This suggests that greater emphasis on the social support role of health visitors could improve some measures of family well-being. Possible areas for future research include a systematic review of social support and its effect on health; developing and testing other postnatal models of support that match more closely the age of the baby and the changing patterns of mothers' needs; evaluating other strategies for mobilising 'non-professional' support; developing and testing more culturally specific support interventions; developing more culturally appropriate standardised measures of health outcomes; providing longer term follow-up of social support interventions; and exploring the role of social support on the delay in subsequent pregnancy.

Contents

List of abbreviations

A&E	accident and emergency (department)
BME	Black or Minority Ethnic (group)
BSL	British Sign Language
CGS	community group support
CI	confidence interval
COSI	Crying or Sleeping Infants (study)
DETR	Department of the Environment, Transport and the Regions
DUFSS	Duke–UNC Functional Social Support (scale)
EPDS	Edinburgh Postnatal Depression Scale
FTE	full-time equivalent
GHQ	General Health Questionnaire
HV	health visitor
IQR	interquartile range
n	number who selected a certain response
N	total number who answered a given question
NCT	National Childbirth Trust
ONS	Office for National Statistics
OR	odds ratio
RCT	randomised controlled trial
RR	relative risk
SD	standard deviation
SHV	support health visitor
SIDS	sudden infant death syndrome
SPSS	Statistical Package for the Social Sciences
SSFH	Social Support and Family Health (study)
SSPO	Social Support and Pregnancy Outcome (study)
SSRU	Social Science Research Unit
UPA	underprivileged area

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

The objective of this study was to address the question of whether increased postnatal support could influence maternal and child health outcomes. It aimed to measure the impact and cost-effectiveness of two alternative strategies for providing support to mothers in disadvantaged inner city areas: a programme of visits from health visitors trained in supportive listening [Support Health Visitor (SHV)] and the services of local community support organisations [Community Group Support (CGS)].

Methods

Design

The Social Support and Family Health (SSFH) Study was a randomised controlled trial which compared maternal and child health outcomes for women offered either of the support interventions with those for control women receiving standard services only. Outcome data were collected through questionnaires distributed 12 months and 18 months postrandomisation. Process data were also collected. There was an integral economic evaluation.

Setting and subjects

Women living in deprived enumeration districts in the London boroughs of Camden and Islington were eligible for the trial if they gave birth between 1 January and 30 September 1999. Women whose babies had died, were seriously ill or had been placed in foster care were excluded from the trial.

Interventions

The SHV intervention consisted of the offer of 1 year of monthly supportive listening visits; the first visit took place when the baby was approximately 10 weeks old. The SHVs' primary focus was on the woman and her needs, with practical support and information provided on request.

The CGS intervention entailed being assigned to one of eight community groups. The groups offered drop-in sessions, home visiting and/or telephone support. They made their standard package of services available to study women for 1 year.

Main outcome measures

The primary outcome measures were child injury, maternal smoking and maternal psychological well-being. The secondary measures were uptake and cost of health services, household resources, maternal and child health, experiences of motherhood and infant feeding. The Edinburgh Postnatal Depression Scale (EPDS) and the General Health Questionnaire (GHQ12) were used to measure maternal depression. The Duke Functional Social Support scale (DUFSS) was used as an indicator of support resources available to participants.

Results

The 731 participants were well matched in terms of socio-economic characteristics and health and support variables. Fourteen per cent of the participants were non-English speaking. Response rates at the two follow-up points were 90% and 82%. At both points there were no differences that could not be attributed to chance on the primary outcomes of maternal depression, child injury or maternal smoking. At both follow-ups there were differences in secondary outcomes: at the first follow-up, there was reduced use of general practitioners (GPs) by SHV children, but increased use of NHS health visitors and social workers by mothers; at the second follow-up, both CGS and SHV mothers had less use of midwifery services (fewer were pregnant), and SHV mothers were less worried about their child's health and development. Uptake of the CGS intervention was low: 19%, compared with 94% for the SHV intervention.

Satisfaction with the intervention among women in the SHV group was high. Based on the assumptions and conditions of the costing methods, the economic evaluation found no net economic cost or benefit of choosing either of the two interventions.

Conclusions

There was no evidence of impact on the primary outcomes of either intervention. The SHV intervention was popular with women, and was associated with improvement in some of the secondary outcomes. This suggests that greater emphasis on the social support role of health visitors could improve some measures of family well-being.

Recommendations for further research

Future research could usefully focus on:

- combining the results of this trial and others into a systematic review of social support and its effect on health
- developing and testing other postnatal models of support that match more closely the age of the baby and the changing patterns of mothers' needs
- evaluating other strategies for mobilising 'non-professional' support
- developing and testing more culturally specific support interventions
- developing more culturally appropriate standardised measures of health outcomes
- providing longer term follow-up of social support interventions
- exploring the role of social support on the delay in subsequent pregnancy.

Chapter 1
Introduction

The study described in this report evaluates the effectiveness of two different support initiatives in improving the health of a multi-ethnic population of disadvantaged inner-city families with newborn infants. The two initiatives are home-based supportive visiting by health visitors, and the services of community support organisations. The Social Support and Family Health (SSFH) study compares both of these with the services routinely available to families. The primary outcomes of interest identified in the study protocol were child injury, maternal smoking and maternal psychological well-being; with additional interest in health service use and health status, and changes in household resources. An economic evaluation, carried out as an integral part of the study, was designed to answer questions about the cost-effectiveness of these different approaches to family support. The study ran from 1 September 1998 to 31 December 2001.

This study was developed primarily as a result of the work of the lead applicants on two pieces of research: a systematic review of randomised controlled trials (RCTs) that showed the effectiveness of home-based social support in preventing child injury[1] and an RCT of supportive home visiting in high-risk pregnancy that demonstrated positive outcomes for child and maternal health.[2–5] The findings of these studies indicated that social support could influence maternal depression, which in turn could, if mothers were happier, lead to a reduction in child injury. This premise led to the development of a programme of social support offered postnatally in home visits by health visitors. The funders of the study, the NHS research and development (R&D) Health Technology Assessment Programme, were also interested in discovering whether this type of support could be offered effectively by lay individuals, as this could potentially reduce the cost burden to the NHS. The cost, logistics and perceived difficulties in sustainability and replication prohibited the development of a 'community mother' programme in London as implemented and evaluated in Dublin.[6] Instead, a pragmatic approach was adopted of working with existing voluntary sector services for families with young children, to assess the impact of this 'non-health professional' support intervention on the outcomes of interest.

The broader context of the SSFH study includes: evidence about the importance and prevalence of particular family health problems in the overall picture of health inequalities, research on social support and health, and evidence about the relevance of social interventions as a means of tackling family health problems.

Family health and health inequalities

Socio-economic inequalities in health are persistent features of most societies that collect relevant data.[7] In the UK, occupational position, gender and ethnicity are all associated with health differences, whether measured as mortality, morbidity, life expectancy or health status.[8] Households with children are an especially at-risk group. Children carry a disproportionate share of the burden of poverty and associated poor health: one in three British children, compared with one in four of the general population, lives in poverty.[9] Young children in socioeconomically disadvantaged families are a high-risk group for injury, child abuse and neglect, sudden infant death syndrome (SIDS), and health problems such as respiratory infections and glue ear; they are less likely to be breast-fed and to have regular well-child care.[10] As the primary carers of young children, mothers are also likely to suffer health problems when this caring work is carried out in circumstances of socio-economic disadvantage.[11]

Injuries are a leading cause of childhood mortality, a major cause of acquired disability and an important source of direct costs to the NHS.[8] The socio-economic gradients for childhood injury death are steeper than for any other child health problem. The gradient is increasing: in 1981, the injury death rate for children in social class V was 3.5 times that of children in social class I, whereas in 1991 it was 5.0 times greater.[12]

Smoking has a wide range of adverse health effects both for the adults who smoke, and for children exposed to passive smoking. Infants of

parents who smoke are substantially more likely to die from SIDS, are twice as likely to suffer serious respiratory infections, and are more likely to suffer from glue ear and asthma. The Royal College of Physicians has estimated that in the UK parental smoking is responsible for at least 17,000 admissions to hospital each year of children under 5 years.[13] Smoking rates are higher and cessation rates are lower in parents, especially mothers, from lower socio-economic groups.[14,15]

Maternal psychological well-being is important both to the health of women and to the well-being of families. Low psychological well-being after childbirth, often characterised as 'postnatal depression', is a major public health problem, affecting between 10 and 80% of women, depending on definition and measurement.[16,17] Psychosocial health in women is strongly associated with socio-economic status. Brown and Harris[18] found that 31% of British working-class mothers with young children fulfilled criteria for depression. Lone mothers are at particularly high risk of poor psychosocial health;[19] in two-parent households, mothers' psychological health may be especially responsive to partner-associated stressful life events, such as unemployment.[20] Both household income and the prevalence of high income inequality appear to be important,[21] suggesting that the relationship between income and health is mediated by psychosocial and material factors.[22]

Mothers' low psychological well-being is linked to problems in children's cognitive and emotional development[23,24] and to enhanced risk of child injury. For example, Sibert[25] compared 100 families of children hospitalised for poisoning with 100 control families matched for socio-economic status and age and gender of the child, and found a higher prevalence of maternal depression among families of cases (36%) than controls (10%). Brown and Davidson[26] examined the link between maternal depression and child injury in central London, reporting an injury rate for children of depressed mothers of 19.2/100 per year compared with 9.6/100 per year for the children of mothers who were not depressed.

Extensive research has uncovered little evidence to support a biological basis for poor psychological health after childbirth, but a wealth of evidence pointing to the importance of social factors, including obstetric intervention,[27–29] stressful life events and low social support.[30,31]

Health service use has a complex and poorly understood relationship with health status.[32–34] The poor health of many children and disadvantaged families is associated with poor access to, and/or low use of, health services. But, although it is widely assumed that health service use produces better health, there is some evidence that the relationship may work the other way around, with more health service use producing poorer health; the important factor may be *appropriate* health service use.[35]

Household resources, including both material and social support factors, are relevant to the health of both adults and children in households. Some of the association between socio-economic status and poor health depends on the direct effect of insufficient material resources to safeguard health. In families with young children these resources include adequate housing, income, access to a healthy diet and a safe physical environment.[36] Inequalities in resource distribution that disadvantage women and children commonly occur within households, posing additional risks to children's health.[37,38] The social support resources may also be skewed, with mothers providing more support than they themselves are able to utilise.[39] Lower socioeconomic status among mothers is associated with poorer social networks and less partner help.[40]

Social support and health

A range of social factors is involved in the pattern of socio-economic differentials in family health, and in 'explaining' worse outcomes among disadvantaged families. Health service interventions to reduce inequalities have shown some effectiveness, although the pattern is mixed and there is a shortage of reliable experimental evidence.[41] There is, however, a considerable body of research suggesting that social intervention programmes may have the capacity to promote health in families with young children, and may thus have the capability to impact on social differentials in health outcomes.[35]

Epidemiological evidence about the relationship between social support and health has long confirmed lay understandings in identifying people's naturally occurring social support as health promoting. The importance of social support to health was 'discovered' in the 1970s, largely as a response to evidence about continuing social class inequalities and the failure of conventional physical risk factor explanations to account for the pattern of individual and social group differences in health and disease.[42–44] Social

connections significantly predict people's chances of staying well or becoming ill; the association between support and health has been shown to hold independently of other factors such as socio-economic status, smoking, alcohol use, level of physical activity, obesity, ethnicity and use of preventive health services.[45,46]

The fundamental element in social support is that individuals are provided with the feeling that they are cared for, that they are esteemed and valued, and are part of a network of communication; it can include both emotional and practical components: both caring and concrete forms of help such as the provision of advice, information, help with domestic tasks, money or other material aid.[46,47] Social support may influence health through a number of pathways: by directly affecting health, by making stress less likely, or by acting as a buffer against the health-damaging effects of stress.[48] These general observations about support and health also apply to childbearing women and families. The importance of social support is confirmed by the 'consumer satisfaction' literature, which documents the persistence over many years of the link between women's dissatisfaction with the formal antenatal and postnatal health services and the failure of these services to provide continuity of care and support.[49,50]

A large body of research suggests that good outcomes for mothers and children are more likely when mothers are socially supported.[51] For example, Williams and Carmichael[52] followed a cohort of 99 families with a newborn infant in urban Australia, and found that the absence of a support network strongly associated with the occurrence of depression. In the USA, Hall and colleagues[53] reported an inverse relationship between the quality of social networks and the prevalence of depression among low-income mothers. The existence of social support may similarly help to reduce smoking[4] and child injuries,[54] alter the extent and allocation of household resources,[38] and change patterns of health service use.[55]

Social intervention programmes to support parents

The most robust evidence for the importance of social support to maternal and child health comes from RCTs designed to test the effectiveness in changing health outcomes of different approaches to providing support for parents. Well-designed studies allow for reliable comparison either between different interventions and/or with outcomes in families receiving routinely provided services. When combined in systematic reviews, the results of such studies provide the best evidence available about the effectiveness and appropriateness of different approaches to providing support.

Systematic reviews informing the context of the SSFH study include three Cochrane reviews of home-based social support,[56] caregiver support for postpartum depression[57] and parent-training programmes.[58] The original version of the home-based support review, completed before the SSFH study was undertaken, was particularly important in establishing the rationale for the trial.

Home-based social support

The Cochrane review of home-based support for socially disadvantaged mothers examined the evidence provided by 11 controlled trials of postpartum home visiting published between 1979 and mid-1995. The outcomes examined varied considerably between trials. Eight trials looked at the effect of home-based maternal support on the incidence of child injury. The pooled odds ratio was 0.74 [95% confidence internal (CI) 0.54 to 1.03]. This result should be interpreted with caution, since some of the included trials had methodological flaws (particularly quasi-random methods of allocation), and there may have been publication bias with authors selectively omitting from published reports effects on injury outcomes that were 'negative' or failed to reach statistical significance.

Six trials in the home-based support review reported the effect on well-child immunisations. In four of the five trials that reported dichotomous outcome data, infants of visited mothers were less likely to have incomplete immunisation. The pooled estimate for the effect of home-based support on incomplete well-child immunisations was 0.56 (95% CI 0.41 to 0.76). Four trials reported the effect of home-based support on children's hospital admissions. In all four there was a lower incidence of hospital admissions in the visited group, suggesting that families receiving additional support are less likely to have babies requiring hospitalisation (OR = 0.65, 95% CI 0.43 to 0.98).

Five trials reported the effect of home-based support on the frequency of emergency department visits. Only two trials reported these as dichotomous outcomes; in one, fewer emergency department visits were made by the

intervention group, while in the other the proportion in the intervention and control groups visiting emergency departments was almost identical.

Overall, the systematic review of home-based maternal support trials shows that this approach has the potential to improve the health of children from disadvantaged families, particularly in relation to rates of childhood injury, immunisation levels and number of hospital admissions. However, many of the primary studies have methodological weaknesses that warrant a cautious interpretation of their results.

Caregiver support for postnatal depression

In the review of caregiver support as a strategy for treating postnatal depression the evidence is based on only two trials, one of cognitive behavioural therapy provided by a psychologist,[59] the other of non-directive counselling provided by health visitors.[60] The combined results showed a reduction in depression at 25 weeks (OR = 0.34, 95% CI 0.17 to 0.69). The women in these trials had been diagnosed as clinically depressed, and the trial interventions were therefore aimed at treatment rather than prevention.

Parent training

Parenting programmes started to become popular in the 1960s and have multiplied more recently with the involvement of a wide range of voluntary organisations.[61] The Cochrane Review of group-based parent training programmes examined the impact on maternal psychological health and included 23 studies, although only 17 provided sufficient data to calculate effect sizes. Meta-analyses showed statistically significant results favouring the intervention group as regards depression, stress, self-esteem and relationship with partner. Other data gave a mixed picture of effectiveness, from statistically significant improved outcomes in the intervention group to no evidence of effectiveness. An interesting finding of a related review on parent-training programmes and child behaviour was that the one study that used a 'placebo' control group – mothers talking and sharing their experiences of motherhood – showed that this was just as effective as professional-led didactic parent training.[62]

Trials of particular relevance to the SSFH study

Individual trials of particular relevance to the design and development of the SSFH study include: Holden and colleagues on health visitor support for maternal depression[60] (included in the Cochrane Review referred to above); the trials conducted in Elmira and Memphis by Olds,[64,65] which have generated evidence of the long-term effectiveness of parent support in improving health and welfare outcomes among both mothers and children;[65–67] a trial by Morrell and colleagues of community support workers that evaluated the effectiveness of this approach in improving mothers' health status, finding no evidence of extra benefit compared with visits by additional community midwives alone;[68] the trial conducted by Johnson and colleagues using 'non-professional community mothers' to deliver a child development programme to disadvantaged first-time mothers[6] which, by contrast, reported a positive impact on child and maternal outcomes; and a recently completed trial by MacArthur and colleagues of redesigned community postnatal care by midwives with extended postnatal contact which found significantly improved mental health among intervention group mothers 4 months after birth.[69]

The SSFH study builds particularly on a previous RCT of supportive home visiting in high-risk pregnancy conducted in England in 1986–8.[2,3] The Social Support and Pregnancy Outcome (SSPO) study employed research midwives to offer supportive home visits to women with a history of low birth-weight delivery. The SSPO study was shown to have a positive impact on a broad range of child and maternal health outcomes measured when the study children were 6 weeks, 1 year and 7 years old.[2,4,5]

Research and policy questions

The research evidence suggests that supporting parents is an important way forward for improving health in disadvantaged families. For this reason it has some prominence in the Acheson Report on health inequalities,[8] and is a key part of government policy to improve health, reduce inequalities and promote family life.[70] For example, the Sure Start initiative is investing £452 million in 1999–2002 in a cross-departmental strategy designed to improve services for 0–3 year olds in deprived localities: home visiting, parent education and support are all variously components of individual initiatives.

Several critical issues about the effectiveness and appropriateness of different approaches to supporting parents remain:

- Much of the most reliable evidence comes from research conducted outside the UK: its relevance to UK settings is unknown.
- There is conflicting evidence – partly, but not wholly, because of methodological problems with existing studies – about the salience of support to different health and welfare outcomes.
- Support interventions can be, and have been, provided by different groups of professionals and by non-professionals. In the Cochrane Review of home-based social support, for example, support was provided in six trials by non-professionals (nurses, physicians and social workers), in three by professionals and in two by a mixture of both.
- 'Support', used as an umbrella term, may cover different approaches, including didactic education and training, and types of therapy and counselling which are not necessarily experienced as supportive.
- Most trials of support interventions exclude people for whom speaking and/or writing English is difficult; the relevance of their findings for multicultural populations is therefore unknown.
- There is not a great deal of information in existing research about the economic costs of different approaches to parent support.

Health visitors

In the UK context, supporting parents has traditionally involved health visitors working for the statutory primary healthcare services. In London in 1998/9 there were over 2.6 million face-to-face contacts between families and health visitors, with around 500,000 families visited.[71] However, policy changes have meant that the role of health visitors increasingly focuses on screening, surveillance, immunisation and child protection, and staff shortages mean that caseloads have to be prioritised, all of which may run counter to the goal of supporting parents.[72,73] There is increasing recognition that the role of health visitors has changed.[74]

A systematic review of domiciliary health visiting found evidence to suggest that this may be associated with a reduction in the frequency of unintentional injury, and improvements in parenting skills, breast-feeding, maternal social support, the detection and management of postnatal depression and children's intellectual development and behavioural problems. There was no evidence that home visiting by health visitors improved the uptake of immunisation or reduced hospital admission and the use of emergency medical services; and insufficient evidence to show an effect on children's illness, diet and physical development, and mothers' informal social support, use of community resources, return to education and work, and family size.[75] The recommendations from this review stressed the need for more studies with rigorous experimental designs, especially to compare the effectiveness and cost-effectiveness of professional and non-professional home visits.

Community support

There has been enormous recent growth in the number of voluntary organisations working in the area of family support.[61] This has followed from the growing interest in a 'mixed economy of welfare', with combined state and private sector services, and from the policy interest in strengthening the 'natural' support, resources of communities. For example, the white paper 'Saving lives: our healthier nation' advocates drawing on community support organisations and structures to manage psychosocial problems.[76] While voluntary sector organisations make many claims to provide services that effectively tackle a range of problems, including child injury and neglect, poor parenting and low psychosocial well-being in mothers, there is as yet little evidence. Most evidence comes from evaluations that ask users of these services for their opinions without attempting either to reach non-users or to assess the value of the service against outcomes in a randomly allocated control group. Studies have shown substantial problems of non-take-up, especially among disadvantaged families, with referrals to voluntary sector support initiatives such as Home-Start and Newpin, and significant levels of criticism among users of the unhelpful nature of the 'support' provided.[77] The voluntary sector components and partnerships funded through Sure Start are likely to prompt similar issues, since the evaluation is not using the design of an RCT.[78]

Previous evidence about the cost-effectiveness of social support for mothers

Several previous studies have reported the costs of different interventions, and some have undertaken economic evaluations. Previous economic evaluation studies of home visitation programmes

alongside RCTs include Brooks-Gunn and colleagues (1994),[79] Dawson and colleagues (1989),[80] Hardy and Street (1989),[81] Morrell and colleagues (2000)[68] and Olds and colleagues (1993).[82] Only one of these (Morrell, 2000)[68] was conducted in the UK, in Sheffield. Another UK study of enhanced postnatal visiting by midwives that incorporates an economic evaluation is being published at the time of writing.[69]

The Sheffield study of a policy of providing home visits by postnatal support workers to newly delivered mothers found no evidence of health benefits at 6 weeks and 6 months, but women were more satisfied with the new service. In a short-term cost-effectiveness comparison, these added benefits perceived by women were not valued, and the intervention group had higher health service costs.[68]

Brooks-Gunn and associates[79] studied a combined home visitation and full-time day nursery programme for families of low birth-weight babies in the USA. The economic evaluation in this study provided estimates of effects on maternal employment, fertility, education and claims for welfare benefits. However, these cannot be solely attributed to the home visitation element.

Also in the USA, Dawson and colleagues[80] found supportive weekly health visiting and parent groups to yield no apparent health benefit at 1 year, and to be associated with higher costs than standard local practice. A third American study of bimonthly parenting and child-care education through home visits carried out by trained community members found health and welfare benefits accompanied by total public healthcare cost savings.[81]

The Elmira Project undertaken by Olds and colleagues in the USA assessed a programme of home visits for women having care in the public healthcare sector during pregnancy and for 2 years after delivery. The public sector costs included in the analysis were those of the programme, healthcare services, crisis services and child protection services, and welfare benefits minus tax revenue due to maternal employment. Subgroup analyses of low-income families at follow-up, when the children were 4 years old, indicated net positive health benefit at net negative costs (savings). When all subjects were analysed together, the programme was associated with a net cost of $1582 per family at 1980 prices, around £2910 in 2001.[82] The economic analysis was based on the data of 'white' women (89% of the original sample). CIs of estimated savings were reported, although not used in sensitivity analysis of results. A 15-year follow-up of the Elmira Project[67] documents long-term effects of the programme, but with no linked economic analysis.

Other studies[6,63,83,84] have provided fragmentary evidence regarding healthcare-related events and the consequences for maternal education and employment of home visitation programmes.

Two economic studies of community voluntary support interventions have been reported in the UK. In Avon, referrals in 26 general practitioner (GP) practices to voluntary support organisations were assessed in terms of their associated costs to the NHS over 4 months. Effects observed related to improvement in anxiety, other emotional feelings, ability to carry out everyday activities, feelings about general health and quality of life. There was a greater cost for the referral group, part of which was the cost of drug prescriptions.[55] Reid and colleagues[85] reported a study conducted in Scotland comparing three interventions for new mothers: a manual on coping skills, an invitation to a postnatal support group and both of these combined. The postnatal support group intervention resulted in additional costs of public provision and personal costs for mothers of attending the programme with no apparent additional benefit in terms of health or satisfaction. A third UK trial, the Crying or Sleeping Infants (COSI) study, had an economic evaluation that considered the costs of two interventions for managing crying and sleeping problems in infants: one behavioural and one educational intervention. Although the study was not primarily focused on community support, one component of the educational intervention was the provision of contact details for a telephone helpline from a voluntary support group. There was shown to be a lack of uptake and effect in the educational intervention. Although the limited use of the helpline was reported, costs of use of this service were not included.[86]

The heterogeneity of previous research incorporating economic evaluations means that its relevance to the SSFH study is limited. While this research suggests an added cost of support interventions, it is impossible to estimate whether the costs of such interventions in 1999–2001 in the UK would be in similar ranges. No studies have systematically compared the economic costs of supportive health visiting, access to voluntary groups and standard services.

Summary

There is evidence from a wide variety of studies that social support promotes health and well-being, and that differences in the availability and use of social support resources may be one factor underlying the poorer health of socially disadvantaged families. There is a paucity of well-designed trials in this area. There are few systematic comparisons between the effectiveness, including cost-effectiveness, of different types of approach. While existing research suggests that service interventions to provide support may enhance a range of outcomes for mothers and children in poor families, the relevance of this approach to all families, irrespective of cultural and ethnic differences, is unclear.

Chapter 2
Methods

Protocol

Study population

The SSFH study was carried out in the inner London boroughs of Camden and Islington. The average Jarman underprivileged area (UPA) scores for the two boroughs are 40 and 49, respectively.[87] Jarman UPA scores include a variety of indicators that reflect material deprivation and other factors predictive of increased healthcare needs (including one-parent families, unskilled workers, unemployment, overcrowding, mobility and ethnic minorities).[88,89] A score of 40 is considerably greater than the national average of zero, thereby indicating much greater than average socio-economic deprivation and healthcare needs. Minority ethnic groups comprise 18% of the population in Camden and 25% of the population in Islington (compared with approximately 6% in the total UK population).[90] No data are collected systematically on language use of residents in Camden and Islington; however, information gathered from schools indicates that 26% of primary school students are not fluent in English.[91] The population of Camden and Islington has high mental health needs; Islington has the highest score in England (122.4) on the mental health needs index and Camden has the third highest score (120.9); the average for England is 100.[91]

Inclusion criteria

The sampling frame for the SSFH study was women who had given birth between 1 January 1999 and 30 September 1999 and were resident in the 'more deprived' enumeration districts of Camden and Islington. As the study was designed specifically to target socially excluded families with young children, 'deprivation' was measured using the '*Index of children in low income households*' from the Department of the Environment, Transport and the Regions (DETR).[92] This index, based on 1991 census data, reflects the proportion of families who are on a low income and have children under 5 years old. For the purposes of the SSFH study, the information team of the Public Health Department of Camden and Islington Health Authority ranked all the enumeration districts in Camden and Islington by the index score, and then grouped them into deprivation categories from 1 (high deprivation) to 10 (low deprivation). Enumeration districts in categories 1–5 were used for trial recruitment.

Exclusion criteria

The following exclusion criteria were applied: women whose baby had died or was seriously ill in hospital, women whose baby had been placed in foster care, and women who had moved (or were in the process of moving) out of Camden and Islington. Women who did not speak English were not excluded.

The two interventions and standard services

The support health visitor (SHV) intervention consisted of the offer of monthly home visits by an SHV for 1 year. The structure of the visits was informal, with a focus on listening to the woman and exploring any issues she wanted to discuss. The women could request more or less frequent visits and could also ask that the visits took place in an alternative venue. Interpreters were provided for the intervention visits where necessary.

The community group support (CGS) intervention arm of the study consisted of the offer of support from one of eight local community groups in the voluntary and charitable sector that provide support and services to postnatal women and their babies. The nature of the intervention was dependent on the standard services operated by each group. These included drop-in activities, home visiting and telephone support.

Routine NHS health visiting services were available to women in the control group and both intervention arms. In the study area these health visiting services involved one postnatal home visit when the baby was 10–15 days old and clinic support thereafter; subsequent home visits were not routinely made, except for women deemed to be at moderate or high risk. Women in all three trial arms were able to access available local community group services.

Further details of the two interventions are given later in this chapter.

Outcome and process measures

The primary outcome measures for the SSFH study were child injury, maternal smoking and maternal psychological well-being at 12 and 18 months postrandomisation. The secondary measures were: uptake of health services, household resources (financial and other), maternal and child health, and experience of motherhood and infant feeding.

Baseline and outcome data were derived from maternal self-report in either self-administered questionnaires or interviews. Maternal self-report was chosen as the means for collecting information as questions about the reliability and validity of medical record data limit the use of medical records in research on health-related events.[93–95] Maternal reporting of childhood injury rates has been shown to be very accurate, even over a 1-year recall period.[96,97] In some studies episodes of health problems reported by mothers significantly outnumber those recorded in medical records.[98,99]

Child injury

Measurement of child injury was based on the mother's recollection of the number of injuries sustained by the index child in the previous 6 months that had required a consultation with a health professional. This question was asked at both follow-up points (12 and 18 months postrandomisation) and the data were combined to form an outcome of 'any injury requiring help from a health professional in either of the two 6-month recall periods'.

Maternal smoking

The women were asked at each of the data collection points whether they smoked cigarettes. Those who said they smoked were asked the average number of cigarettes they smoked each day.

Maternal depression

Several measures were used to assess maternal psychological well-being. The Edinburgh Postnatal Depression Scale (EPDS),[100] a screening tool for postnatal depression, was used at baseline and at the first follow-up questionnaire at 12 months postrandomisation. Scores from the answers to the ten questions in this scale were combined to form an overall score. Women with a score of 12 or above are at higher risk of postnatal depression.

At the second follow-up at 18 months postrandomisation the General Health Questionnaire (GHQ12) was used. This questionnaire was designed to measure short-term changes in mental health (depression, anxiety, social dysfunction and somatic symptoms).[101] Twelve questions are asked, which require the women to assess whether 'in the last few weeks' things have been 'better than usual', 'same as usual', 'worse than usual' or 'much worse than usual'. A composite score was developed using Likert scoring of the responses (0–3). A higher final score indicates a more severe condition.[102]

In addition, the participants were asked in both follow-up questionnaires the simple question (used in the previous SSPO study) as to whether they had felt 'fairly cheerful' or 'low spirited and depressed' in the previous weeks. This question was included because of the high numbers of women who did not have English as a first language and for whom the standard measures have not been validated and may not have been appropriate.

Health service usage

This outcome was measured by asking women about their use over the previous month for themselves and the index child of a variety of health services (GP, health visitor, social work and hospital doctor), and in the previous 6 months (for children) the use of hospital services, including accident and emergency (A&E) services. The uptake of immunisations was included as a variable to measure health service usage.

Maternal health

The mother's health status was measured by her view of her own health over the past month and her use of medication in the past week.

Child health

The child's health was measured using two variables: mother's perceptions of her child's general health and the child's use of medication in the previous week.

Infant feeding

At the first follow-up, two variables were used to measure infant feeding: timing of cessation of breast-feeding and timing of introduction of solid foods.

Experiences of motherhood

Measures of mother–child interaction included questions on mothers' perceptions of the ease or difficulty of looking after the index child, their particular worries about the child's health, and the child's development.

Household resources

Measures of this outcome included both financial and other resources available to the woman. On both follow-up questionnaires, financial resources were measured by the woman's view of her current financial situation (compared with how it had been 1 year before) and by the proportion of mothers in paid employment. At the second follow-up, an additional question about weekly household income was included.

Other resources were measured by women's views of the support given to them by their partner (where relevant) and by overall feelings of support recorded in both follow-up questionnaires.

For the women who had a partner at that time, six questions were asked about the frequency of partner help with child care and household-related tasks. A composite score of partner support was compiled from the answers to these six questions.

The women were asked to rate the overall degree of support they had experienced in the previous 6 months. The Duke–UNC Functional Social Support scale (DUFSS)[103] was used at the second follow-up as a measure of participants' interactions with, and support from, other people in their lives. This is an eight-item scale, with Likert scoring (1–5) on questions of confidant and affective support. A lower score indicates better support.

Sample size

The sample size calculation for the SSFH Study was based on the injury and depression outcome measures. The calculation was initially determined on the basis that the aim of the study was to compare outcomes in supported and non-supported mothers. Originally, there was only one intervention group; however, during commissioning the funders of the study asked that professional and non-professional support be compared within the same trial. This would allow for analysis that combined the two support groups and would thus compare supported mothers with unsupported mothers. In addition, the size of the sample allowed for comparisons (albeit with less power) between each support group and the control group.

Estimation of study size required information on the incidence of childhood injury, and the prevalence of depression in disadvantaged inner-city populations. In a follow-up study of 1000 randomly selected families in Newcastle upon Tyne, the cumulative incidence of injury in the first 2 years of life was 26%.[93] Because socio-economic disadvantage is a strong risk factor for child injury, the incidence was hypothesised to be higher among children living in the deprived inner-city boroughs of Camden and Islington. For depression, the rates of depression were approximated from those found at 1 year postpartum (44%) in the participants of the SSPO trial.[4] The initial calculation was based on a study of 800 participants (400 control; 400 intervention, with 200 within each intervention arm).

Power of trial with 800 participants

Based on an estimated cumulative incidence of injury of 35% (injuries requiring medical attention) in the first 2 years of life, a study of 800 participants (400 intervention; 400 control) would have over 80% power to detect a risk ratio of 0.70 at the 0.05 level of significance, allowing for 10% loss to follow-up.

Based on the prevalence of maternal depression of 40%, a study of 800 participants would have over 90% power to detect a 12% reduction in prevalence of depression (from 40% to 28%) at the 0.05 level of significance, allowing for 10% loss to follow-up. When comparing the control group of 400 to the intervention group of 200 participants, the study would have over 75% power to detect a 12% reduction in prevalence of depression (from 40% to 28%) at the 0.05 level of significance, allowing for 10% loss to follow-up.

Methods of data collection

Baseline questionnaire data were collected after the women had consented to take part in the study. Two outcome questionnaires were sent at 12 and 18 months after randomisation. All three questionnaires were produced in booklet form, and consisted of sections on maternal health and well-being, the child's health, help from other people and questions about the household. The lengths of the questionnaires were 28 pages (baseline, but see below), 20 pages (first follow-up) and 19 pages (second follow-up). Additional questions were asked at first follow-up of women allocated to the two interventions, to gain their views about the intervention to which they were assigned. Additional sheets were included for data about the women's other children under 5 (analysis of these data is not included in this report).

A reminder letter and second copy of the questionnaire were sent for both follow-up questionnaires if the questionnaire was not returned after 2 weeks. A subsequent letter was

sent after another 2 weeks if the questionnaire was still not returned. Following this, a telephone call was made to the woman (or a home visit if a telephone number was not available).

Interviews were used to administer questionnaires to collect baseline and outcome data for women who did not have sufficient literacy in English to complete the questionnaires by themselves; most of these interviews were conducted face to face, with a small number conducted by telephone. Interpreters accompanied researchers to conduct interviews at baseline and subsequent data collection points for women who did not speak English.

In the first follow-up questionnaire the women were asked to complete a slip giving their current contact details and the contact details of a friend or family member for use should the woman move. The letter accompanying the questionnaire explained that all who returned it would be entered into a prize draw for supermarket vouchers (£100 first prize, £50 runner-up). Women who did not return their second follow-up questionnaires were sent a £5 Boots voucher with a second copy of the questionnaire, as information became available during the study from a Cochrane Review of methods of influencing responses to postal questionnaires which suggests that financial incentives of this kind improve response rates.[104]

An integral process evaluation was part of the design of the SSFH study. While RCTs can address questions about effectiveness, understanding why something 'worked' or not requires additional information about the processes involved in developing and implementing interventions and measuring their impact.[105] Such information provides a context for interpreting trial outcomes. It focuses on variables that can "influence the implementation of treatments and the analysis of relative differences in their effectiveness".[106] Including an integral process evaluation is increasingly recognised as good practice in RCTs of social and behavioural interventions,[107] although this commonly does not happen.[108]

The process evaluation in the SSFH study included: questions (some open-ended) about their experiences of, and comments on, the research in the second follow-up questionnaires completed by intervention and control group women in the study; transcribed interviews with SHV intervention group women; formal interviews and informal feedback from the community groups; interviews with the research health visitors; and forms filled in by both SHVs and community groups concerning their contacts with Study women. The process data relating to the two interventions are reported in Chapters 4 and 5, and for the study as a whole in Chapter 8.

Data analysis

Data were double entered into a Paradox database by two different data-entry staff. The two data sets were checked by computer for inconsistencies. When differences occurred, a check was made of the original and the error corrected. The clean data set was transferred to the Statistical Package for the Social Sciences (SPSS) for analysis.

Analysis was carried out on an intention-to-treat basis. As recommended, no formal test was done for significant differences in baseline characteristics between the study groups. Commonly accepted critiques of this approach observe that it confuses the conduct of randomisation, chance bias and adjustment for baseline difference issues.[109] In the analysis, each intervention arm was compared to the control group on outcome variables. The main tables were then rerun with both intervention arms combined. The denominator reported in the tables reflects the number of women who answered a given question. Results are expressed as relative risks (RR) with 95% CI. The bootstrap statistical test was used to calculate mean differences to allow for non-normal distributions of these statistics, which are mostly quite skewed.[110] Epi Info's StatCalc was used to determine RRs and Stata was used to carry out bootstrap percentiles.

Ethics approval

Ethics approval for the SSFH study was granted by the Great Ormond St Hospital for Sick Children NHS Trust/Institute of Child Health Research Ethics Committee, and also by the Local Research Ethics Committee of the Camden and Islington Community Health Services NHS Trust. Additional approval was granted for a supplementary data collection exercise with Camden and Islington health visitors for the economic evaluation of the study.

Assignment

Recruitment and consent

The SSFH study's informed consent procedure was designed to meet the ethical requirement of full and open information for informed choice about participation in research, including special provision for those whose first language is not

English or who find reading difficult.[111] Working with interpreters was chosen over translating recruitment materials. It was felt that the interpreters could provide the opportunity for questions to be asked and answered, and thus potentially increase access to otherwise unreachable families.

A team of 11 researchers (2.5 whole-time equivalents) carried out the informed consent and recruitment process. Names of eligible women were passed to the research team 3–5 weeks after the women had given birth. Letters of invitation and an information leaflet about the study were sent to the addresses on the selected birth lists with reply slips providing women with the choice of not taking part or indicating a preferred time for an appointment to discuss the trial. Short summaries were included in the six different languages (Bengali, Cantonese, Greek, Gujerati, Somali and Turkish) indicated by the Health Authority as being most commonly spoken, giving the woman a telephone number to call if she would like an interpreter; the information leaflet was also translated into Bengali as this was the language spoken by the largest number of the ethnic minority women in the sample. The consent and recruitment interview was then either carried out following return of the reply slip or, if the reply slip was not returned, a researcher called at the woman's home. Interpreters were provided by the interpreting service of the local NHS Community Trust or through community groups, other council interpreting services or personal contacts.

An average of two house calls was made in an attempt to carry out the consent and recruitment visit. At this visit, as clear an explanation as possible was given of the purposes and design of the study, including the randomisation process. Women who agreed to take part signed a consent form which made it clear that all name-identifiable information given would be kept confidential to the study team, except in cases where child protection issues arose. It also made it clear that they were free to withdraw at any time without giving a reason and without this affecting their current or future care or the services available to them.

Following informed consent, the women were given a baseline questionnaire or interview. If the baseline questionnaire was not returned after 4 weeks, a member of the research team made a further visit to offer to help participants to complete the questionnaires. As recruitment proved to be slower and more difficult than expected, the baseline questionnaire was shortened 6 weeks into the recruitment process from 28 to 17 pages, and from then on it was administered by a researcher at the initial consent visit, with an interpreter if required.

Randomisation and allocation concealment

Recruitment to the trial took place over a 9-month period. On the day after they were recruited, women were randomised to one of the three arms of the study: the offer of SHV support, the offer of CGS, or standard services. Before randomisation, information was collected on housing tenure, lone parenthood and parity. A reasonable balance with respect to these potential confounding factors was achieved by the use of minimisation.[112] An independent research administrator, who had no contact with the study participants and was entirely unaware of their individual circumstances, carried out the randomisation using the MINIM software program. MINIM kept a tally of randomisation that could not be overwritten by the operator. Participants were informed in writing or by telephone, and by an interpreter where necessary, to which group they had been allocated.

Blinding

Owing to the nature of the intervention, it was not possible for either the trial participants or the researchers to be blinded to the allocation to group. Data enterers were not involved in recruitment or data collection. They were blind to allocation at the second follow-up, but not at the first follow-up, when the questionnaires had additional sections for women in the two intervention groups. A main reason for selecting postal questionnaires to collect outcome data was to eliminate possible bias due to interviewer awareness of group allocation. In the minority of cases where language or literary problems meant that follow-up data were collected using interviews rather than questionnaires, it was difficult to prevent interviewers knowing women's group status.

Preparation for the trial

The SHV intervention

Consultation

Discussions were held with Primary Care Management representatives of the Camden and Islington Community Health Services NHS Trust

to determine the ways in which the SHV intervention could work in conjunction with the statutory health services. Various models of interaction were considered, including ones involving training existing Camden and Islington health visitors to provide the intervention. It was eventually decided that the best strategy was to carry out an external recruitment process for the SHVs who would work on the study. The SHVs were based at the Social Science Research Unit and managed by the research team.

Recruitment and training

Advertisements were placed in *The Nursing Times*, *The Guardian* and the internal job vacancy bulletin of Camden and Islington Community Trust. In order to be considered, applicants had to meet the essential criteria of: being a qualified health visitor with at least 2 years' experience; having excellent communication and listening skills; demonstrating the ability to work harmoniously as a member of a team; and understanding, and being committed to, the RCT method of evaluation. Desirable criteria were previous work experience in Camden and Islington and previous involvement in research.

Five SHVs were appointed: two working full time and three working 60% of the time. All five had over 8 years' experience as health visitors and were employed on NHS grade G.

A 3-day training course was provided for the SHVs at the start of the study. This involved: the design of, and rationale for, RCTs; previous work on social support, home visiting, child accidents and maternal depression; and background information on the SSFH study. An external training team provided an additional training day on the listening model of support. The external trainers were experienced in working with health visitors, and focused their training on providing listening visits for women with postnatal depression, using an approach that challenges health professionals to reflect on their practice and change from an 'interventionist' to a 'listening' mode. After the first year, the trainers met twice more with the SHVs to help them to focus on ways of supporting each other and on methods for ending their time with their individual caseloads of women.

The nature of the SHV intervention

The intervention by the SHVs consisted of the offer of monthly home visits by the allocated SHV for 1 year. The five SHVs each covered a distinctive geographical area and the women were allocated to one of them based primarily on the geographical area in which they lived. The assignment of women to specific SHVs who lived in 'border' areas was sometimes changed, however, to help to balance the caseloads among the five SHVs. The women could request more or less frequent visits and could also ask that the visits took place in an alternative venue. The structure of the visits was informal, with a focus on listening to the woman and exploring any issues she wanted to discuss; during some visits, the SHVs collected tape-recorded process data. If asked by the women, the SHVs answered specific questions about, for example, the health or care of the baby, but they did not initiate discussion of such issues. Guidelines were drawn up by the research team and the SHVs for dealing with any child protection issues that might arise in the course of intervention visits. These guidelines were also agreed with the manager dealing with child protection issues at the Trust.

The SHVs were independently responsible for their caseloads, and determined their own schedules and working patterns. A variety of methods was used to support their work. One-on-one meetings were held at regular intervals with a member of the research team; for the first year, fortnightly meetings were held with all five SHVs and a member of the research team to discuss issues arising from the intervention. This allowed both for support of the SHVs and an opportunity to discuss and standardise practice in providing the intervention.

The SHVs kept a record of each contact they had with the women they were supporting. A form was filled in for each visit, which detailed the length of contact, the main topics discussed, the SHV's perception of the woman's stress level and the degree to which the SHV felt she had been of help at the visit. A similar form was filled in for telephone calls with the women in their caseload.

The CGS intervention

The CGS intervention arm of the study consisted of eight local community groups from the voluntary and charitable sector, which offered support and services to postnatal women and their babies. To select the most appropriate community groups to take part in the study, the research team contacted local councils, the Health Authority, the Community Health Council and a number of voluntary sector organisations for up-to-date information about local and national groups for mothers and babies. Community groups were considered for participation if they fulfilled three

criteria: all or part of their time was spent supporting or providing services for mothers and babies; they were local, which meant that national organisations had to have a local group or services in Camden or Islington to be considered; and they had secure funding for the duration of the SSFH study.

This exercise generated a list of 22 possible candidates (Appendix 1). Each was contacted by a member of the research team who explained the study. Eight groups agreed to take part: the African Association for Maternal and Child-Care International, Home-Start Camden, Home-Start Islington, the Holborn Community Association, Hopscotch Asian Women's Centre, the National Childbirth Trust (NCT)–Hackney and Islington Branch, Parents and Co., and Parentline (now called Parentline Plus). The African Association withdrew from the study because of staff shortages 2 months before the intervention began, and was replaced by Finsbury Park Homeless Families' and Refugees' Centre.

Each group was asked to agree and sign a 'willingness to work together' document outlining terms and conditions, including the provision of research expenses and £100 per woman referred to each group.

Because the community groups were offering the kinds of support they normally provided, they were not given any special training in supporting the women. They were asked to participate in a 1-day research methods workshop at the start of the study and two further half-day research feedback sessions at 6 and 12 months after the start of the intervention. The aim of these research days was to facilitate groups' participation in the research, and to provide them with background information about the study and guidance in the procedures needed for collecting data.

At the research methods workshop (carried out with four groups individually, with one joint day for the other four groups) information was exchanged about the study aims, design and timetable, about the requirements on groups to provide data on women referred to them, and about the nature of the different groups' aims, type of service, staff and volunteer levels.

At the two half-day research feedback sessions, the groups discussed with the research team the take-up of the community group intervention by women in the study, and the process of understanding and disseminating the research findings.

Nature of the support offered by community groups

Home-Start Camden and Home-Start Islington are part of Home-Start UK, a home-visiting befriending scheme in which trained volunteers offer regular support, friendship and practical help to families with children under 5 who are under stress and experiencing difficulties.[113] The volunteer provides the families with a listening ear, reassurance, help in building self-confidence, shared parenting skills and links into other community services. Volunteers must have experience of bringing up children themselves.

In addition to their home visiting and befriending service, Home-Start Islington runs a mother and baby drop-in group several times a week. This takes place either at the centre where there is a crèche available, or in the local park or swimming pool.

Holborn Community Association is a leisure and recreation facility part funded by Camden Council.[114] It provides a drop-in mother and toddler group each weekday, including baby gym and messy play sessions for older babies. It also provides play schemes during the holidays, an information and advocacy service, a 'good neighbour' scheme, a luncheon club, a Bengali women's group with crèche, and an outreach worker.

Hopscotch Asian Women's Centre offers a variety of services to the mainly Bangladeshi local community.[115] These services include English as a second language, craft and computer classes, both with a crèche, a morning drop-in, an after-school homework club, information and advocacy, summer play schemes, a GP-led health session, a toy library and a home-visiting service for isolated families.

Parents and Co. works with parents with children under 5 living in the Camden area.[116] It offers support groups in a number of locations around the borough for parents going through difficult times. It also runs separate group sessions for young mothers, Somali women and women with learning difficulties. For those parents confined to the home, Parents and Co. provides a home worker who supports parents by listening and giving encouragement. It also offers group work for whole families.

Parentline provides a national freephone helpline for anyone parenting a child or young person who is in need of support, guidance and information.[117]

Parentline's trained volunteers provide a listening ear, use basic counselling skills, offer non-directive suggestions to support parents and help them to find their own solutions to parenting problems. Each parentline volunteer answers an average of three calls during a 4-hour session.

The National Childbirth Trust is a national charity providing antenatal classes, postnatal support groups, breast-feeding advice and a range of other services to pregnant and postnatal women and their families.[118] Most classes and groups meet in members' homes, but some branches, including *Hackney and Islington*, have set up drop-in groups for mothers and babies in a local health centre or community hall.

Finsbury Park Homeless Families' and Refugees' Centre offers support, advice and advocacy, drop-in sessions, a women's group and children's activities to homeless families, refugees and asylum seekers.[119]

Supporting the women allocated to CGS

Once a study woman had been randomly allocated to the CGS intervention, assignment to one of the community groups was done by the research team on a pragmatic basis using information gathered from the woman at baseline about her preference for type of community service (home visit, drop-in group or telephone helpline), her proximity to the services and the referral capacity of the individual community groups. Once the assignment had been made, the group was notified of the woman's name, address and telephone number (when available). It was then up to the group to make the first contact by telephone, letter or home visit, as appropriate, and to offer her support over the period of a year.

All of the groups were asked to keep detailed records of all contacts with the women assigned to them. Different record sheets were provided for recording telephone, group and home visit contacts. The groups were also asked to note when referrals were made to other voluntary or statutory services, and to rate how helpful they felt they had been to individual women.

A dedicated member of the research team was allocated to the CGS intervention arm. Groups had access to the researcher at any time during the working week. Regular visits and telephone calls were made to each of the groups to collect record forms, maintain contact and exchange information.

Economic evaluation

Aim

The aim of the economic evaluation was to assess the relative cost-effectiveness of the SHV and CGS interventions compared with receiving only the services ordinarily provided for mothers of young children in Camden and Islington.

The methods for the economic evaluation were based on published recommendations.[120,121] The cost analysis involved six consecutive steps. These were:

1. Defining the perspective.
2. Identifying the resources and costs to be measured.
3. Measuring use of resources.
4. Estimating unit costs used to value resource use.
5. Estimating and comparing costs and outcomes arising as a result of each intervention.
6. Considering the uncertainty around the results.

Defining the perspective

The perspective was defined to include that of the providers of the services used by mothers in the trial and their children, as well as the perspectives of the mothers themselves.

Identifying resources and costs to be measured

Areas of resource use considered to be important sources of cost were identified based on previous related studies.[68,122–124] *Table 1* describes these key costs for each trial group. The costs of mothers using either intervention were limited to transport and medication and did not include valuation of mothers' time. Similarly, costs of health and social service use omitted this component.

Measuring resource use

Resource use by women and children in the trial was measured for services and resources associated with the key costs. Data on resource utilisation were obtained from the questionnaires filled in by the trial women at 12 and 18 months postrandomisation, and from records of contacts kept by the providers of the two interventions.

Estimating unit costs to value resource use

Unit costs for each type of resource use were estimated. *Table 2* lists the services included in the costing, measures of resource use and the source(s) of data used for estimating the value of the unit costs of these services.

TABLE 1 *Key costs by trial group*

Costs	Intervention: SHV	Intervention: CGS	Control group
Support interventions			
SHV programme: home visit costs	✓	×	×
SHV programme: telephone call costs	✓	×	×
Costs of initial contact with community group	×	✓	×
Costs of using community group services	×	✓	×
NHS costs			
GP services and prescriptions	✓	✓	✓
Health visitor services	✓	✓	✓
Midwife services	✓	✓	✓
Hospital services (for children only)	✓	✓	✓
Secondary mental health services	✓	✓	✓
Other agencies			
Social services	✓	✓	✓
Community group services	✓	✓	✓
Costs to mothers			
Medications (over-the-counter)	✓	✓	✓
Transport to healthcare and community services	✓	✓	✓

Estimating and comparing intervention costs and outcomes

Data on resource use by women in the trial were multiplied by the value of these resources (unit costs) and summed over all the different types of resources used by each woman in the trial to estimate total cost per woman at 18 months postrandomisation. Use of services reported in each questionnaire was assumed to have been at the same level over the preceding period.

Considering uncertainty

The final stage of the economic evaluation was to consider uncertainty around the results, including reporting statistical variation in the final cost estimates, and sensitivity analysis to test key assumptions. Sensitivity analysis varied the assumptions used in the 'base case analysis', that is, the set of assumptions agreed at the outset for the analysis.[121,131] Key assumptions in the base case analysis were that the discount rate for future costs is 6%, that volunteer time given to community group activities is valued at zero opportunity cost, and that the use of resources reported at the 12- and 18-month period was typical of use in the preceding period.

Costing the two interventions

The SHV intervention

Costs of providing the SHV intervention were estimated over the period of the trial. Two periods were sampled for estimation of time use by the SHVs in 1999 and in 2000, to allow for changes in workload and practice during the trial. The costs included salary, buildings (capital overheads), recurring administration and support costs (revenue overheads), the use of interpreter services, travel expenses, and expenses in materials and equipment used in home visits. A proportion of annual salary, capital and revenue overheads and travel expenses was deducted from the calculation of costs to reflect the fact that some of the SHVs' time was dedicated to research protocol activities, rather than to supporting the trial women. Data on staff time were obtained from record forms completed by the five SHVs each time they had any kind of contact with a study participant. These were complemented by information from time diaries filled in retrospectively by the five SHVs. These asked about the proportion of SHVs' time allocated to research and support activities, and about the travel and administrative time involved in each of these. The cost per visit and cost per telephone contact for women in the SHV group were based on salaries for a full-time equivalent grade G health visitor based in London of £24,713 for 1990–2000 and £26,212 for 2000–1. Interpreters were costed on the basis of the actual payments made by the project, at £29.37 per hour (including VAT).

Information on salary and travel costs for both the SHVs and the interpreters were obtained from the Finance Office of the Social Science Research Unit, where the SHVs were employed. Capital and

TABLE 2 *Measurement and valuation of resource and service use*

Resource/service	Measure	Source	Valuation
SHV intervention: visits and calls			
Staff	Time and grade	Prospective activity record forms	Local data
Interpreter's service	Time	Prospective activity record forms	Local data
Consumables	Type and no.	Programme manager and finance officer at SSRU	Local data
Travel	Average cost per visit	Programme manager and finance officer at SSRU	Local data
Equipment	Type and no.	Programme manager at SSRU	Local data
Overheads			Published London data[125]
CGS intervention			
Staff	Time and role/job title	Centre coordinators' questionnaires	Local data
Consumables	Typical expenditure per quarter	Centre coordinators' questionnaires	Local data
Equipment	Type and no.	Centre coordinators' questionnaires	Local data
Overheads	Expenditure in quarter	Centre coordinators' questionnaires	Local data
NHS costs			
Health visitor services Staff	Time and grade	Prospective activity record forms	Local data
Overheads			Published London data[125,126]
Doctor services	Type and no.	Follow-up questionnaires	Published London data[125,126]
Prescriptions	Type and no.	Follow-up questionnaires	Published London data[127,128] and local data
Hospital services (children only)	Type and no.	Follow-up questionnaires	Published London data[125,126]
Other agencies			
Independent community group services	Type and no.	Follow-up questionnaires	Nationally published data[129,130]
Social worker	No. of contacts	Follow-up questionnaires	Published London data[125,126]
Women's costs			
Over-the-counter medications	Type and no.	Follow-up questionnaires	Prices charged in major UK retail chain
Travel to healthcare	Type and no.	Follow-up questionnaires	London Transport
Travel to independent community group centres	Average cost per visit	Follow-up questionnaires	Women's reports

revenue overheads for the SHV service were assumed to be equal to £717 and £4995, respectively, for 1990–2000 and £738 and £5131, respectively, for 2000–1, in accordance with publicly available data for home visiting services in London.[126] The cost of capital overheads excluded any cost element associated with the use of clinical premises, as none was used in providing this intervention.

The CGS intervention

Costs of providing community group services for each of the eight community groups involved in the intervention were based on data provided for the period from January to March 2000. This period was chosen, after negotiation with the coordinators of the eight groups, as a time during which the groups were likely to be active within the study, and in order to minimise problems of recalling events in the early part of the study. CGS costs included salary costs, capital and revenue overheads, cost of equipment, and materials and consumables. The value of unpaid voluntary work was excluded from the base case analysis but included in the sensitivity analysis using the principle of the opportunity cost of time spent in voluntary work. Expenditure data on salaries, material and overheads, and use of staff time for each community group for the period January–March 2000 were collected using a self-completion questionnaire addressed to each group's coordinator. The data gathered were analysed using a step-down cost accountancy approach for allocating common costs between the different services offered by each community group.[121]

Since this costing exercise covered only the first quarter of 2000, it assumed unit costs to be typical for the whole fiscal year (April 1999–March 2000). While this assumption may be subject to criticism primarily owing to the high variability of the frequency and mix of services provided in most groups, the cost estimates for community groups were varied in the sensitivity analysis. Use of community groups by women included an initial contact and any recorded subsequent visit to, or contact with, the group. Cost estimates based on data for the first quarter of 2000 were applied to contacts with the community groups recorded for the period April 2000–March 2001.

Estimating costs for other resources used by trial participants

The first and second follow-up questionnaires completed by the study women included questions about use of health and social services and other community services. Women's responses gave the frequency of contact with doctors (differentiating between GP surgeries, hospitals and home settings), health visitors (at clinics, home or over the telephone), and other healthcare workers, social workers and community voluntary services. To limit any possible problems of recall in questions about previous health use, questions were asked at each follow-up about primary health and community services only for the previous month, and about hospital use for the previous 6 months. This strategy follows the findings of Petrou and colleagues, which indicate that although hospital use was accurately reported, self-report of community health service use can be under-reported, and this effect became greater with the longer the period of recall.[132] The questionnaires also included questions about the use of medications by mothers and their children.

The cost to the NHS per contact with doctors was derived from publicly available sources[125,126] and adjusted to reflect local variation in practice. Prescription medications were assigned a cost based on national publicly available data.[127,128]

The cost to the NHS per contact with statutory NHS health visitors was estimated from a costing exercise undertaken especially for the SSFH study at the Camden and Islington Community Health Services NHS Trust. This involved sampling one health visitor and one member of support staff at random from each of the 15 health visitor teams working across the Trust. The sampled health visitors and support staff were asked to fill out time diaries for one week in April 2001. The diaries were similar to those completed by the SHVs. The data collected about client contact, travel and administrative time were valued in money terms using salary and employer's 'on-cost' data provided by the Trust's finance office for 1999–2000 and 2000–1 for both health visitors and support staff. Revenue and capital overheads were assumed to be the same as for the SHVs. The cost per NHS health visitor visit was based on an average visit length of 48 minutes: the cost per telephone call was based on an average duration of 6.3 minutes.

Costs to the NHS per contact with other health workers and social services were obtained from published data using values specific to London.[125,126] Costs to the community groups of community voluntary services contacts other than those provided in the CGS intervention were also based on published data.[129,130] The cost per telephone contact was assumed to be equal to that

in the Parentline service, one of the eight community support groups in the community group support arm of the study. Visits to A&E, outpatient appointments and inpatient days at hospital were valued using figures obtained from publicly available data for London.[126] The figures for hospital stay were adjusted to reflect salaries prevailing in Camden and Islington. Appendix 2 shows the costs derived from these sources and used in the estimates of costs in each trial arm of the study.

The questionnaires completed by mothers collected data for the previous month for some services and over the previous 6 months for others. It was therefore necessary to make assumptions about service use for the periods for which no resource use-related data were collected. In the base case analysis, women were assumed to have used services at the same rate over the preceding period. An alternative assumption tested in the sensitivity analysis was that overall resource use was at a monthly rate equal to average use between reported use at 12 and 18 months.

Costs to women

Women were asked about their 'out of pocket' costs for attending healthcare and community groups. The probable costs to women, at average high-street prices, were estimated for the over-the-counter medications that they reported having taken.[127,128]

Women contribute their time in caring for children and participating in the interventions. This also has an opportunity cost. The economic study did not attempt to quantify and value this time, or that of the other informal support that women receive from family and friends.

Analysis methods

Costs were all expressed in year 2000 prices. Healthcare and community voluntary and transport service cost figures from previous years were reflated using the Hospital and Community Health Services pay and prices index, and the Consumers' Price Index. The statistical uncertainty around differences in means and medians in aggregate costs per woman between each intervention and the control group for NHS, social services and women's costs was expressed using bootstrap estimation of confidence intervals.[110] Final results were subject to sensitivity analysis of key assumptions about unit costs (including the cost of voluntary work), discount factors, observed variance in resource use, and interpolations of resource use outcomes to periods between follow-up points.

Chapter 3

Recruitment details and baseline characteristics

Recruitment details

In total, 731 women were recruited to the SSFH study. This represents 58% of the 1263 women who were eligible to participate in the trial (*Figure 1*). Since mothers, rather than children, were the unit of randomisation, multiple births mean that there are more children than mothers in the study. Seven of the 731 mothers had twins and one had triplets. For each of the multiple births one child was selected at random as the index child. Additional information was collected on the other child, as for all other children under 5 years in the household. (This information is not presented in this report, but will be the subject of later analysis.)

In the recruitment process, 3089 visits were made to the homes of the women who appeared on the recruitment lists. Of these visits, 1474 were to the 731 women who agreed to take part in the study. Recruitment therefore meant an average of two visits to each woman's home, with a range of between one and ten visits. Multiple house calls were required because women could not be found at home, the timing of the visit was inconvenient, women had changed accommodation and/or it became apparent that an interpreter was needed for recruitment. The original intention was to make only three house calls per woman, but this plan was revised as by the third visit contact had been made with a smaller proportion of women than expected.

Recruitment overall was slower than anticipated, with a variety of factors influencing this. Initially, there were fewer births than had been predicted to women resident in the deprived enumeration districts that comprised the study area. The mobility of the population was also a factor: an unexpectedly high number of women was no longer at the home address given to the hospital at the time of the birth (often because they had been moved between types of temporary accommodation); others were in the process of moving out of Camden and Islington. When women were given a choice to participate, a significant number declined. Language and literacy also had an impact on recruitment, with 14% of the women requiring an interpreter to assist with the recruitment process. This was a very time-consuming process: until a house call was made, language needs were undetermined; if an interpreter was needed time had to be spent making arrangements for that visit, and the recruitment visit with an interpreter lasted on average twice as long as one carried out in English. In addition to the women who needed interpreters, approximately 30% more of the women had English as a second language. (This figure is approximate as first language information is not available for all the women who declined to participate.) For some of these women who were proficient in speaking English, literacy in English was a challenge, so self-completion of the baseline questionnaire proved difficult.

Owing to the complexities encountered in the recruitment process, several changes were made early on to ensure that an adequate number of participants could be recruited. The funders were approached and additional funds were obtained for the cost of using interpreters in the study. The planned recruitment period was extended for 3 months. The women who declined to take part in the study were more likely to be younger and have fewer children than those who were recruited. The mean birth weight of the babies born to women who declined was similar to that of women who were recruited (*Table 3*). Although more of those who declined than those who were recruited identified themselves as belonging to a 'non-white' ethnic group, fewer of these required an interpreter at the time of the recruitment interview (*Table 4*).

As discussed earlier, interpreters were used in the recruitment process for 14% of the 1263 eligible women. Interpreters for 25 different languages were employed, with the largest proportion needed for Bengali-speaking women. *Table 5* shows the percentages who were recruited or declined with interpreters from the different languages.

The main reasons given for declining to participate in the study were being too busy, not being interested in the study, or already having enough support (*Table 6*). On 13 occasions another member of the household refused on the woman's

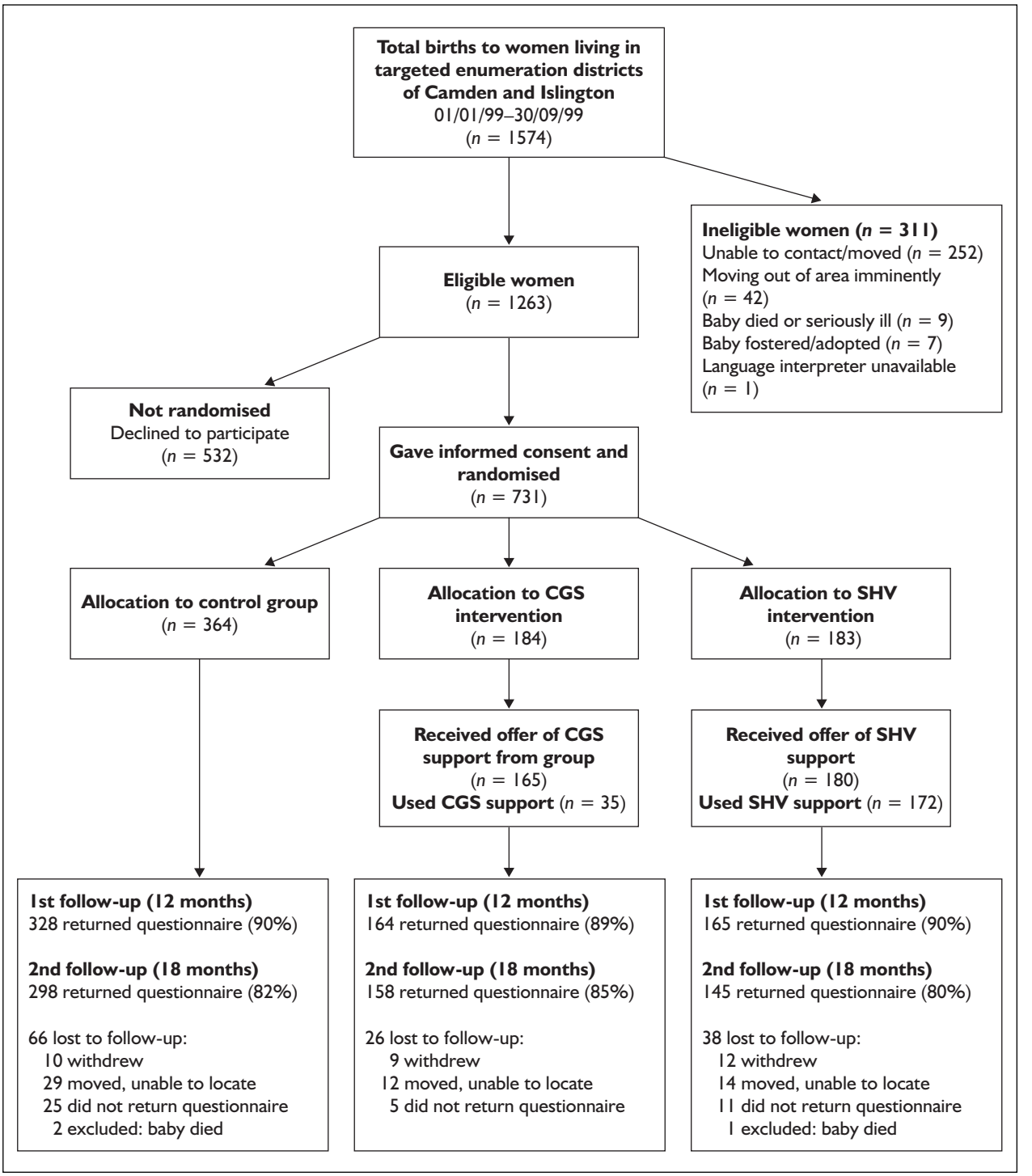

FIGURE 1 *CONSORT flow chart of participants in the SSFH study*

TABLE 3 *Characteristics of women who were recruited or declined*

	Recruited			Declined		
	N	**Mean**	**SD**	***N***	**Mean**	**SD**
Age (years) at birth of index child	731	29.57	5.87	518	29.05	6.00
Parity	731	1.87	1.06	494	1.34	1.37
Birth weight of baby (g)	731	3303	601	429	3308	566

TABLE 4 *Ethnicity and language: women who were recruited or declined*

	Recruited		Declined	
	n/N	**%**	***n/N***	**%**
Ethnic group: 'white'	420/729	58	202/459	44
Needed interpreter at recruitment visit	108/731	15	73/532	14

TABLE 5 *Recruitment using interpreters*

First language	Women needing interpreters	Recruited		Declined	
	N	***n/N***	**%**	***n/N***	**%**
Bengali	66	30/66	46	36/66	55
Somali	22	12/22	55	10/22	46
Turkish	17	12/17	71	5/17	30
Spanish	12	11/12	92	1/12	8
Chinese	7	3/7	43	4/7	57
Albanian	7	4/7	57	3/7	43
Arabic	6	4/6	67	2/6	33
Portuguese	6	4/6	67	2/6	33
Lingala	6	6/6	100	0/6	0
French	5	2/5	40	3/5	60
Kurdish	4	3/4	75	1/4	25
Farsi	3	3/3	100	0/3	0
Polish	3	2/3	67	1/3	33
Vietnamese	3	2/3	67	1/3	33
Romanian	2	2/2	100	0/2	0
Tigrinya	2	2/2	100	0/2	0
Urdu	2	0/2	0	2/2	100
Amharic	1	1/1	100	0/1	0
Twi	1	1/1	100	0/1	0
BSL	1	1/1	100	0/1	0
Punjabi	1	1/1	100	0/1	0
Newari	1	1/1	100	0/1	0
German	1	1/1	100	0/1	0
Kosovan	1	0/1	0	1/1	100
Hindi	1	0/1	0	1/1	100
Total	181	108	60	73	40

BSL: British Sign Language.

behalf. For 12 of these, the proxy refuser was the woman's partner, for one her mother; all were ethnic minority women.

Power of the study

The number of participants in the study (731) was fewer than originally anticipated (800). The true power of the study was therefore reduced from the original calculation. Modifying the original formula with the participant numbers, the actual power of the study was as detailed below.

Based on an estimated cumulative incidence of injury of 35% (injuries requiring medical attention) in the first 2 years of life, a study of 731 participants (367 intervention; 364 control) would have over 80% power to detect a risk ratio of 0.70 at the 0.05 level of significance, allowing for 10% loss to follow-up.

Based on the prevalence of maternal depression of 40%, a study of 731 participants would have over 85% power to detect a 12% reduction in prevalence of depression (from 40 to 28%) at the 0.05 level of significance, allowing for 10% loss to

TABLE 6 *Main reason for declining to participate in the study*

	n/N	%
Not interested	129/532	24
Too busy: in general, with kids	92/532	17
Too busy: working	22/532	4
Have enough support	17/532	3
Woman's family did not approve/refused for her	15/532	3
Did not want to be allocated to interventions	13/532	2
Baby was ill	8/532	2
Too busy: moving house	8/532	2
Involved in other research projects	8/532	2
Preoccupied with housing problems	7/532	1
Woman was too tired or unwell	7/532	1
Too busy: studying	6/532	1
Family problems	5/532	1
Away for long periods	5/532	1
'Nothing in it for me'	1/532	0
No reason given	189/532	36

follow-up. When comparing 363 control group to 183 intervention, the study would have 70% power to detect a 12% reduction in prevalence of depression (from 40 to 28%) at the 0.05 level of significance, allowing for 10% loss to follow-up.

Summary

Of the women eligible to take part in the study, 58% agreed to do so. In total, 731 participants were recruited. Interpreters were used to recruit 15% of the women who agreed to participate. Women who agreed to take part were more likely to be 'white' and to have had more children than those who declined. Over one-third of the women gave no reason for declining, but of those who did, the main reason was because they were 'not interested' in participating.

Baseline characteristics of recruited women

Over the whole sample, just under half (49%) of all the women in the study were having their first baby (*Table 7*). In the question asked on ethnicity, 42% of the women ticked boxes indicating that they thought of themselves as being from a Black or Minority Ethnic group (BME). For 39% of the women, English was not their first language. Just over one-quarter (26%) described themselves as lone parents, although only 12% said that they did not have a partner at that time. The average age of mothers when the index children were born was 30 years, and the baseline questionnaires were completed when the babies were on average 9 weeks old.

TABLE 7 *Baseline demographic characteristics*

		Total	
		n/N	%
First baby		355/731	49
Male baby		382/731	52
Ethnicity: BME		309/729	42
English not first language		282/731	39
Lone parent		189/731	26
Does not have a partner		86/731	12
		Mean	**SD**
Mother's age at birth of index child (years)	730	29.57	5.81
Baby's age at baseline (weeks)	731	9.25	3.45

BME, Black or Minority Ethnic group.

TABLE 8 *Baseline socio-economic characteristics*

	n/N	%
Woman receives income support/ jobseeker's allowance	236/731	32
Woman receives housing benefit	255/731	35
Partner[a] has had paid work in last month	441/610	72
Partner[a] social class 5, 6 or 7 (*lower supervisory/technical/semi-routine*)	209/591	35
Weekly household income ≤ £200	354/642	55
Money worries 'all the time'	149/727	20
Left full-time education aged <16 years	69/728	10
Left education with no qualifications	117/712	16
Mother smokes	192/730	26
Partner[a] smokes	249/619	40
Social housing[b]	510/731	70
Overcrowded housing[c]	343/727	47
'Disadvantaged'[c]	547/731	75
	Mean	**SD**
Household size	731 3.99	1.62

[a] Of women who had a partner at baseline.
[b] Includes council housing association and temporary accommodation.
[c] Includes at least one of: lone parent, teenage parent, income ≤ £200/week, left education <16 years, living in social housing.

Households, money, education and employment

Table 8 gives data for the sample as a whole on employment, income, education and housing. About one-third of the sample overall were on income support or jobseeker's allowance, or receiving housing benefit. Of women with partners, 72% had partners who were employed, and 35% had partners in lower supervisory, technical, routine or semi-routine occupations.

TABLE 9 *Comparison between SSFH sample and national data*

	National data (%)	SSFH data (%)
Households with no working adult	16[a]	26
Receive housing benefit	25[b]	38
'Rented' accommodation	31[c]	70
Ethnicity: BME	6[a]	42
Families headed by lone parent	16[d]	22[f]
Obtained no educational qualifications	15[e]	16

[a] ONS-UK (1999).
[b] Family Resources Survey (GB) (1999/2000); family households with children 0–5 years.
[c] ONS-UK (1996–8), General Household Survey; all family households with dependent children.
[d] As a percentage of all families with dependent children.
[e] ONS–UK (2000), women 16–49 years.
[f] Four per cent of the women who considered themselves to be a lone parent had a partner living with them at the time of the baseline; these 26 women have been removed for the purposes of comparison with the ONS figures.
BME, Black or Minority Ethnic group.
ONS, Office for National Statistics.

TABLE 10 *Baseline health*

	n/*N*	%
Assisted or Caesarean delivery	242/723	34
Baby 'difficult' to care for	67/727	9
Baby back to hospital since birth	258/712	36
Bottle-feeding	263/729	36
'Special health needs': mother or child/children[a]	226/727	31

[a] 'Special health needs' as defined by the woman herself.

Over half (55%) of the sample had a weekly household income of £200 or less. One in five (20%) described themselves as worrying about money 'all the time'. The figure for those leaving full-time education without qualifications was 16%. The proportion living in social housing was 70%. Nearly half said their housing was overcrowded; the average household size was four. At the time the baseline data were collected, 26% of the mothers were smokers, and of those with partners, 40% had partners who smoked.

We classified three-quarters of the sample (75%) as being 'disadvantaged'; including those who fulfilled at least one of these criteria: lone parent, teenage parent, income ≤ £200/week, left education <16 years, living in social housing. Some comparisons between the SSFH study sample and the national picture are given in *Table 9*. These show that the study sample was relatively disadvantaged,

TABLE 11 *Baseline social support*

	n/*N*	%
Not very much/no contact with family	202/730	28
Help by family 'poor'/'fair'	222/718	31
Partner helps 'rarely'/'never'	171/609	28
Not very much/no contact with friends	232/730	31
No close friends	85/727	12
Has not used community services for mothers and babies	522/728	72

TABLE 12 *Baseline stress and depression*

	n/*N*	%
Last year rather/very difficult	397/726	55
High/quite high level of stress	277/713	39
Not as much/no control over life	298/721	41
EPDS score: 12 or above	201/707	28
	Mean	**SD**
Maternal depression: EPDS score	707 8.94	5.37

which was the intention behind the sampling procedures used.

Health and social support

Tables 10–12 show the health and social support profile for the study population as a whole. One-third of the mothers (34%) had experienced assisted or Caesarean deliveries, and one in ten (10%) described their babies as 'difficult' to care for (*Table 10*). More than one in three (36%) of the babies had been taken back to hospital for a health care problem. Just over a third (36%) of the mothers were bottle-feeding their babies. Nearly one in three (31%) of the families had special health needs.

A minority of the women (5%) described themselves as 'not at all supported'. Of women with partners, 28% said their partners 'rarely' or 'never' helped with household tasks. A similar proportion of the women lacked contact with friends and family and family help, and nearly three-quarters (72%) said they had not used any local community services for mothers and babies (*Table 11*). In comparison, a government survey estimates the proportion of women nationally with a perceived 'severe lack of support from family and friends' to be 11%.[133]

The stress levels shown in *Table 12* are further indicators of the general level of adversity affecting the study women; for example, two out of five (39%) described their current level of stress as 'high' or 'quite high' and the proportion with an EPDS score above 12 (the threshold for being at

TABLE 13 *Baseline demographic characteristics by trial arm*

	SHV			CGS			Control		
	n/N		**%**	***n/N***		**%**	***n/N***		**%**
First baby	87/183		48	92/184		50	176/364		48
Male baby	97/183		53	106/184		58	179/364		49
Ethnicity: 'not white'	84/183		46	78/182		43	147/364		40
English not first language	73/183		40	70/184		38	139/364		38
Lone parent	53/183		29	47/184		26	89/364		25
		Mean	**SD**		**Mean**	**SD**		**Mean**	**SD**
Mother's age at birth of index child (years)	183	29.50	5.87	183	29.68	5.92	364	29.55	5.75
Baby's age at baseline (weeks)	183	8.97	3.50	184	9.57	3.78	364	9.22	3.24

TABLE 14 *Baseline socio-economic characteristics by trial arm*

	SHV		CGS		Control	
	n/N	**%**	***n/N***	**%**	***n/N***	**%**
Social housing	127/183	69	126/184	69	257/364	71
Left full-time education aged < 16 years	14/182	8	23/183	13	32/363	9
Left education with no qualifications	25/176	14	39/179	22	53/357	15
Partner social class 5, 6 or 7 (lower supervisory/technical/ semi-routine)	49/142	35	55/150	37	105/299	35
Weekly household income ≤ £200	90/160	56	95/169	56	169/313	54
Mother smokes	42/183	23	55/184	30	95/363	26
Partner smokes	48/151	32	76/158	48	125/310	40
'Disadvantaged'	136/180	76	139/182	76	272/357	76

TABLE 15 *Baseline health and support by trial arm*

	SHV			CGS			Control		
	n/N		**%**	***n/N***		**%**	***n/N***		**%**
Assisted or Caesarean delivery	65/183		36	58/184		32	119/364		33
Baby 'difficult' to care for	18/183		11	16/184		9	33/364		10
Baby back to hospital	55/183		31	68/184		37	135/364		38
Bottle-feeding	68/183		37	69/184		38	126/364		35
'Special health needs': mother or child/children	56/182		31	59/184		32	111/361		31
Had no support	11/178		6	9/178		5	17/361		5
Partner helps 'rarely'/'never' with household tasks	47/148		32	37/154		24	87/307		28
		Mean	**SD**		**Mean**	**SD**		**Mean**	**SD**
Maternal depression: EPDS score	183	8.75	5.65	184	8.75	5.16	364	9.08	5.33

risk of postnatal depression) was 28%. The mean EPDS score for the sample as a whole was 9. Epidemiological studies have consistently shown postnatal depression rates in early weeks after delivery to be about 10%.[31]

Baseline characteristics of study women across trial arms

Tables 13–15 show that the women in each of the two intervention groups and the control group were well matched in terms of baseline demographic and socio-economic characteristics, and with respect to baseline health and support variables. (For information on statistical testing of difference at baseline, see Chapter 2, Data analysis section.)

Parity, lone parent status (*Table 13*) and housing tenure (*Table 14*) were variables used for minimising differences in randomisation. The other variables in *Tables 13–15* are either outcome variables (health, health service use, household resources, smoking, infant feeding) or those for which a chance imbalance might affect the study results (type of delivery, baby's gender, ethnicity, mother's education, existing support).

Summary

The sample as a whole was relatively disadvantaged, with 70% living in social housing and 26% categorising themselves as lone parents. Over one-quarter of the women scored above the threshold of risk for postnatal depression on the EPDS. The women in the three arms of the study were similar to each other in terms of baseline demographic and socio-economic characteristics, and with respect to baseline health and support variables.

Chapter 4

The SHV intervention

Assignment to, and usage of, the SHV intervention

Assignment

Of the 731 women recruited to the study, 183 (25%) were allocated to the SHV intervention. The five SHVs had caseloads that were predominantly determined by geography, so these differed in composition (*Table 16*). For instance, one of the SHVs had a caseload with a high proportion (9/31) of women from Bangladesh.

Pattern of use

The plan outlined in the study protocol was that the SHVs would offer the women a programme of monthly visits in their homes for 1 year. The women allocated to this intervention were able to determine how frequently they would like to be visited, and there was opportunity for them to change the frequency of visits as the year progressed. The total number of visits to women carried out by the five SHVs was 1293; this consisted of 1786 hours of support. The mean number of visits with each woman was seven, with a range between 0 and 22 visits (*Table 17*). In addition to these visits, the SHVs made a further 211 attempted visits where the woman was not in or was unavailable for the visit.

Eleven women had no visits: three of these could not be contacted following allocation (all had been moved from temporary accommodation); two said that they had hoped to be allocated to either the control or community group intervention and chose not to have SHV visits; the remaining six women said they were too busy for, or uninterested in, receiving SHV visits. There were a few discrepancies in the numbers of visits reported by the women and by the SHVs. As the women were being asked to remember back over the period of a year, some of these discrepancies might be accounted for by difficulties in recall. For other women, their intervention period had carried on past the point of the completion of the first follow-up questionnaire, so numbers would have changed after this point.

Visits lasted on average for 83 minutes, with a range between 5 and 300 minutes (*Table 18*).

There was variation among the five SHVs in the average number of visits and average length of visits (*Table 16*). The SHV intervention was planned as a 12-month programme. The average length of the intervention in practice was 10 months, with a mode of 12 months. The majority of the women (105/183, 57%) had between 10 and

TABLE 16 *Caseloads of the five SHVs and variations in practice*

	SHV A	SHV B	SHV C	SHV D	SHV E
FTE	**1**	**1**	**0.6**	**0.6**	**0.6**
Women allocated	50	47	31	29	26[a]
First language other than English	32%	38%	65%	38%	31%
Interpreters used	5 women: 3 Turkish 1 Spanish 1 Gujerati	3 women: 2 Bengali 1 French	9 women: 6 Bengali 1 Spanish 1 Somali 1 BSL	4 women: 1 Somali 1 Farsi 1 Turkish 1 French	2 women: 1 Turkish 1 Bengali
Variations					
Range of visits	0–22	0–13	0–11	0–20	1–16
Mean	6.8	6.6	4.8	8.8	9.0
Mode	3	8	2	11	9
Average length of visit (minutes)	92	76	81	85	77

[a] A lower proportion of women was allocated, as SHV E took 3 months' maternity leave during the intervention period.
FTE: full-time equivalent.

TABLE 17 *Number of visits for women allocated to the SHV intervention*

No. of visits[a]	SHV women	
	n	%
0	11	6
1	12	7
2	13	7
3	14	8
4	11	6
5	8	4
6	12	7
7	15	8
8	14	8
9	16	9
10	13	7
11	20	11
12	8	4
13	7	4
14	2	1
16	1	0.5
18	3	2
19	1	0.5
20	1	0.5
22	1	0.5
Total	183	100%
Mean: 7.07 visits Median: 7 visits		

[a] Only includes visits where the SHV spent time with the woman; does not include attempted visits when woman was not in/unavailable.

TABLE 18 *Length of time per visit for women who used the SHV intervention*

Length of time per visit (minutes)	Visits	
	n	%
5–30	66	5
31–60	291	23
61–90	584	45
91–120	277	21
120–300	75	6
Total visits	1293	100%

13 months between allocation and their last home visit. Just over one-quarter of the women (49/183, 27%) had less than 10 months, and the remaining 16% (29/183) had between 14 and 20 months of contact. Reasons for extending the visits beyond 12 months were mainly logistical, for example, planning a convenient time for a final visit around holidays, periods abroad and work hours. For some, the reasons were to do with personal crises or a difficulty in separating from the SHV.

TABLE 19 *Overall support provided in the SHV intervention*

Type of support	Total minutes of support	Mean minutes per woman allocated (*N* = 183)
Home visits	107,150	586
Telephone support	3,642	20
Overall support	110,792	603

Telephone support was available and offered by the SHVs between visits or in lieu of them, according to the women's preferences. Over 3640 minutes of support were provided over the telephone by the SHVs (*Table 19*).

Level of participation in the intervention

Low participation in the intervention was defined as having had four or fewer visits by the SHV. Sixty-one women (33%) fell into this category. The average duration of overall support for these women was 155 minutes.

Medium participation was defined as having between five and nine visits by the SHV. Sixty-six women (36%) were in this category. For this group the average total duration of support was 577 minutes.

High participation in the intervention was ten or more visits. Fifty-six women (31%) fell into this category. The average total duration of overall support for a woman in this group was 1112 minutes.

Baseline levels of parity, age, lone parent status, depression, stress levels, tenure and full-time employment were similar for the women who used the intervention at different levels (low, medium and high) (*Table 20*). There were differences in level of usage by language and ethnic group; English-speaking 'white' women were more likely to have had medium or high usage of the intervention. Women who had high usage of the SHV intervention were more likely to return their first follow-up questionnaire [100% (56) of 'high' users returned first follow-up versus 70% (43/61) of 'low' users].

Nature of intervention

Location and timing of visits

Most visits took place in the women's homes, but a small proportion of women chose to have visits in

TABLE 20 *Use of SHV intervention by women's characteristics*[a]

	Low use		Medium use		High use	
	n/*N*	%	*n*/*N*	%	*n*/*N*	%
English not first language	35/61	57	24/66	36	14/56	25
BME women	36/61	59	30/66	46	18/56	32
Not first child	27/61	44	38/66	58	31/56	55
Returned to work full time	8/44	18	7/65	11	6/56	11
Lone parent	18/61	30	19/65	29	16/55	29
Rented housing	41/61	67	46/66	70	40/56	71
Age <25 years	12/61	20	16/66	24	13/56	23
Depressed	14/60	23	17/64	27	13/54	24
High/medium stress	24/61	39	22/64	34	27/55	49

[a] All from baseline questionnaire ($N = 183$), except for 'returned to work', which is from the first follow-up questionnaire ($N = 165$).
BME, Black or Minority Ethnic group.

alternative locations. For five women who returned to work during the intervention, the SHV carried out the supportive listening intervention during the woman's lunch hour near to her place of work. A few women chose to have visits in cafes or burger bars instead of their home. Some of the visits included SHVs accompanying women to appointments at their request; for example, trips to the Citizens Advice Bureau, Social Services, local housing office and the viewing of a potential school for an older child. In one case a SHV joined a woman on the long journey to visit her partner in prison. On a few occasions the SHVs were also asked to join a woman on more social excursions; for instance, shopping or attending a mother and toddler group.

The vast majority of visits took place between 09.00 and 17.00 h Monday to Friday. A small number of women asked to have visits in the evening or at the weekend. In 44% of the SHVs' visits, other people (other children, partners, other family members, interpreters) were present for at least part of the time.

Although the primary function of the intervention was to listen to the woman, the SHVs were to provide information or advice if women requested it of them. At just over one-quarter of the visits (28%), the SHV suggested that the woman seek additional help or information elsewhere. These informal referrals were primarily to the named health visitor (at 9% of visits), other health professionals (6%), and local community services for mothers and children (3%). On 32 occasions the SHV suggested counselling, either for the woman herself or couples counselling with her partner.

At nearly half of the visits (47%), the SHV recorded that she provided information to the woman. This predominantly took the form of information on child health-related issues, parenting questions (notably on infant feeding) and maternal health-related issues. However, the requests for information also included diverse topics such as financial budgeting, how to make a complaint about poor NHS services, energy efficiency in the home and how to hang curtains.

Women's views of the SHV intervention

The first follow-up questionnaire asked women allocated to both intervention arms of the study some questions about their intervention experiences.

Views on number of visits by the SHV

The majority of women (87%) said that the number of visits they had from the SHV was 'just right'. Eight per cent of the women said they would have liked more visits, and 5% would have liked fewer (*Table 21*).

TABLE 21 *Women's feelings about number of visits from the SHV*

	SHV women	
	n	%
Too many visits	7	5
No. of visits just right	130	87
Too few visits	12	8
Total	149	100

TABLE 22 *Women's opinions of the SHVs*

	SHV women	
	n	**%**
I have found her very helpful indeed	82	54
She has given me about the right amount of help	47	31
She has not given me enough help	2	1
I have not liked her visiting me	6	4
Other	15	10
Total	152	100%

Those women who felt that they had had too many visits had between three and ten SHV visits (three visits, $n = 2$; seven to nine visits, $n = 3$; ten visits $n = 2$). Those women who felt that they had too few visits had between one and 22 visits (one to three visits, $n = 2$; seven to nine visits, $n = 5$; 10–12 visits, $n = 3$; 13 to 22 visits, $n = 2$).

There was no significant difference in women's satisfaction with the number of visits they received from the SHV between those who had high, medium or low intervention usage.

Overall opinion of the SHV intervention

When asked to tick the statement that best reflected how they felt about the SHV who visited them, over half of the women said that they found the SHV 'very helpful indeed'. Just over 5% either felt that they had not received enough help or had not liked the visits of the SHV (*Table 22*).

Those who had 'other' opinions about the SHV included eight women who said that they had not asked for or needed help from the SHV, five women who were unclear about the role of the SHV, one who said she enjoyed the visits, and one woman who said she had been too busy to see the SHV:

> "She didn't help me because I didn't ask her."

> "She was very nice, but wasn't actually any help in terms of mothering. Sometimes I wondered what the sessions were actually for."

> "She was very kind and polite and helpful, but I have to help myself."

Relationships with the SHVs

When describing their relationships with the SHVs, nearly all the women said that the SHV had listened to them. Three-quarters felt that the SHV had been able to spend a lot of time with them (*Table 23*).

TABLE 23 *Women's descriptions of their interactions with the SHVs*

	SHV women	
	n/N	**%**
SHV has given me good advice	123/144	85
SHV has listened to me	141/146	97
SHV has done practical things to help me	76/145	52
SHV has been able to spend a lot of time with me	108/145	75
SHV has made me feel worried about my baby	3/147	2

Women with 'low' usage of the intervention were less likely to feel that the SHV had given good advice, listened, done practical things or spent a lot of time with them (*Table 24*).

Comparisons with NHS health visitors

At the beginning of the first follow-up, all women in the study were asked the questions referred to in *Table 24* about their NHS health visitor. Those in the SHV group were additionally questioned about their SHV health visitor. When comparing these sets of answers, the women in the SHV group were more likely to have positive opinions about their SHV than about their NHS health visitors (*Table 25*). This is hardly surprising given that the SHVs were specially trained to be responsive to mothers' needs and the intervention allowed them the opportunity to spend considerable time with the women. The comparison highlights many difficulties identified by NHS health visitors relating to their workloads.[72]

When asked an open-ended question about differences between their NHS health visitor and the SHV, seven of the 132 women who answered this question thought there were no differences. Ten women mentioned at least one positive thing about their NHS health visitor. The remaining 115 women all made positive comments about SHVs in comparison to NHS health visitors. Themes that featured strongly included:

- seeing the SHV more regularly than the NHS health visitor
- the SHV being non-judgemental/not an authority figure
- the SHV having more time
- the SHV concentrating 'on me, not just my child'
- having a better relationship, 'continuity' with the SHV

TABLE 24 *Women's descriptions of their interactions with the SHVs by level of use*

	Low use		Medium use		High use	
	n/*N*	%	*n*/*N*	%	*n*/*N*	%
SHV has given me good advice	15/30	50	55/59	93	53/55	96
SHV has listened to me	28/31	90	59/60	98	54/55	98
SHV has done practical things to help me	6/31	19	33/59	56	37/55	67
SHV has been able to spend a lot of time with me	10/29	35	49/62	79	49/54	91
SHV has made me feel worried about my baby	0/31	0	2/61	3	1/55	2

TABLE 25 *Women's opinions about the SHVs and NHS health visitors (HVs)*

	NHS HV		SHV	
	n/*N*	%	*n*/*N*	%
HV has given me good advice	96/132	73	123/144	85
HV has listened to me	101/132	77	141/146	97
HV has done practical things to help me	47/132	36	76/145	52
HV has been able to spend a lot of time with me	37/132	28	108/145	75
HV has made me feel worried about my baby	12/132	9	3/146	2

- the NHS health visitor being where you turn for contacts in the community, etc.

Typical comments were:

> "[The SHV provided] mainly the luxury of time to really talk. She focused on me as well as my baby. She had an open mind. She is not obsessed by weight charts."

> "[The SHV] is only for me. She spends a lot of time and she comes privately to me at home. She really tries to help with general things as well as medical things. The statutory health visitors never ask other things unless I ask. The clinic ones don't really explain and the health visitor doesn't really know me very well, so they can't really comment. The SHV gave me extra information, even from newspapers. [The SHV] uses an interpreter."

> "Much more time: an hour to chat at each visit, whereas at the health centre you know there's a queue of people waiting, and you don't want to use up too much of the health visitor's time."

> "At my clinic you are very rushed and you have no privacy. You also never know which health visitor is running the clinic so there is no continuity."

> "My normal health visitor focuses on the baby, NOT my welfare or that of my partner. I felt that I got to know [my SHV] and I felt that I could confide in her. My other health visitor is a stranger to me and it is a very superficial relationship."

Views on the SHV visits

In open-ended questions, the women were asked what they liked and disliked about the visits of the SHV.

Of the 183 allocated to the SHV group, 128 women wrote comments about the things they liked about the visits from their SHV. The things that were most frequently noted as being liked were having someone to listen, the friendliness of the SHV and the opportunity to discuss personal issues:

> "I have loved having visits from [my SHV]. I feel like she has all the time in the world for [my baby] and me and so I can build up to an emotional or stressful subject rather than blurting it out. She has always made me feel like I am doing a good job with the children, even when the house looks like a bomb hit it and I'm in my nightie at 10.30 am. She has been so helpful in finding groups, writing letters for housing, etc. [Her] visits gave me time to think about my relationship with [my children] in a positive way."

> "I liked speaking with her. My English improved because she spoke English. She is very friendly and kind."

> "I have been able to tell her many personal things, with confidence (she wouldn't tell it to a soul). She has really listened to me and when I have needed it she has given quite good advice."

> "It's nice to be honest, without being worried."

"She was more like a friend than a health visitor. She really listened and helped. I was always miserable when she came, when she left I was happy. She was excellent!"

"I was very bitter about things that happened at the hospital when I gave birth to my daughter. She helped me especially by letting me talk about this and get it off my chest. She listened really well and got to know me. I really liked her visits."

"[The SHV visit] was an occasion, something to plan ahead for. In the early days it created a bit of structure in my life, later when I went back to work, it underlined/brought back the fact that I was not just a worker, but a working MOTHER."

Table 26 lists the main positive aspects raised by the women.

Twenty-five women wrote comments about things that they *disliked* about the visits from the SHV. The main themes were time pressure, which made the visits difficult to fit in, and a feeling that the visits were pointless or unnecessary:

"Now I'm back at work, an hour visit is a precious chunk out of my day/week."

"Lasted too long. I think they might have been much more useful in the very early months. Felt obliged to meet up for research project when often busy or had little time for $1^1/_2$ hr chat."

"When [the SHV] first came, I thought she was going to offer practical suggestions and information about health issues (like the health visitor at my doctors). It took a few visits for me to realise that she was coming in the role of a 'counsellor' – to offer emotional support for me and give me time to talk. I realised that she was trained not to give me advice but to let me figure things out for myself. I think it would have been helpful to have had this explained at the beginning because once I understood this I made myself talk to her in depth and 'made the most of her'. I then found the visits very helpful but I was occasionally frustrated that she couldn't share with me advice from her experience of hearing from so many mums in my situation."

"Visits have seemed very pointless. She has not been able to offer any useful advice although she has listened. She has also been a bit erratic about visits and neither of us enjoy the visits as they cut into the day and don't really help with anything."

Table 27 lists the negative issues raised by the women.

SHVs' views on their intervention

Visit record sheets

After each visit the SHV completed a record sheet where she noted the key features of the visit, including an assessment of the woman's anxiety

TABLE 26 *What women liked about SHV visits*[a] *(N = 128 women)*

	n
Having someone listen to me	32
Nice/friendly personality of the SHV	31
Having a chance to talk about my life and my problems (not just the baby)	25
Good advice or suggestions from SHV	25
SHV gave help or support	25
Company	19
Non-judgemental attitude	15
The SHV becoming a friend	15
Gave me confidence about my ability to mother	13
Support from non-family member/unbiased source	12
SHV acted as a practical 'advocate' for me (re housing, child care, social services, etc.)	11
Being under no time pressure	8
She provided information for me	8
She cheered me up/made me laugh	8
Being given the chance to think about the experience of motherhood	8

[a] Some of the 128 women who answered this question gave multiple answers.

TABLE 27 *What women disliked about SHV visits*[a] *(N =25 women)*

	n
Time pressures: hard to fit visits into already busy life	13
Visits felt pointless or unnecessary	5
Wanted less concentration on feelings, more practical help	3
Didn't want the visits to come to an end/becoming reliant on visits	5
Questions from SHV too personal	2
Project lasted too long: better if just in early months	2
Difficult to concentrate on the visits: distracted by my children	1
'Friendship' with SHV initially felt too forced	1
Embarrassment over untidiness of the house	1
Once guests were over when she visited and it was difficult	1
Felt selfish always talking about myself	1
Didn't talk about my feelings because she didn't ask the right questions	1
Talking about parenthood is difficult	1

[a] Some of the 25 women who answered this question gave multiple answers.

TABLE 28 *SHVs' assessment of women's situations*

	Visits	Score given by SHV
	N	**Mean (SD)**
Level of anxiety (1 = very anxious, 5 = very relaxed)		
Beginning of visit	1291	3.68 (0.82)
End of visit	1277	4.03 (0.72)
Level of difficulty of woman's situation (1 = very difficult, 5 = not at all difficult)	1290	3.25 (0.98)
Social support needs (1 = needs a great deal of social support, 5 = no particular need)	1250	3.37 (1.0)
SHV self-assessment of helpfulness (1 = very helpful, 5 = not at all helpful)	1253	3.04 (0.80)

level and the difficulty of her situation at that time. In addition, the SHV was asked to rate how helpful she felt she had been to the woman during that visit.

Overall, the SHVs assessed the women's anxiety level at the end of their visits to be lower than at the beginning of these. However, on the whole the SHVs perceived the women to be relaxed both before and after the visits. On average, they perceived the women they were visiting to be dealing with situations of intermediate level of difficulty, and to have relatively moderate social support needs. The SHVs assessed their own usefulness during the visits at the median between very helpful and not at all helpful (*Table 28*).

Interviews with SHVs

Interviews were carried out with the SHVs at two points in the study: once in the middle of the intervention period, and once at the end of their involvement with the study. Common themes that emerged from these interviews included the following.

- *Support for this type of intervention*: the SHVs felt that supportive listening visits were worthwhile and on the whole liked by the women; they enjoyed working in this manner; they got to know the women and learned to give them space and trust them. All said that working in this way had revolutionised their practice.

  > "The best thing is having time for people. Being able to develop a relationship that feels much more interesting and less superficial I guess."

  > "This model focuses a lot more on support, it frees me up to do that. I don't have all these tasks to worry about. I don't have all the constraints."

  > "It's challenging using the supportive listening model because I'm forever having to really say to myself 'say less, say less, not more, not more!'"

  > "I think mostly the women enjoyed it … Some of the women we were seeing have good support networks and some don't, but I think whichever group they fell into, it's still nice to get this attention from somebody with a sort of professional background, which they particularly valued."

- The SHVs interpreted the *variation in their practice* (regarding number of visits, length of time spent per visit, etc.) as being predominantly influenced by the nature of their caseloads; for instance, how many women required interpreters and the number in temporary accommodation who were moved several times and with whom it was difficult to maintain contact. They allowed that the personalities and personal styles of the SHVs had also influenced their individual practice; some found it easier than others to work in a purely 'listening' rather than 'doing' mode.
- The SHVs were at times overwhelmed by the sheer *burden and complexity of problems* faced by some of the women, including domestic violence, debt, asylum seekers awaiting deportation, bereavement, alcoholism/drug addiction, housing difficulties, relationship difficulties and mental illness.
- They remained frustrated by the '*ones that got away*'; that is, women who moved or became hard to reach during the course of the

intervention. There was also regret that some women chose not to participate in the visits, especially in situations where the SHV perceived that the women might ultimately have benefited from them:

> "There was one particular client who was single and unsupported and in a mother and baby home, and I would have like to have worked with her, but you know I never really got the opportunity, cause she was never there and I went on and on trying to find her, I mean I saw her once, but it just didn't happen, and that is one of my regrets."

- They had worries about the *cultural appropriateness of the intervention*. They discussed the awkwardness of trying to implement this intervention in certain settings, especially with interpreters, and notably in Bangladeshi households where other people were often present. They offered some success stories across cultural/linguistic boundaries; but recounted other very difficult situations:

> "Working with an interpreter was difficult. The visits I did without an interpreter [with women who had English as an additional language] were so different and the things that we talked about too. It was much more open communication and that could be to do with trusting one person and the complexities of learning to trust two people."

- They felt that *the intervention would not be effective* overall, despite all the visits. They were unsure that the outcomes being measured could be influenced substantially by the intervention they provided. They did not think that the intervention would hurt, but felt that the women's problems were either too entrenched or too major to be significantly affected by a once a month visit. All of the SHVs felt that they had success stories, but also had women for whom the intervention would not impact:

> "On the outcome of smoking, I actively said to someone smoking, 'Don't give up!' [laughs] One of the women was a recently reformed alcoholic who wants to give up smoking, I said 'yes, fine, but don't rush … don't do it right now, wait until you feel stronger.' I was afraid that she would give up the smoking and go back on the alcohol."

> "I think the intervention has to have some benefit, I think it will affect people's confidence, but I don't know about the health outcomes."

> "I think that our intervention works for some practical things and psychological things definitely, but I don't think it will come out on the outcomes … I never did think it would affect the outcome measures, not in a short space of time … A longer length of time on a larger number of people in the intervention might get some differences."

Unit costs of the SHV intervention

The unit costs of providing the intervention reflect whether the contact was at home or by telephone, whether or not a SHV made successful contact with the mother at the visit, and whether an interpreter was present (*Table 29*). The mean cost for the five SHVs per hour of home visit was £58, with a range from £49 to £76. The lowest point in this range is equivalent to the cost of NHS health visitor home visits at £49 per hour (see Appendix 2). The costs of the SHV intervention home visits were higher when interpreters were used, by the amount charged for the interpreting service. This included cases where interpreter costs had to be paid for an unsuccessful visit. The unit cost of a telephone call in the SHV intervention was lower than for NHS health visitors.

The difference between the SHV intervention costs per hour and those of NHS health visitors may be explained by several factors. First, the costs were estimated on the basis of the actual grades of staff working in both services, and the research health visitors were of higher overall grades and thus more expensive than average Camden and Islington NHS health visitors. Second, the research study resulted in fluctuating and unrepresentative workloads for the study health visitors, which were not typical of NHS health visitor workloads, so that the cost per visit might be artificially inflated when there were fewer visits to be done within the available hours worked. Third, because they were not working as practice-based staff, coordinating the visits was less easy for the SHVs, and they resulted in more complicated schedules and travelling arrangements. Fourth, the apportionment of overheads between different aspects of the work of the health visitors in the different services reflected their different range of duties. SHVs did not have to run clinics, for example. For all these reasons, the additional cost per hour would not necessarily be higher than standard NHS health visitor costs were the SHV intervention to be adopted in routine practice.

Summary

Of the 183 women allocated to the SHV intervention 172 (94%) had at least one home visit

TABLE 29 *Unit costs of the SHV intervention*

	Unit costs (£, year 2000 prices)			Comments
	Base case unit cost	Range		
Home visit per hour	58	50	78	Based on time diary exercise and expenditure data for the fiscal year 1999/2000. Sensitivity range is based on the variation among the five SHVs
Home visit per hour with interpreter	88	80	108	Cost of interpreter per hour: £30 in 2000 prices
Attempted visit[a]	29	22	38	Value of time spent in travel derived from SHV diaries. Includes travel time, travel expenses and overheads. Sensitivity range based on variation among the five SHVs
Attempted visit including interpreter	59	52	68	Cost of interpreter per hour: £30 in 2000 prices
Telephone contact per minute	0.6	0.4	0.7	Sensitivity range based on the variation among the five SHVs

[a] Prearranged visit to woman's house where she was either not in or unavailable.

by their SHV. The total number of visits carried out by the five SHVs was 1293; this consisted of 1786 hours of support. The average number of visits with women was seven; visits lasted on average for 83 minutes. English-speaking white women were more likely to have had higher usage of the intervention.

Overall, the women allocated to this intervention were positive about it: 85% said that the SHV either was very helpful or gave the right amount of help. The women were significantly more positive about their relationships with their SHVs than about those with their NHS health visitors.

The SHVs were positive about the supportive listening model as a way to practise, but they were sceptical about whether it would significantly change outcomes for the mothers in the SSFH study, as they felt their problems were complex and, for many, entrenched. In addition, the SHVs were concerned about the transferability of the listening model of the intervention across cultural boundaries.

Chapter 5

CGS intervention

Assignment to, and usage of, the CGS intervention

Assignment

In total, 184 women were randomised to the CGS arm of the study. All of the study women had been asked the following question in the baseline questionnaire: "If you were to be allocated to the community group support, what type of community group would you prefer to have? *Rank the three in order* home support, drop-in support, telephone support". Overall, 34% of the women said they would prefer home support, 38% had chosen drop-in support, 25% expressed a preference for telephone support, and the remaining 3% had no preference. Assignment to the individual community groups for the 184 allocated to this arm of the study was based on these expressed preferences, taking into account geographical proximity, and giving some women their second choice in areas where their preferred type of group was not available. Women who could not speak English were not assigned to the telephone helpline.

Table 30 shows that the largest single group of women was referred to Parentline (34%), followed by the NCT (23%) and Parents & Co. (22%). Three groups were assigned four or fewer women.

Community groups were informed immediately after a woman was assigned to them; they were then asked to contact the woman with an introduction to, and details of, the service(s) they offered. Making this initial contact was an alteration to three of the groups' normal service (Holborn Community Centre, NCT, Parentline), but it was common practice for the other five. The NCT group admitted that they had not always been able to carry out this initial contact with women in the study.

Women were asked in the first follow-up questionnaire whether the group to which they had been assigned had ever been in contact with them. Of the 161/184 women who answered this question, 119 (73%) said the group had been in contact, 39 (24%) reported no contact and three women (2%) could not remember whether or not they had been contacted.

Women allocated to CGS were asked at 12 months whether they had ever *taken up* this offer. Only 29 (18%) of the 164 women who returned the questionnaire said they had done so. Cross-checking with the information kept by the community groups revealed that the groups recorded offering support to 26 women. Only 20 of these corresponded with the women who said

TABLE 30 *Assignment of women to, and women's reported use of, the community groups*

Name of group	Women assigned to group		Women reported initial contact[a]		Women said they used services[a]		Groups said women used services	
	n/*N*	%	*n*/*N*[a]	%	*n*/*N*[a]	%	*n*/*N*	%
Hopscotch	3/184	2	2/2	100	2/2	100	2/3	67
Parents & Co.	41/184	22	29/37	78	6/37	16	6/41	15
Holborn Community Centre	14/184	8	10/14	71	5/14	36	2/14	14
Parentline	63/184	34	46/56	82	7/56	13	4/63	6
NCT	42/184	23	17/36	47	2/36	6	3/42	7
Home-Start Islington	16/184	9	12/14	86	6/14	43	7/16	44
Home-Start Camden	4/184	2	3/4	75	1/4	25	1/4	25
Finsbury Park Homeless Families & Refugee Centre	1/184	1	0/1	0	0/1	0	1/1	100
Total	184/184	100	119/164	73	29/164	18	26/184	14

[a] As reported by 164 women assigned to CGS who completed the first follow-up questionnaire. Numbers (*N*) are given for the number of allocated women who responded to this questionnaire.

TABLE 31 *Discrepancies in reporting by women and community groups of use of the CGS intervention*

Group	Discrepancies
Hopscotch	None
Parents & Co.	Four women in common, plus: two women reported using drop-in groups – not recorded by group group recorded multiple home visits for one woman – not reported by woman one woman used service but did not return questionnaire
Holborn Community Centre	Two women in common, plus: three women reported using drop-in facilities – not recorded by group
Parentline	Three women in common, plus: four women reported using service – not recorded by group group recorded a call from one woman – not reported by woman *Note: two additional women reported attempting to use the service, but were unable to get through to the helpline*
NCT	Two women in common, plus: group recorded one woman attending two group sessions – not reported by woman
Home-Start Islington	Six women in common, plus: one woman used service but did not return questionnaire
Home-Start Camden	None
Finsbury Park Homeless Families and Refugee Centre	Group recorded one woman consulting drop-in – not reported by woman

they had used the service (see *Table 31* for details of the discrepancies in reporting). There were two main reasons for the discrepancies. First, women sometimes used services anonymously (drop-in groups, telephone helpline), either by choice or because staff available on the day were unfamiliar with the research and the recording protocols. Second, women interpreted 'use of services' more strictly than the groups did: women sometimes did not count home visits as 'use of services' and gave reasons for not attending drop-in activities. In addition, not all the women returned the first follow-up questionnaire and the community group had records of use for two women who were in this group. Given the nature of the discrepancies, it was decided that the most appropriate estimation of use of services for the analysis was an amalgamation of the accounts of both the women and the community group records. *Table 32* shows the amalgamated data.

Overall, the use of the offered community group support service among the women *allocated* to this arm of the study was 35 out of 184 (19%).

The community groups that had the most success in uptake of services were those that offered a home-visiting service as part or all of their service (Parents & Co., Home-Start, Hopscotch and Holborn Community Centre).

TABLE 32 *Use of CGS intervention: amalgamated data from women and community groups*

Name of group	No. allocated to group	Total who used services	
		n	%
Hopscotch	3	2	67
Parents & Co.	41	8	20
Holborn Community Centre	14	5	36
Parentline	63	8	13
NCT	42	3	7
Home-Start Islington	16	7	44
Home-Start Camden	4	1	25
Finsbury Park Homeless Families & Refugee Centre	1	1	100
Total	184	35	19

This 19% usage of the specific community groups to which they were allocated can be compared to general usage of *any* community service for mothers with children aged under 5 in the three arms of the trial. At first follow-up, similar proportions, nearly half of women, from each of the three arms had *ever* used a community service for mothers and babies (*Table 33*). At the second follow-up, community service use in the *previous month* was measured; again similar proportions,

TABLE 33 *Use of any community services for mothers and children by trial arm*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
1st follow-up (12 months): ever used any community service for mothers and children								
Ever used	77/165	47	75/158	48	158/326	49	0.96 (0.79 to 1.17)	0.98 (0.80 to 1.19)
2nd follow-up (18 months): used any community service for mothers and children in previous month								
Used in previous month	54/145	37	62/158	39	111/298	37	1.00 (0.77 to 1.29)	1.05 (0.83 to 1.34)

TABLE 34 *Services provided to CGS women as reported by community groups*

Type of service	Total time (minutes)	Total no. of contacts[a]	No. of women who used this type of service	Range of contacts per woman	Average: no. of contacts per women; time per contact
Home visiting	8,940	79	20	1–28	3.95 contacts 114 minutes
Drop-in activities	6,285	49	11	1–16	4.45 contacts 128 minutes
Support and information on telephone	667	67	51	1–5	1.31 contacts 10 minutes
Total	15,892	195			

[a] Includes multiple use by some women.

over one- third, of the women had used these services during that time.

Pattern of usage

Overall, the community groups reported providing 264 hours 52 minutes of contact to women assigned to them. (This is an under-reporting of actual time spent, as the community groups did not have records of contacts with nine women who said they used the services: five used drop-in activities and four phoned the telephone helpline.) Some of this recorded time was spent explaining and offering groups' services to the women, who then chose whether or not to use them. Some groups used more than one means of providing services to the women, and some women used more than one type of services within their allocated community group. The largest component of total contact time was home visiting, used by 20 women. A smaller number of women (11) used drop-in activities, but the average number of contacts and average time per contact was highest for these women. Telephone was the means used to contact the largest number of women (51), but took the least time (*Table 34*).

Analysis of socio-economic data by use and non-use of community group support (*Table 35*) shows that there were no significant differences in socio-demographic characteristics between users and non-users.

Reasons for non-use

There were various reasons why women said that they did not take up the offer of CGS. The perceived lack of need for the services offered and the groups' failure to make contact were two main reasons women gave for non-use. *Table 36* shows the reasons given in the first follow-up questionnaires for the women allocated to the community support arm who responded to this questionnaire, excluding those assigned the telephone helpline. The most common reasons were that women were too busy or had a full social life (22%), or that there was no initial contact by the group (19%). *Table 37* shows the reasons given for not using the telephone helpline by the woman allocated to that service. The most common reason given for not using the service

TABLE 35 *Women's socio-demographic characteristics and use of CGS*

Characteristic[a]	Used service		Did not use service	
	n/N	%	*n/N*	%
English not first language	17/35	49	53/149	36
BME women	17/35	49	61/147	42
Not first child	17/35	49	75/149	51
Returned to work full time	3/33	9	15/129	12
Lone parent	9/35	26	38/149	26
Rented housing	24/35	69	102/149	69
Depressed	6/35	17	32/149	22
High/medium stress	18/35	51	57/149	39

[a] All characteristics from baseline questionnaire (*N* = 184), except for 'returned to work', which is from the first follow-up questionnaire (*N* = 164).

TABLE 36 *Reasons why women did not use the CGS intervention (home visiting and drop-in support)*

	n	%
Too busy/full social life	24	22
No initial contact by group	21	19
Too far away	9	8
Don't speak her language/other women 'not like her'	5	5
Didn't want to go out on own	4	4
No crèche for older children	2	2

N (of women) = 108; women allowed to choose multiple reasons

TABLE 37 *Reasons why women did not use telephone support*

	n	%
Had no problems	24	38
Forgot about the helpline/lost their phone number	17	27
Rather speak to someone in person/don't like that sort of thing	12	19
Didn't think they could help me	8	14
Had no time	2	4
Hours inconvenient	2	4
No privacy to phone	1	2

N (of women) = 63; women allowed to choose multiple reasons

was having no problems (38%), followed by forgetting about the helpline or losing the telephone number (27%).

In addition to the reasons that had been offered as options to tick in the questionnaire (listed in *Tables 36* and *37*), women gave other reasons for not using the services offered to them. For the telephone helpline women added that they were getting support from elsewhere (friends, family, GP) and did not need extra support, they might have used it for a first child, but not with subsequent children, and they were uncertain about whether staff were qualified to answer their questions. For women allocated to the other community groups, reasons for not using the services included going back to work, having other social networks, not feeling the need for the services, moving home, and feeling that their child was too young to be taken to the group.

Nature of the CGS intervention

Home visiting was provided to women in the study by five groups: Home-Start Islington, Home-Start Camden, Parents & Co., Hopscotch and Holborn Community Centre. One woman received 28 home visits, and another 15 visits. The remaining 18 women who had home visits received between one and six visits, with the majority receiving only one. Seventeen of the 20 women who had home visits (85%) did not speak English as their first language. This high proportion may be partially explained by the groups making contact in person to explain their services to women who might have lower literacy or comprehension through letters or telephone calls. In addition, three of the community groups employed Bangladeshi outreach workers to carry out home visiting: seven of the women who received home visits were Bengali speaking.

Women attended *drop-in activities* provided by five of the community groups: Homestart Islington, NCT, Parents & Co., Holborn Community Centre and Finsbury Park Homeless Families and

Refugees Centre. One woman attended 16 drop-in activities, but the remaining ten women who used them took part in between one and nine drop-in sessions.

Telephone contacts made for information and support were recorded by six groups: Home-Start Islington, NCT, Parents & Co., Parentline, Hopscotch and Finsbury Park Homeless Families and Refugees Centre. In all, 51 women had this kind of support.

Topic areas covered during CGS support

The main themes covered in home visits and in support offered by the community groups over the telephone centred on the baby, the woman and the family. When discussing the baby, issues regarding the baby's health were raised most frequently (24 times), followed by baby feeding (19), sleeping (8) and crying (4). Discussion focusing on the woman concentrated on relationship difficulties (22), feelings of isolation and loneliness (13), the woman's physical health (12), depression (8), relationships with other family members (7) and coping with parenting (7). One woman only spoke of the joys of parenthood. Family issues raised included worries over the behaviour of older children (9), housing problems, including racial harassment (9), access to English as a second language courses (10) and information about local resources (5).

Women's views of the services

Out of the 29 women shown in *Table 30* as having reported using CGS, 25 answered a question about their satisfaction with the service they had received. Five found the group very helpful indeed, seven said the group had given them about the right amount of help, three women said that they did not get enough help from the group, and nine women had disliked the service. One more woman said that the services were "unsuitable" because they were too far away from her home.

Women said that the most helpful things about using the community services included enabling them to meet other mothers, having visitors come to their home when it was difficult to go out, being listened to and being given some good advice:

> "Met other people, they all have the same problems as me. Two friends now, we're all stuck at home, can't leave the kids. My son has stayed in the crèche, gives me a break. My kids can play with other children now. Can take two toys home every week."

> "It was someone coming to see me, I didn't have to go anywhere, also helped me to get out occasionally."

> "It got me in contact with people living locally I would not have met otherwise. It gave me an idea of numbers of services available in the area."

> "Embarrassed at first to tell people my problems in case they told other people about family problems. The staff told us it was confidential and now I've talked about my childhood and all sorts of family things in the group."

> "It is very good to have help at the end of the phone when needed."

Comments made by women about the things they liked least about their community group included that the group did not offer the practical help they needed, they had been given poor advice, that women 'like them' did not use the service, the hours were inconvenient and that it was disorganised or unfriendly:

> "When I attended the service I found it was very disorganised and I found the activity quite boring and did not feel welcome."

> "My baby and I enjoyed [the service] but no member of staff was obvious, made no effort to introduce themselves or make new callers welcome. Eventually I asked who was staffing the [service] and introduced myself."

> "I rang once over a fairly simple issue and I seemed to know more than they did and I found it no help at all although she was nice … I was rather disappointed and didn't ring again as I thought what's the point."

> "I felt as though I had no really bad problems to discuss with their parent groups."

Community groups' views of their intervention

Initial views

During the prestudy training sessions the community groups expressed reservations about whether a social support intervention would be able to make a difference to women's lives, considering the complexity of problems they faced. The problems the groups identified as being possible barriers to the effectiveness of the intervention were housing and homelessness, poverty and isolation.

They were also aware of the difficulties of reaching and working with women whose first language was not English, in terms of both language and

cultural appropriateness. Some of the groups had already confronted this issue by employing staff or recruiting volunteers who spoke other languages (mainly Bengali), and had adapted existing services by running dedicated sessions or providing an outreach worker. However, other groups had little or no experience of offering their services to people from a wider range of cultural backgrounds. Even those that did recognised that there would be occasions when they would be working with women with whom they had had limited contact or experience, such as refugees, who in addition to the usual list of social and economic problems may also be suffering major trauma.

Another area of concern to the community groups was about raising women's expectations over and above what their group could realistically offer. Some groups feared that the model of support they use (befriending and encouraging the woman to bring about change for herself and her family) would be inappropriate for women in the study. They were concerned that study women might have problems far greater than their own inner resolve to do something about them, and might therefore expect the community groups to help them in ways that were not part of their normal service.

Despite these concerns, the community groups expressed enthusiasm for participating in the research. Several groups said that they hoped that the combination of research and service provision would strengthen their ability to influence government policy and help them in their search for funding. One group hoped that the study would point out the deficit in provision for families who do not speak English.

Feedback from community groups during the intervention

At research feedback sessions

The groups had an opportunity to discuss the progress of the intervention and their views on implementation at two research feedback sessions. Their main concern was the low uptake of their services by women in the study. First, they talked about the practical and time-consuming difficulties they had in making initial contact with many of the women. Some women had moved or refused to open the door, and there were many instances of disconnected telephones. Some group workers said they felt inexperienced and lacked the resources to facilitate effective communication with women who did not speak English. They expressed frustration at the numbers of women to whom they gave information, but who never used their service. This presented them with a quandary about how long they should keep trying to get the women to use their service, particularly if their normal service did not include actively soliciting women to attend.

Their second area of concern for the community groups was the appropriateness of the service they offered (which varied between the groups according to what services they provided). Confronted with some women with such a high level of material deprivation, groups said they sometimes felt that other health and social services were more appropriate and referred women on where they could. They were also concerned that a value system that encourages and promotes children's needs was a luxury for some families. They were unsure whether women from different cultural and ethnic backgrounds were comfortable talking about personal and family issues with a stranger or in a group. Conversely, one group said that they felt, on the whole, that the more middle-class study women allocated to them had tried the service, but not continued because they felt uncomfortable with the more economically deprived women who were their main users.

Community group record sheets

When the community groups had contacts with study women, they were asked to rate whether they thought they were doing any good in terms of reducing the woman's anxiety (if she had any), and whether they thought the contact had been helpful to the woman.

On the whole, groups rated their contacts as being on the helpful end of the scale; nearly half of the contacts (45%) were rated as 'quite helpful'. Very few rated their contact as either very helpful (12%) or unhelpful (4%) (*Table 38*).

The groups were also asked to rate their perception of the woman's anxiety level at the start of each home visit or telephone call, and again at the end.

In over half of the contacts (57%), community groups recorded a reduction in the woman's level of anxiety after their contact with her (*Table 39*). This varied little between type of contact. There were eight instances when the group worker recorded a higher anxiety level in the woman at the end of the contact than at the beginning. Four of these were recorded during visits to one woman who was going through a particularly distressing time in her relationship with her husband. She

TABLE 38 *Community groups' self-ratings of helpfulness*[a]

	Telephone	Home visit	Total	
	n	*n*	*n*	%
Very helpful	5	12	17	12
Helpful	15	19	34	24
Quite helpful	28	34	62	45
Not very helpful	12	9	21	15
Unhelpful	1	4	5	4
Total	61[b]	78[c]	139	100%

[a] Drop-ins were not rated because these were group rather than individual settings.
[b] Missing data for six telephone calls.
[c] Missing data for one visit.

TABLE 39 *Community groups' ratings of women's anxiety levels following contact*

	Telephone	Home visit	Total	
	n	*n*	*n*	%
Reduced anxiety	34	48	82	57
Stayed the same	25	25	54	37
Increased anxiety	1	6	8	6
Total	60[a]	79	144	100%

Source: Community Group Record Sheets.
[a] Missing: 7.

also received more contacts over a longer period than any other women using the community groups.

These ratings show that community groups felt that on the whole they were being helpful and reducing anxiety among women who were using home visiting and telephone services.

Reflection and suggestions

Following the completion of the intervention, interviews were carried out with key workers in the community groups. They were asked to reflect back on their involvement in the study and to think about whether taking part had made them consider changing their service or the way they offered it. A summary of the suggestions put forward about possible changes in practice is given in *Table 40*.

The community group workers attributed low uptake of their services to several factors. One was that study processes did not always work as planned. They felt that some of the women allocated to them lived too far away to make use of

TABLE 40 *Community groups: suggested changes in own future practice*

- Find out more about the language and cultural background of the local community
- Recruit, train and fund interpreters
- Create a skill share/exchange/information database for community services to use
- Training and supervision for all workers and volunteers within and across community groups
- For some groups, replace volunteers with paid staff to provide a long-term service
- Where possible, make first contacts with women face to face
- Never rely on messages left on a telephone answering machine
- Be clear about what you can and cannot offer, and refer to more appropriate services whenever possible
- Assign a volunteer to a new mother to help her settle in
- Provide a home-visiting service for housebound women
- Provide transport for women who cannot get to the centre unassisted
- Provide a service and information for women with very young babies
- Make the venue for a drop-in as non-threatening and accessible as possible

their services. Others felt that the recruitment process of the study had left some women confused about the services their group could offer. Sign-in or identification procedures that were instituted to gather data about service use specifically for the study did not always work as planned, so they felt that uptake might have been under-recorded. The service one group was able to provide was severely compromised by the volunteer staff being in personal crisis and resources being too stretched to provide adequate cover; some allocated women were not contacted by this group:

> "[The study] highlighted our limitations. We were all voluntary, we kept it going, but it was by the skin of our teeth … there was a time when it could have folded."

> "We don't have a formal registration system, so people coming in and identifying themselves as part of the survey wasn't a natural thing."

> "They lived too far away, or had unrealistic expectations of what we did …"

> "I might have briefed the women differently or more in depth about the kind of services we offer."

A second reason workers gave for low uptake was that study women were more culturally diverse than their usual service users, or at a different stage of motherhood. A proportion of these women may have found the services on offer to be inappropriate or unnecessary.

> "Not everybody that has a child necessarily experiences stress or feels that they want home visiting support … in many cases some access to a group or other service would be more acceptable … You're taking in absolutely everybody who has a child in that catchment area … A referral normally would come … through a health visitor [who judges] whether she feels somebody might benefit … [and] meet the criteria, feeling under stress … completely appropriate referrals."

> "They were referred when the children were babies … our service isn't necessarily right for them. [They] will maybe come back when their child is … older."

A third factor that workers felt contributed to low uptake was a difficulty in contacting many women: a group that chased referrals assiduously had a higher uptake than groups that were less proactive. High uptake was attributed to a range of services being provided to serve the diverse needs of the study sample, and to a strong and multicultural staff team:

> "We work with a very wide range of babies, from newborns up to three and a half year olds … We do a lot of home visiting and outreach work … we can take six, eight, ten weeks of home visiting before we enable a woman to come out to one of the groups, and we follow everybody up five times if they don't, so if a woman is very shy or doesn't speak English, or she has a mental health problem, or a disability and can't get her children down the stairs, we find out … We are both [task oriented and social] … We give a holistic service."

Although the community groups were disappointed with the overall level of support they had been able to provide to the women in the study, several groups spoke of individual success stories where they could see that women had benefited from using their services: depression had lifted, English and parenting classes had been taken, loneliness had been relieved.

Unit costs of the CGS intervention

The unit costs of each of the services (home visits, centre-based activities and telephone support) used by women allocated to the CGS intervention are shown in *Table 41*. The unit costs for particular services vary between the different groups. This reflects differences between the groups in resources available, numbers of mothers and children present at each session (for group sessions), and the length of time over which the service was provided. The highest cost for a home visit was for Home-Start Camden, which also had the longest average time per visit (4 hours).

There were considerable differences in the estimated costs per hour for each type of service. Outreach costs per hour varied between £15 and £188. Costs per hour for mothers' groups varied from £55 to £179. The reasons for variation include the allocation of fixed overheads to the actual workload. Groups facing the same fixed costs of rent and other overheads with lower workload would have higher unit costs. A further reason for differences in cost between community groups was differences in reliance on volunteers. Some, such as Hopscotch and Parents & Co., used no volunteers for outreach services. The base case analysis excludes volunteer costs. When the estimated value of volunteer time is added to the costs, differences in unit costs between groups are reduced. In the case of the mothers' groups, the hourly costs represent costs for different sized groups of mothers and children, but the range of costs does not obviously reflect this.

TABLE 41 *Unit costs of CGS intervention services*

	Unit costs (£, year 2000 prices)			Comments
	Base case unit cost	**Costs including volunteer time**	**Cost per hour of service provided (including volunteer input)**	
Home visits				
Outreach: Hopscotch	31.45	31.45	188.72	Visits lasted average 10 minutes, no volunteer input
Outreach: Holborn[a]	31.06	31.06	62.12	Visits lasted average 2 hours, no volunteer input
Outreach: Finsbury Park[b]	Data not available	Data not available	Data not available	Assumed the same as Outreach Holborn for the analysis
Home visiting: Parents & Co.	57.57	57.57	28.78	Visits lasted average 2 hours, no volunteer input
Home visiting: Home-Start Islington	24.23	36.72	14.69	Visits lasted average 2.5 hours, volunteers involved
Home visiting: Home-Start Camden	38.26	78.22	19.55	Visits lasted average 4 hours, volunteers involved
Centre-based activities				
Mothers' group: Hopscotch	57.22	57.22	171.67	Mothers and carers support group run for 3 hours per session once a week; average attendance: 9 carers/mothers. No volunteer input
Mothers' group: Holborn[a]	31.05	35.96	143.82	Sewing/social morning sessions run once a week for 3 hours; average attendance: 12 women. No volunteer input
Mothers' group: Finsbury Park[b]	Data not available	Data not available	Data not available	Assumes the same as Mother's group Holborn for the analysis
Drop-in: Holborn[a]	11.84	13.89	55.55	Messy Play & Arts session run twice a week for 2 hours each; average attendance: 8 adults, 12 children. Volunteers involved
Drop-in: Home-Start Islington	25.25	29.35	176.09	2-hour service run once a week; average attendance: 12 adults. Volunteers involved
Drop-in: NCT	19.95	23.02	103.60	2-hour service run once a week; average attendance: 9 adults. Volunteers involved
Telephone support				
Home-Start Camden	3.79	3.79	18.19	Average duration 12.5 minutes, no volunteer input
Home-Start Islington	Data not available	Data not available	Data not available	Costs assumed the same as Home-Start Camden
Parentline	8.00	8.00	24.39	Average duration 20 minutes

[a] Holborn Community Centre, Bedford House.
[b] Finsbury Park Homeless Families and Refugee Centre.

Summary

Overall, only 35 of the 184 women (19%) allocated to the CGS intervention used the services on offer. The community groups reported providing 264 hours 52 minutes of contact (195 contacts in total) to women assigned to them. The groups that had the most success in uptake of services were those that offered a home-visiting service as part or all of their service. The perceived lack of need for the services offered and the groups' failure to make contact were two main reasons women gave for non-use of the CGS intervention. Of the women who used the services and commented on their satisfaction with them, half found that the group had given them enough help or were very helpful; half were more dissatisfied with the help they had been given. The community groups reflected on possible changes to the way they make initial contact with potential users of their services, and to the nature of the services they deliver in order to be more accessible to a broader range of women. They also reported some individual success stories where they could see that women had benefited from using their services.

Chapter 6

Main outcomes at 12 months postrandomisation (first follow-up)

Response at first follow-up

The first follow-up questionnaire was sent to women 12 months postrandomisation, when their babies were approximately 14 months old. This questionnaire was completed by 657 of the 731 women in the study, a response rate of 90%. Of these questionnaires, 68% were completed by the woman and returned by post, 12% were completed in the woman's home with the assistance of an interpreter and a researcher, 12% were completed in the woman's home with a researcher, and 8% were completed over the telephone with a researcher.

Response rates for the first follow-up were similar across the three arms of the trial, as were the ages of the babies when the women returned the questionnaires (*Table 42*).

Similar proportions of women across the three arms of the trial completed the questionnaire either by themselves or by interview at home with a researcher. However, more of the control group women compared with women in the two intervention groups completed the questionnaire over the telephone. Fewer of the control group completed the questionnaire with the help of an interpreter (*Table 42*).

The main reason for non-response to the first follow-up questionnaire was women moving accommodation without leaving a forwarding address (*Table 43*). With a majority of participants

TABLE 43 *Reasons for non-response to first follow-up questionnaire*

	n/N	%
Moved	25/74	34
Unable to contact	18/74	24
Withdrew from study	18/74	24
Too busy at that time	6/74	8
Abroad at that time	4/74	5
Baby died	2/74	3
Woman unwell	1/74	1

TABLE 42 *Response by trial arms to first follow-up questionnaire*

	SHV			CGS			Control			Total		
	n/N		%	*n/N*		%	*n/N*		%	*n/N*		%
Response rates												
Responded	165/183		90	164/184		89	328/364		90	657/731		90
Method of completion												
Postal	115/165		70	109/164		67	222/328		68	446/657		68
Interview with researcher and interpreter	23/165		14	27/164		17	29/328		9	79/657		12
Interview with researcher	20/165		12	21/164		13	39/328		12	80/657		12
Telephone interview	7/165		4	7/164		4	38/328		12	52/657		8
Timing of first follow-up												
	N	Mean	SD	*N*	Mean	SD	*N*	Mean	SD	*N*	Mean	SD
Age of index child (months)	165	14.87	2.07	164	14.80	2.01	328	14.76	1.97	657	14.80	2.01
	Mean difference (95% CI) SHV/control: 0.12 (–0.26 to 0.49)			Mean difference (95% CI) CGS/control: 0.035 (–0.34 to 0.41)								

TABLE 44 *Characteristics of responders and non-responders to first follow-up questionnaire*

	Responders			Non-responders		
	N	**Mean**	**SD**	***N***	**Mean**	**SD**
Age (years, at birth of index child)	657	29.69	5.71	74	28.46	6.57
Parity (at baseline)	657	1.87	1.1	74	1.86	1.2
		n	**%**		***n***	**%**
First language: not English	657	247	38	74	35	47

living in rented or temporary accommodation, there was high mobility throughout the study. Many women kept the study informed of their current addresses, others were eventually tracked through health records, but some were inevitably lost to follow-up. Eighteen women chose at this stage to withdraw from the study.

The women who did not respond to the first follow-up questionnaire were similar to women who did respond in terms of their age and parity. More non-responders did not speak English as their first language (*Table 44*).

The next section of this chapter describes some of the responses to the first follow-up by the SSFH study women as a whole. This provides a general context for the presentation of outcome data and economic costs in the second half of the chapter.

The context: life with a 14-month-old baby

Maternal well-being

When they completed the first follow-up questionnaires, the women were continuing to adjust to the physical and emotional demands of caring for a young baby, and balancing these with other family commitments, their own personal needs, and often caring for other children and paid employment as well. Women were asked whether they had found the past 12 months easy or difficult. First-time mothers, in particular, talked about how their lives had been enriched by the transition from being a single person or part of a partnership to becoming part of a family unit:

> "Being a mother fills me with joy and I feel blessed. I don't feel the country as a whole embraces mothers and their children. But against the odds we continue forward."

> "[What has made me happy is] falling in love with my baby. Sharing the experience with my partner. Coping with the changes, our relationship, surviving the changes. Feelings of being a good parent – seeing my partner be a good father."

> "[I have been happy] seeing [my baby] take his first steps, laughing with him, watching him explore, hearing him say his first words. Sitting on my own and painting, finishing a good book, having two lovely holidays with our extended family. Going out a few times with [my partner] on our own."

The process of adjusting to the new baby was more difficult for the women in the sample who were lived in markedly disadvantaged circumstances. Positive feelings had to compete with experiences of unrelenting work and/or overwhelming problems. Over half of the women (52%) said they had found the previous year 'rather' or 'very' difficult (*Table 45*). Almost one-third reported having high levels of stress (32%), and 40% said they had not enough or no control over their life. Women, especially those who had previously been waged, described the loss of status they experienced since becoming a mother. In all, 29% of the women reported feeling depressed and a further 48 women (7%) indicated that they had felt both depressed and cheerful at times in the last few weeks. A total of 28% of the women registered a score or 12 or above on the EPDS screening tool, indicating a risk of postnatal depression:

> "Everyone warns you [motherhood] is hard work but nobody tells you it is also tedious, mundane, and repetitive, and can make you feel stupid and worthless."

> "Being a mother is good when you have everything. But when you have no money, no partner and you're doing everything on your own then it isn't nice at all."

> "Juggling motherhood and work, and feeling guilt about both."

> "I'm depressed because none of my friends have babies and most of them have moved on and I spent nearly most of my time in the flat by myself and the baby."

TABLE 45 *Maternal well-being at first follow-up*

	n	%
Last year rather/very difficult	333/646	52
Very high/quite high current level of stress	204/642	32
Not as much control as desired/no control over life	257/641	40
Felt low spirited or depressed in last few weeks	235/652	36
EPDS score 12 or above	171/607	28
Physical health 'good'	504/649	78
Taken medication in the past week	377/651	58

TABLE 46 *Index child's health and development at first follow-up*

	n	%
Generally healthy	613/650	94
Given medication in past week	419/657	64
Given antibiotics in last week	67/657	10
Had injury in past 6 months	91/651	14
Easy to look after	479/647	74
Breast-feeding initiated	562/657	86
Developing normally	609/640	95

Nearly eight out of ten women (78%) said that their health had been 'good'; 20% said it had been 'not very good'. A further 11 women (2%) added a comment that their health was 'mixed' or 'varied' over the previous month. Overall, 58% of the women had taken some form of medication (excluding vitamins) in the previous week; 48% had taken painkillers during that time. Women who had experienced poor health, exhaustion and sleeplessness had found this difficult to cope with:

> "My health seems to have deteriorated since the birth … I have developed asthma and coughing fits. I suffer from incontinence when coughing."

> "After a year of broken nights, I am beyond exhaustion some days …."

Index child's health

Most mothers (94%) thought that their child was generally healthy. Thirty per cent had particular worries about their baby's health, most commonly about weight gain, recurring coughs and colds and adverse effects of vaccination. Just under half of the women (47%) reported that their baby had had colic either 'sometimes' (30%) or 'a lot' (17%).

Two-thirds of the babies (64%) had been given some form of medication in the previous week. Half of the children had been given paracetamol or other painkillers, and 10% had been taking antibiotics (*Table 46*). Fourteen per cent of the mothers reported that their baby had had an accident in the last 6 months where the help of a health professional had been sought, usually for a fall on the head, injury to the mouth or a burn. From the information given about treatment received, it appeared that over one-third of mothers sought medical help to reassure themselves, and that no treatment had been necessary.

> "My baby fell over the broken side of the dropside on his cot … having pulled himself up to standing. He was taken to A&E. No after effects or complications. I have since turned the cot round with the broken side near the wall."

> "Older child pushed pushchair down a short flight of stairs, baby fell on to his face. I'd left the two children for a few moments on the balcony outside the flat and gone back to get something."

Experiences of being a mother

Many mothers described their relationships with their babies as being intensely joyful and unremittingly tiring. Three-quarters of the women (74%) said their baby was easy to look after, 13% difficult, and a further 13% wrote on the questionnaire that their baby was both of these:

> "I never considered how much joy he would bring … Once you love a child, no man will ever come close to meaning that much!"

> "[Being a mother] is the most amazing and yet the most awful thing at the same time."

> "I like the close relationship I have with my daughter, but I was not prepared for the bombshell of having a baby and looking after another human being 24/7. I feel isolated, lonely and very trapped in motherhood."

Most (86%) of the mothers had breast-fed. Compared with national data collected a few years earlier, the rate of initiating breast-feeding among study participants was higher than the national average (86% vs 68% for England and Wales). There was a greater prevalence of breast-feeding at 6 weeks (72% vs 44%), 4 months (55% vs 28%), 6 months (39% vs 22%) and 9 months (28% vs 14%).[134] Overall, 24% of the women in the study reported giving their baby solid food before 16 weeks of age.

Only 5% had worries about their child's development (*Table 46*).

Household resources

Just over one-third of women (35%) were in paid employment when they completed the first follow-up survey, returning to work on average when their baby was 6 months old. Overall, 16% of the women said that they were in a better financial position, 40% said that this had stayed the same, and 44% were worse off than before the baby was born. Money problems were a source of worry for many women. Economic necessity forced some women to work when they would rather have been at home. Women mentioned unemployment, redundancy and living on state benefits as reasons why their financial situations were difficult. Mobility was restricted for many: 43% of the women had no use of a car at all. In addition, when asked what were major difficulties in the last year, one in ten women mentioned housing (*Table 47*). As noted earlier, many had moved recently or were in the process of moving, and a large number were homeless (in hostel or bed and breakfast accommodation) or living with their families in overcrowded conditions:

> "[What's made me happy has been] moving house – we now have a garden for my daughter to play in. And changing job – it is more flexible."

> "Having the option not to return to work."

> "Husband has no job – have to go on income support and we don't have any money. If there is not enough money you can't buy things for the baby. That makes me sad."

> "My accommodation [is] a simple bed-sit, nowhere to sleep or play, pests, everything … the toilet outside, no gate on stairs. I have to watch him constantly."

> "… being stuck in the poverty trap with the spiralling feeling that there is no hope and no way out …"

TABLE 47 *Household resources at first follow-up*

	n	%
Women in paid work – full time	83/655	13
– part time	148/655	23
Currently studying	80/650	12
Does not have use of car	276/640	43
Housing listed as a major difficulty in past year	71/657	11
Financial situation worse than 1 year previous	287/647	44

Support from partner, family and friends

The women were asked about the overall support they had received in the past 6 months. Nearly three-quarters of the women (72%) had a partner who lived with them at the time of the first follow-up questionnaire, a further 12% had a partner who lived elsewhere, and 16% did not currently have a partner. Around two-thirds (65%) of women with a partner were happy with the relationship, 30% felt mixed and 5% felt unhappy. Difficulties arose with a change in roles, lack of energy, little time together, the partner working long hours or his lack of interest in his family:

> "I think having a baby changes an equal balanced relationship and tends to throw each person into traditional roles. A big adjustment, it's hard."

> "He works in an Indian restaurant … comes home at 2.30am … and sleeps in the morning. He is only around for a few hours a day. He pays the bills and buys the groceries, but does nothing else around the house or with the children."

Some single parents found being alone easier than being with an unsupportive partner. A number of single women, however, felt totally isolated. One in ten women without a partner felt 'not at all supported': 9% of single parents had contact with family less than monthly, and 6% had less than monthly contact with friends:

> "He is moving back to Spain. It's hard to be ending things, but better not to be always fighting and never sure of where things are going. At least now I can get on with my life."

> "Don't have a family – they're all abroad. No contact with a single person for 8 months after she was born. I shout, lonely, crying all the time."

Nineteen per cent of the women felt 'totally' supported, 34% felt well supported, a further 41% felt fairly well supported and 6% felt not at all supported. For 48% of women, the person who had given them the most support was their partner, for 32% a family member and for 14% a friend. Two per cent of women felt supported by no one and 10% felt supported only by one person. Ten per cent of women had no one to talk to if they felt unhappy (*Table 48*).

Over half (52%) of the total sample saw family members at least once a week, whereas one-fifth of women rarely saw their families and a further 7% never did. Six per cent had less than monthly contact of any sort (either by telephone or in person) with any family members. Mothers were the most supportive family members, followed by sisters. Lack of family support was especially difficult for women with greater expectations of help from a family network, or women whose partners were absent or not supportive:

"[I was happy having] Mum staying with me – very helpful, I felt myself again, able to go out."

"[Since I have] moved, I no longer have my mother's help. I used to live with her. Now I need to get the kids ready to go out, even if all I need is one thing from the shops."

"I am depressed because my husband doesn't support me at all. I feel very homesick. He doesn't want my mother and father to come over, instead he called his parents who gave me a hard time."

Over two-thirds of women (68%) saw a friend at least once a week, and 12% saw a friend less than monthly. Women felt positive about spending time with other mothers and children of the same age and re-establishing friendships socially and at work. Isolation from friends contributed to depression:

"Good times with friends and their children."

"The support of one very good friend."

"Normally I am subject to mood swings and a lot is to do with not knowing other people with children who are local."

At first follow-up, 47% of the women in the study as a whole had used some form of community groups or services for mothers and babies in the past year, an increase in use of 20% from when the babies were just a few weeks old. Mothers in part-time employment reported using the community services more often than other women. Services used most commonly were mother and toddler groups (67%) or one o'clock clubs (44%), heard about most commonly from family or friends.

"What made me happy was that my health visitor put me in contact with a voluntary organisation to help me go out with the children."

"I was amazed at how much G loved going to playgroups. Once he could walk it was such a relief to let him run around with new toys/children and it was a nice way to meet other mothers and socialise."

"There's not enough support for mothers in this area. Some mothers can't keep it together. Unless something's going on with the children, I have to pay. To go through Social Services there has to be abuse."

Trial results: first follow-up

This section of the chapter examines the evidence of the effectiveness of each intervention separately for the primary and secondary trial outcomes.

TABLE 48 *Social support at first follow-up*

	n	%
Living with partner	472/655	72
Partner 'rarely/never' looks after children	71/534	13
Partner 'rarely/never' helps with household tasks	178/534	33
Happy with relationship with partner	345/533	65
See family less than monthly	179/638	28
Speak with family on telephone less than monthly	46/637	7
See friends less than monthly	74/641	12
Speak with friends on telephone less than monthly	154/640	24
Has no close friends	53/656	8
No one to talk to if feeling down	63/628	10
Never used community services for mothers and babies	336/649	52
Overall feelings of support: not at all supported	39/654	6

This is followed by an analysis of the two intervention groups combined and by a discussion of possible differential effectiveness among particular subgroups of study women.

The three primary outcomes

Maternal depression

Maternal psychological well-being was measured in two ways: by calculating the women's score on the EPDS and through their self-assessment of mood in the previous few weeks.

Self-reported feelings of depression

Women were asked to categorise their feelings in the last few weeks as either 'fairly cheerful' or 'depressed or low-spirited'. The percentage of mothers who reported feeling 'low or depressed' was similar in all three groups (*Table 49*).

EPDS scores

A score of 12 or above on the EPDS screening tool indicates that the woman could be at risk of postnatal depression. The mean EPDS score was lower in both intervention arms, and a reduction of 4% was found in the proportion of SHV women compared with the control group scoring above 12; this difference is, however, compatible with the play of chance (*Table 49*).

There were 50 cases where the EPDS was not completed, primarily when the follow-up questions were asked over the telephone. Similar proportions from the three trial arms did not fill in the EPDS (25 control, 16 SHV and nine CGS women). However, those women who did not

TABLE 49 *Maternal depression at first follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Maternal assessment of mood in previous month								
Depressed or low spirited[a]	58/164	35	56/163	34	121/325	37	0.95 (0.74 to 1.22)	0.92 (0.72 to 1.19)
EPDS score above depression threshold								
12 or over	38/149	26	43/155	28	90/303	30	0.86 (0.62 to 1.19)	0.93 (0.69 to 1.27)
Mean EPDS score								
	N	**Mean (SD)**	***N***	**Mean (SD)**	***N***	**Mean (SD)**	**Mean difference (95% CI) SHV/control**	**Mean difference (95% CI) CGS/control**
EPDS	149	8.23 (5.4)	155	8.50 (5.9)	303	8.98 (5.3)	–0.75 (–1.75 to 0.35)	–0.48 (–1.59 to 0.61)

[a] Includes women who indicated that they had been both cheerful and depressed in the previous month.

TABLE 50 *Injuries requiring help from health professional at first follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Injury in past 6 months								
Injured	24/164	15	19/161	12	48/326	15	0.99 (0.63 to 1.56)	0.80 (0.49 to 1.32)
Mean no. of injuries								
	N	**Mean (SD)**	***N***	**Mean (SD)**	***N***	**Mean (SD)**	**Mean difference (95% CI) SHV/control**	**Mean difference (95% CI) CGS/control**
	164	0.17 (0.44)	160	0.12 (0.34)	325	0.16 (0.42)	0.01 (–0.07 to 0.10)	–0.04 (–0.11 to 0.03)

complete the EPDS were more likely to self-report as being low or depressed (55% vs 35% of those who had also completed the EPDS). This 20% difference was unlikely to be a chance finding (27/49 vs 208/603; RR 1.60, 95% CI 1.21 to 2.10).

Child Injury

At first follow-up, the proportion of index children sustaining an injury in the previous 6 months that required medical attention was 3% less for the CGS group than for the control group, but this was likely to be a chance finding. Similar proportions of injuries were sustained in the SHV and control groups (*Table 50*). Likewise, the mean number of injuries requiring medical attention in the past 6 months was similar in the three arms of the trial (*Table 50*).

Maternal smoking

Four per cent fewer SHV women than control group women reported smoking at first follow-up, but this difference was compatible with the play of chance (*Table 51*). Similar proportions of women in the three groups smoked more than ten cigarettes per day.

The six secondary trial outcomes

Health service use

Maternal health service use in the last month

Women were asked whether they had used any of a

TABLE 51 *Maternal smoking at first follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Woman smokes								
Smokes	39/165	24	44/164	27	90/327	28	0.86 (0.62 to 1.19)	0.97 (0.72 to 1.33)
No. of cigarettes smoked per day								
10 or more	26/165	16	27/164	17	53/327	16	0.97 (0.63 to 1.50)	1.02 (0.66 to 1.55)

list of health services in the past month (for their own health needs, not just for their child or children) and, if yes, the number of times. Women allocated to the SHV intervention were more likely than control group women to have seen their NHS health visitor at the surgery or at home, and to have spoken to the NHS health visitor on the phone about issues of their own health. Similarly, SHV women were more likely to have seen a social worker in the past month (*Table 52*).

When comparing the number of times that individual health services were used, SHV women spoke to their NHS health visitors on the telephone more times than control group women and they made fewer visits to both GPs at the clinic and hospital doctors.

Overall, however, there was similarity between control and SHV women when comparing the proportion who had used at least one health service for their own health needs in the past month, and those who had used none (*Table 52*).

When comparing the CGS group and the control group, there were no substantial differences in maternal healthcare use at the time of the first follow-up. The CGS group was similar to the control group in the proportions having contact with the services, as well as the number of visits to those services (*Table 52*).

Index child's use of health services
Table 53 shows health service use by the index child in the past month. A variable was created that compares children who had used at least one health service with those who had used none of these in the last month (*Table 53*). A reduction of 7% was found in usage by SHV children compared with the control group. This finding is compatible with the play of chance.

Eleven per cent fewer of the mothers in the SHV group than in the control group had taken their babies for consultation with their GP at the surgery or clinic. The mean *numbers of contacts* by SHV children with the GP at the clinic and with a hospital doctor were also lower. As with the mothers, the children in the SHV group were more likely to have seen an NHS health visitor at home in the previous month, but the difference in the mean number of times they had this type of contact was compatible with the play of chance.

Use of these health services by babies in the control and CGS groups was similar; there were no large differences between the groups and none where a chance effect could be ruled out.

Use of hospital services in past 6 months
A slightly greater proportion of index children from both intervention groups compared with children in the control group had used hospital services in the past 6 months. The largest increase was in usage of outpatient services, where there was a 5% increase for SHV children. This could be a chance finding (*Table 54*).

Maternal health

Rating of own health
Both the SHV intervention and the CGS intervention women had a lower risk than control group women of rating their physical health as 'not very good/mixed'. Overall, 18% of women in the SHV group and 19% of CGS women said they had poor health, whereas 26% of control group women reported that this was the case (*Table 55*).

Women's use of medication in previous week
The women were asked which, if any, medications they had taken in the previous week. *Table 55* shows that the two intervention arms were similar to the control group in terms of maternal use of medication.

TABLE 52 *Maternal use of health services in previous month at first follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Use of health services								
Use of any health service	87/165	53	84/162	51	175/326	53	0.99 (0.83 to 1.18)	0.96 (0.80 to 1.15)
GP at clinic/surgery	71/165	43	67/164	41	152/328	46	0.93 (0.83 to 1.18)	0.88 (0.71 to 1.10)
Doctor in hospital	20/165	12	21/164	13	43/328	13	0.92 (0.56 to 1.52)	0.98 (0.60 to 1.59)
Doctor at home	3/165	2	4/164	2	7/328	2	0.85 (0.22 to 3.25)	1.14 (0.34 to 3.85)
NHS health visitor at clinic/surgery	13/165	8	7/164	4	9/328	3	2.87 (1.25 to 6.58)	1.56 (0.59 to 4.10)
NHS health visitor at home	10/165	6	5/164	3	6/328	2	3.31 (1.23 to 8.96)	1.67 (0.52 to 5.38)
NHS health visitor on telephone	11/165	7	1/164	1	3/328	1	7.29 (2.06 to 25.77)	0.67 (0.07 to 6.36)
Midwife	10/165	6	8/164	5	20/328	6	0.99 (0.48 to 2.07)	0.80 (0.36 to 1.78)
Social worker	7/165	4	2/164	1	3/328	1	4.64 (1.22 to 17.71)	1.33 (0.22 to 7.90)

Mean no. of episodes											
	N	Mean	(SD)	*N*	Mean	(SD)	*N*	Mean	(SD)	Mean difference (95% CI) SHV/control	Mean difference (95% CI) CGS/control
GP at clinic/surgery	165	0.65	(0.88)	164	0.70	(1.10)	328	0.83	(1.31)	–0.18 (–0.36 to 0.02)	–0.13 (–0.36 to 0.08)
Doctor at home	165	0.02	(0.19)	164	0.05	(0.41)	328	0.02	(0.14)	0.002 (–0.03 to 0.04)	0.03 (–0.02 to 0.11)
Doctor in hospital	165	0.17	(0.50)	164	0.23	(0.89)	326	0.29	(1.40)	–0.12 (–0.31 to 0.03)	–0.06 (–0.26 to 0.14)
NHS health visitor at clinic/surgery	165	0.12	(0.48)	164	0.07	(0.45)	328	0.04	(0.25)	0.08 (0.02 to 0.17)	0.03 (–0.03 to 0.12)
NHS health visitor at home	165	0.07	(0.30)	164	0.03	(0.17)	328	0.02	(0.21)	0.05 (–0.004 to 0.10)	0.01 (–0.03 to 0.04)
NHS health visitor on phone	165	0.13	(0.58)	164	0.01	(0.08)	328	0.01	(0.01)	0.12 (0.05 to 0.22)	–0.003 (–0.02, 0.02)
Midwife	165	0.13	(0.56)	163	0.06	(0.31)	327	0.17	(1.12)	–0.04 (–0.20 to 0.10)	–0.10 (–0.26 to 0.002)
Social worker	164	0.07	(0.40)	164	0.03	(0.28)	328	0.02	(0.17)	0.05 (0.001 to 0.14)	0.02 (–0.02 to 0.07)

TABLE 53 *Index child's use of health services in previous month at first follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Use of health services								
Use of any health service	100/165	61	112/162	69	221/326	68	0.89 (0.77 to 1.03)	1.02 (0.90 to 1.16)
GP at clinic/surgery	63/165	38	78/162	48	161/326	49	0.77 (0.62 to 0.97)	0.97 (0.80 to 1.18)
Doctor in hospital	22/165	13	21/162	13	49/326	15	0.89 (0.56 to 1.41)	0.86 (0.54 to 1.39)
Doctor at home	3/165	2	4/162	3	8/326	3	0.74 (0.20 to 2.76)	1.01 (0.31 to 3.29)
NHS health visitor at clinic/surgery	52/165	32	52/162	32	103/326	32	1.00 (0.76 to 1.31)	1.02 (0.77 to 1.34)
NHS health visitor at home	11/165	7	8/162	5	9/326	3	2.41 (1.02 to 5.71)	1.79 (0.70 to 4.55)
Mean no. of episodes								
	N	Mean (SD)	*N*	Mean (SD)	*N*	Mean (SD)	Mean difference (95% CI) SHV/control	Mean difference (95% CI) CGS/control
GP at clinic/surgery	165	0.60 (0.81)	162	0.80 (1.23)	326	0.81 (1.07)	–0.21 (–0.37 to 0.03)	–0.004 (–0.20 to 0.24)
Doctor in hospital	165	0.15 (0.41)	162	0.18 (0.56)	326	0.25 (1.70)	–0.10 (–0.37 to 0.04)	–0.08 (–0.35 to 0.07)
Doctor at home	165	0.02 (0.19)	162	0.03 (0.16)	326	0.04 (0.30)	–0.02 (–0.06 to 0.03)	–0.02 (–0.06 to 0.02)
NHS health visitor at clinic	165	0.40 (0.67)	162	0.41 (1.0)	326	0.41 (0.78)	–0.01 (–0.14 to 0.12)	–0.001 (–0.16 to 0.22)
NHS health visitor at home	165	0.07 (0.28)	162	0.11 (0.88)	326	0.03 (0.21)	0.04 (–0.004 to 0.09)	0.08 (–0.02 to 0.25)

Index child's health

Mother's assessment of child's health

Although fewer women in both the SHV and CGS intervention groups said that their child's health was 'not very good', the differences were slight between these mothers and those in the control group (*Table 56*).

Child's use of medication in previous week

Similar proportions of babies in the three trial arms had been given at least one form of medication in the previous week (*Table 56*). However, when looking at specific types of medication given, 5% fewer SHV and CGS babies than those in the control group had received asthma medication, and 12% fewer SHV mothers than those in the control group had used skin ointment for their babies. Both of these are unlikely to be chance differences.

Colic

Mothers were asked whether their baby had suffered from colic. Four per cent fewer of CGS compared with control group women said that their baby had experienced colic, but this could have been a chance difference (*Table 56*).

Immunisations

The proportion of women who had had their children immunised (95% overall) was similar across the arms of the trial (*Table 56*).

Experiences of motherhood and child development

Looking after the baby

Analysis of women's responses to the question about whether the baby was 'easy' or 'difficult' to look after showed that a slightly greater

TABLE 54 *Index child's use of hospital services in previous 6 months at first follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Use hospital services								
Outpatient visits	37/161	23	37/156	24	58/319	18	1.26 (0.88 to 1.82)	1.30 (0.91 to 1.88)
A&E visits	46/159	29	40/150	27	83/312	27	1.09 (0.80 to 1.48)	1.00 (0.73 to 1.38)
Overnight stays	13/164	8	13/162	8	19/326	6	1.36 (0.69 to 2.68)	1.38 (0.70 to 2.72)
Mean no. of episodes								
	N	Mean (SD)	*N*	Mean (SD)	*N*	Mean (SD)	Mean difference (95% CI) SHV/control	Mean difference (95% CI) CGS/control
Outpatient visits	161	0.49 (1.44)	156	0.39 (0.81)	319	0.30 (0.76)	0.18 (–0.05 to 0.44)	0.08 (–0.05 to 0.25)
A&E visits	159	0.38 (0.71)	150	0.35 (0.67)	314	0.36 (0.70)	0.03 (–0.10 to 0.16)	0. 01 (–0.14 to 0.12)
Inpatient episodes	164	0.08 (0.35)	162	0.06 (0.24)	326	0.07 (0.31)	0.01 (–0.05 to 0.08)	–0.01 (–0.06 to 0.04)
No. of inpatient days	164	0.18 (1.02)	162	0.25 (1.35)	326	0.73 (10.1)	–0.55 (–2.18 to 0.13)	–0.48 (–1.95 to 0.25)

TABLE 55 *Maternal health and use of medication at first follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Physical health in the past month								
Not very good/mixed health	30/163	18	30/160	19	85/326	26	0.71 (0.49 to 1.02)	0.72 (0.50 to 1.04)
Taken medication in the past week								
Any form of medication[a]	88/164	54	87/163	53	176/324	54	0.99 (0.83 to 1.18)	0.98 (0.81 to 1.12)
Painkillers	81/164	50	74/163	45	157/324	49	1.02 (0.84 to 1.23)	0.94 (0.82 to 1.17)
Vitamins	40/164	24	42/163	26	87/324	27	0.91 (0.66 to 1.26)	0.96 (0.70 to 1.32)
Decongestants	15/164	9	21/163	13	40/324	12	0.74 (0.42 to 1.30)	1.04 (0.64 to 1.71)
Alternative remedies	17/164	10	14/163	9	40/324	12	0.84 (0.49 to 1.43)	0.70 (0.39 to 1.24)
Antibiotics	11/164	7	14/163	9	22/324	7	0.99 (0.49 to 1.99)	1.26 (0.66 to 2.41)
Antidepressants	8/164	5	7/163	4	15/324	5	1.05 (0.46 to 2.43)	0.93 (0.39 to 2.23)
Sleeping pills	3/164	2	4/163	3	8/324	3	0.74 (0.20 to 2.76)	0.99 (0.30 to 3.25)
Tranquillisers	1/164	1	0/163	0	5/324	2	0.40 (0.05 to 3.35)	
Other medication	11/164	7	17/163	10	36/324	11	0.60 (0.32 to 1.15)	0.94 (0.54 to 1.62)

[a] Excludes women who only took vitamins or alternative remedies.

TABLE 56 *Index child's health and use of medication at first follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Physical health in the past month								
Not very good/mixed health	6/165	4	9/164	6	22/321	7	0.53 (0.22 to 1.28)	0.80 (0.38 to 1.70)
Taken medication in the past week								
Any form of medication[a]	109/165	66	107/164	65	203/328	62	1.07 (0.93 to 1.23)	1.05 (0.92 to 1.21)
Painkillers	89/165	54	82/164	50	154/328	47	1.15 (0.96 to 1.38)	1.06 (0.88 to 1.29)
Skin ointment	23/165	14	39/164	24	83/328	26	0.55 (0.36 to 0.84)	0.94 (0.67 to 1.31)
Vitamins	35/165	21	32/164	20	71/328	22	0.98 (0.68 to 1.40)	0.90 (0.64 to 1.31)
Cough medicine	25/165	15	30/164	18	54/328	17	0.92 (0.60 to 1.42)	1.11 (0.74 to 1.67)
Decongestants	22/165	13	27/164	17	45/328	14	0.97 (0.60 to 1.56)	1.20 (0.77 to 1.86)
Antibiotics	17/165	10	15/164	9	35/328	11	0.97 (0.56 to 1.67)	0.86 (0.48 to 1.52)
Alternative remedies	11/165	7	8/164	5	25/328	8	0.87 (0.44 to 1.73)	0.64 (0.30 to 1.39)
Diarrhoea medicine	3/165	2	6/164	4	16/328	5	0.37 (0.11 to 1.26)	0.75 (0.30 to 1.88)
Asthma medicine	2/165	1	2/164	1	18/328	6	0.22 (0.05 to 0.94)	0.22 (0.05 to 0.95)
Other medication	5/165	3	8/164	5	9/328	3	1.10 (0.38 to 3.24)	1.78 (0.70 to 4.52)
Incidence of colic								
Had had colic	76/160	48	71/160	44	153/320	48	0.99 (0.81 to 1.21)	0.93 (0.75 to 1.14)
Incidence of immunisation								
Index child immunised	152/164	93	154/160	96	305/321	95	0.98 (0.93 to 1.03)	1.01 (0.97 to 1.05)

[a] Excludes children who were only given vitamins or alternative remedies.

proportion of mothers in the two intervention groups compared with those in the control group found their baby 'not easy' to look after (*Table 57*), but this difference could have been due to chance.

Mother's worries about child health

When comparisons were made between the trial arms, both intervention groups had smaller proportions of women with particular worries about their child's health than control group women. Fewer mothers in the SHV group (24%) had worries about their child's health than mothers in the control group (35%). This was unlikely to be a chance finding (*Table 57*).

Mother's views about child development

The two intervention groups were both less likely to worry that their child was developing normally, but the differences were small (*Table 57*).

TABLE 57 *Perceptions of motherhood, child health and development at first follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Mother's perception of ease of looking after index child								
Not easy	46/163	28	42/160	26	80/324	25	1.14 (0.84 to 1.56)	1.06 (0.77 to 1.47)
Mother's worries about index child's health								
Worried	39/162	24	44/164	27	112/324	35	0.70 (0.51 to 0.95)	0.78 (0.58 to 1.04)
Mother's views about index child's development								
Not normal	8/162	5	5/156	3	18/322	6	0.88 (0.39 to 1.99)	0.57 (0.22 to 1.52)

TABLE 58 *Infant feeding*

	SHV			CGS			Control			RR (95% CI) SHV/control	RR (95% CI) CGS/control
	N	*n*	%	*N*	*n*	%	*N*	*n*	%		
Breast-feeding mothers stopping by 26 weeks											
Stopped breast-feeding	77/140		55	76/140		54	134/277		48	1.14 (0.94 to 1.38)	1.12 (0.92 to 1.36)
Introduction of solid foods											
Earlier than 16 weeks	42/160		26	40/159		25	70/317		22	1.19 (0.85 to 1.66)	1.14 (0.84 to 1.60)

Infant feeding

Cessation of breast-feeding

Both intervention groups had higher proportions than the control group of women who had initiated breast-feeding and had stopped it before 26 weeks. Compared with the control group, 7% more of the SHV women and 6% more of the CGS women had given up breast-feeding by that point (*Table 58*). This difference was compatible with the play of chance.

Introduction of solid foods

The participants were asked to say how old their baby was when first given solid foods. The standard recommendation from health professionals in the UK is that solid foods are not introduced to babies until 16 weeks of age.[135] As with breast-feeding cessation, women from both intervention groups were somewhat more likely than control group women to have introduced solid foods before 16 weeks, but these may be chance differences (*Table 58*).

Household resources

Four variables were chosen to represent the social and economic resources available to the women at the time of the first follow-up questionnaire: current financial situation and material circumstances; maternal employment status; support from partner; and maternal views of the overall support received from all sources.

Current financial situation

Women were asked whether their financial situation was better than, worse than or the same as it was before the baby was born. *Table 59* compares the relative risks. Although fewer of the women in both intervention groups than in the control group were in a worse financial situation, these differences could have been due to chance.

Paid employment

Women in either full- or part-time employment were compared with those not in paid employment across the arms of the trial. Slightly fewer women in both interventions than in the control group were currently employed, but the time at which the women returned to employment was similar across the three arms of the trial (*Table 59*).

Support of partner

The proportion of women without a partner was similar in all three arms of the trial. Six questions were asked about the frequency of partners' help with child care and household tasks: looking after

TABLE 59 *Household resources at first follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Financial situation compared with before baby was born								
Worse off	67/164	41	69/160	43	151/323	46	0.87 (0.70 to 1.09)	0.92 (0.75 to 1.14)
Mother in paid employment								
Not working	107/165	65	108/162	67	209/328	64	1.02 (0.89 to 1.17)	1.05 (0.91 to 1.20)
Overall feelings of support								
Not at all/fairly well supported	70/163	43	74/163	45	163/328	50	0.86 (0.70 to 1.06)	0.91 (0.75 to 1.12)
Current partner status								
Does not have a partner	27/164	17	27/164	17	50/327	15	1.08 (0.70 to 1.65)	1.08 (0.70 to 1.65)
Level of support from partner (women with partners)								
Score 12 or less[a]: rarely or never gives support	14/132	11	15/133	11	38/267	14	0.75 (0.42 to 1.33)	0.79 (0.45 to 1.39)
Mean partner support score[a] (for women with partners)								
	N	Mean (SD)	*N*	Mean (SD)	*N*	Mean (SD)	Mean difference (95% CI) SHV/control	Mean difference (95% CI) CGS/control
	132	17.98 (4.0)	133	17.87 (3.9)	267	17.73 (4.7)	0.25 (–0.58 to 1.19)	0.15 (–0.78 to 1.02)

[a] Higher scores indicate better support from partner.

the children, bathing the baby, feeding the baby, doing household tasks, shopping for groceries and cooking for the family. There were four possible answers: regularly, sometimes, rarely or never. Combining the answers to these six questions created a composite variable of partner support. The composite score went from a minimum of 6 to a maximum of 24. The mean score for all women with a partner was 17.8, indicating that partners provided support on average 'sometimes'. Levels of partner support were broadly similar in the three trial arms. The relative risk of having a score of 12 or less on the composite variable (indicating partner giving support rarely or never) was lower for women in both intervention arms than in the control arm of the study, but this was compatible with the play of chance (*Table 59*).

Self-reported views of overall support

The women were asked to rate the overall support that they had received in the past 6 months from all sources (partner, family, friends, health professionals, etc.) as one of four categories: 'not at all supported', 'fairly well supported', 'well supported' and 'totally supported'. For the purposes of analysis the four categories have been regrouped into two categories: not at all/fairly supported and well/totally supported. The risk of having poor support was lower in both intervention arms, with a 7% difference between the SHV and control group, but these differences could have been chance findings (*Table 59*).

Summary of results from 12-month postrandomisation follow-up

There was a 90% response rate to the first follow-up questionnaire.

Primary outcomes

There was no evidence of difference between either intervention group and the control group in the three primary outcomes: maternal depression, child injury and maternal smoking. Measures used were: mean EPDS scores or an EPDS score of 12 or above, self-reported feelings of depression, child injury rates and mean numbers of injuries, and numbers of maternal smokers and mean number of cigarettes smoked.

Secondary outcomes

Patterns of health service use for both mothers and index children were different in the intervention and control groups. Women in the SHV group had fewer visits in the previous month than those in the control group to GPs at surgeries and hospital doctors, and a higher proportion of SHV compared with control group women had made use of NHS health visitor services for their own health needs, had talked to NHS health visitors on the telephone and had seen a social worker. As regards children's use of services, 11% fewer SHV than control group children had seen a GP in the previous month, and SHV children were more likely to have seen an NHS health visitor at home. These were unlikely to be chance differences.

There was some difference in maternal health, with fewer women in both intervention groups than in the control group reporting poor health. Mothers' perceptions of their children's health were similar across the three groups. There was no evidence of difference in overall use of medication by mother or child. Fewer SHV and CGS babies than babies in the control group had asthma medication, and fewer SHV than control group mothers had used skin ointment for their babies.

On the outcome of maternal–child interaction, there were no differences between the groups in mothers' perceptions of the ease or difficulty of looking after their babies. Smaller proportions of SHV and CGS than control group mothers had particular worries about their child's health; these were unlikely to be chance findings. There were some differences between the proportions of women who had stopped breast-feeding before 26 weeks or introduced solids before 16 weeks (both higher in the intervention groups), but these differences could be due to chance.

There were small differences favouring the intervention groups for household resources as measured by current financial situation and maternal perceptions of social support, but again these could have been due to chance.

Economic evaluation

As noted in Chapter 2, the economic evaluation necessarily employed limited measures of costs and outcomes from the perspectives both of service providers and of mothers in the SSFH study.

Cost of health and social service use in the previous month at 12 months

Table 60 shows costs in the previous month of health services and social worker contacts. In both intervention groups, the mean cost was lower than in the control group, but the 95% confidence intervals are wide, and are consistent with either increase or decrease in these costs. In the SHV arm of the trial, the costs of healthcare were £45 lower than in the control group, with 95% confidence limits between a net reduction of £119 and a net increase of £8 per mother. For the CGS arm, the reduction was £30 (95% CI –£108 to £33). The main reason for lower costs in the SHV group was the reduction in contacts with primary care doctors. In both trial arms there were fewer hospital inpatient days; this affects mean costs disproportionately, because inpatient days have a relatively high unit cost.

Personal costs of medications and travel for mothers in the previous month at 12 months

Table 61 shows very little difference in the estimated costs for mothers based on their reported use of over-the-counter medications, and estimates of travel to healthcare and community groups. The reduced cost of travel in the SHV group reflects the reduction in the number of primary healthcare contacts reported at this stage.

Comparison of results at first follow-up between the control group and the combined intervention groups

Additional analysis of the main outcome variables was carried out which compared the combined data at first follow-up from the two intervention groups and the control group (see Appendix 3).

Primary outcomes

For the outcome of maternal depression, fewer women in the combined intervention group than the control group reported being depressed (–2%) and fewer scored over the depression threshold on the EPDS (–3%). Similarly, there was a reduction for the intervention group when compared with the control group in the proportion of mothers who smoked (–3%) and in the number of children who had had an accident that required medical attention in the previous 6 months (–2%). For all three of these primary outcomes, the differences may have been a result of chance.

TABLE 60 *Cost of reported use of NHS and social care services in the previous month by women in the SSFH Study at 12 months (£)*

	SHV intervention			CGS intervention			Control group			Mean difference SHV – control (95% CI)	Mean difference CGS – control (95% CI)
	N	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)		
Primary and social care services at 12 months	165	79.65 (92.51)	47.58 (10.55–117.24)	164	90.02 (149.60)	47.58 (10.55–119.04)	328	97.11 (146.91)	71.69 (10.55–128.77)	–17.58 (–37.65 to 3.94)	–7.09 (–33.13 to 23.22)
Hospital at 12 months	154	21.23 (75.92)	0 (0–11.13)	142	23.38 (78.45)	0 (0–16.6)	304	49.26 (552.55)	0 (0–11.13)	–28.03 (–97.36 to 15.48)	–25.95 (–96.83 to 18.31)
Total healthcare services at 12 months	154	100.63 (134.07)	58.24 (16.60–145.71)	142	115.70 (186.32)	50.55 (16.09–133.51)	304	145.92 (601.53)	79.42 (21.10–145.76)	–45.29 (–119.04 to 8.32)	–30.22 (–108.55 to 32.64)

Bootstrap confidence intervals.
IQR: interquartile range.

TABLE 61 *Personal costs of travel and medications for mothers at 12 months (£ at 2000 prices)*

	SHV intervention			CGS intervention			Control group			Mean difference SHV – control (95% CI)	Mean difference CGS – control (95% CI)
	N	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)		
Total costs[a]	162	33.83 (23.07)	32.96 (15.46–51.72)	152	36.52 (23.74)	34.76 (19.66–56.07)	321	36.44 (24.75)	35.04 (17.81–55.07)	–2.55 (–7.28 to 2.05)	0.08 (–4.55 to 4.53)
Travel costs	164	1.60 (1.16)	1.50 (0.50–2.24)	156	2.02 (1.98)	1.66 (1.00–2.88)	326	1.97 (1.97)	1.66 (1.00–2.66)	–0.37 (–0.62 to –0.10)	0.06 (–0.32 to 0.48)
Medications	163	32.44 (22.85)	31.96 (13.96–49.72)	160	33.83 (23.42)	31.96 (14.82–52.89)	322	34.51 (24.30)	33.76 (18.00–51.76)	–2.08 (–6.25 to 2.19)	–0.68 (–5.07 to 3.82)

Total costs are based on different subgroups of the women who provided complete data, so are not precisely the sum of the travel and medication costs in the table.
[a] Total excludes fees paid to community groups, as data were not collected at 12 months.

Secondary outcomes

Maternal use of health services varied between the combined intervention group and the control group, with increased use of NHS health visitors in clinics and over the telephone for the intervention group. This mean increase of 0.06 contacts in the previous month was unlikely to be the result of chance. Index children in the combined intervention group used GP and NHS health visitor services slightly less frequently than children in the control group at first follow-up, with the exception of seeing NHS health visitors at home, which was greater for the combined intervention group (mean difference 0.06; 0.003 to 0.15).

When considering the outcome of maternal health, 7% fewer mothers in the combined intervention group than the control group rated their own health as 'not very good'. This difference was unlikely to be a chance finding. The use of medication by the mothers in the previous week was broadly comparable between the intervention and control groups. The health of the index children was assessed similarly by the mothers in the two groups, as was the reporting of medication use in the past week, except that asthma medication was used by 5% more of the control children than the intervention children; this was unlikely to be a chance finding.

Similar proportions of the mothers in the two groups did not find the experience of looking after the index child to be an easy one. Mothers in the combined intervention group were less likely to have worries about their child's development or health. The 9% reduction in numbers of intervention mothers worrying about their child's health was probably not the result of chance. Fewer intervention mothers than control mothers were still breast-feeding when their child was 26 weeks old (–6%) and more intervention mothers introduced solid foods before their baby reached 16 weeks of age (+4%). Both of these differences may be chance findings.

Similar proportions of women in the two groups were in paid work and 5% more control mothers than intervention mothers said that their financial situation was worse than it had been at the time their baby was born. Overall support given was judged to be poor ('not at all supportive' or 'fairly supportive') by 6% more control mothers than intervention mothers. Similarly, of the women with partners, more control women than intervention women said that their partner helped rarely or never (+4%). All of these variations in household resources were compatible with the play of chance.

Comparison of results at first follow-up between the SHV group and the combined control and CGS groups

Because of the low uptake within the CGS arm of the trial and the subsequent similarities between it and the control group, experimental analysis was carried out combining the CGS and control groups and comparing this with the SHV group. Appendix 4 includes tables with the results of this analysis.

Primary outcomes

There was a slightly lower incidence of depression and decreased incidence of smoking among SHV women compared with the combined control/CGS women. The children of SHV had experienced marginally more injuries than the children in the combined group. These differences were all consistent with the play of chance.

Secondary outcomes

All differences found on secondary outcomes between the SHV and combined control/CGS group were likely to be chance findings, except for a reduction in the number of visits to the GP for the SHV children (mean difference –0.21; –0.38 to –0.04), increased maternal use by SHV women of NHS health visitors (on telephone, mean difference 0.13; 0.04 to 0.21) and a reduction in the use of skin ointment in SHV children (mean difference 0.56; 0.37 to 0.85).

Subgroup analysis: first follow-up

Exploratory analysis was carried out on six study subgroups to see whether there was any indication of differential effect that might inform future research agendas. The study was not originally powered for analysis by subgroups, and as such was less likely to show statistical differences.

As the main analysis was carried out on an intention-to-treat basis, exploratory subgroup analysis was carried out in each intervention group to determine whether the outcomes were influenced by the 'dose' of the intervention received. At randomisation, three variables were used to minimise chance differences between the trial arms: tenure (as a proxy for social disadvantage), parity and lone parenthood. These three were selected because they were considered to be indicators of groups that might have the greatest need for postnatal support interventions.

As such, additional subgroup analysis was carried out with data from these three groups. Finally, because of the culturally diverse nature of the SSFH sample, a subgroup analysis of women whose first language was not English was undertaken.

Women who received medium or high SHV intervention

When comparing the women in SHV intervention who had 'medium or high' participation in the intervention (five or more visits from the SHV, $N = 121$) with control group women ($N = 328$), there was little variation in the risk of smoking, depression or child injury at first follow-up. On secondary outcomes, there were differences in both maternal and child health service usage that were unlikely to be the result of chance: increased use by mothers of NHS health visitors (+6% in clinics, +5% at home, +5% on the telephone) and social workers (+4%), increased use of NHS health visitors for the children at home (+6%), but decreased use of GPs for the index children (–12%).

Women who used CGS intervention

When comparing the 33 women who had actually used the CGS intervention (and responded at the first follow-up) with control group women ($N = 328$), no notable differences were found on any of the primary or secondary outcomes.

Socially excluded women

The aim of the study was to recruit women in socially and economically disadvantaged circumstances. Although recruitment was carried out in historically disadvantaged areas (see Chapter 2) and the sample was relatively disadvantaged compared with national norms (see Chapter 3), there were participants who could not be classified as being disadvantaged. As such, a composite 'socially excluded' variable was created from six variables, which measured financial or social deprivation. These included tenure (women living in council, housing association or temporary accommodation), benefits (women in receipt of housing benefit, income support or jobseeker's allowance), education (leaving school at 16 years or younger), residency status (asylum seekers, refugees or women granted exceptional leave to remain), relationship status (has no partner) and household social class (social classes 5, 6, 7, 8 or 9).[136] (Where social class information was available for both a woman and her partner and there were differences in their class codings, the household social class was taken to be the higher of two.) Women who scored on two or more of these characteristics were classified as 'socially excluded' for the purposes of this subgroup analysis.

When comparing the socially excluded SHV women ($N = 96$) with similar control women ($N = 177$), there were similar levels of depression and child injuries, but there were 10% fewer SHV women who smoked at first follow-up. This finding was potentially a result of chance (RR 0.73; 0.49 to 1.08). More of these SHV women than control women used social workers (+6%) and NHS health visitors (on the telephone and at home for themselves and their child, all +6%). These differences in health service use were unlikely to be chance findings. Similarly, 15% fewer socially excluded SHV mothers than similar control mothers were worried about their child's health (RR 0.58; 0.37 to 0.89) and fewer of these women were dissatisfied with the support given to them by their partner (RR 0.50; 0.24 to 1.03). There was little variation between the socially excluded women in the CGS group ($N = 91$) and in the control group on any of the primary or secondary outcomes.

First baby

When comparing first-time mothers in the SHV group ($N = 74$) with those in the control group ($N = 154$) fewer scored above the depression threshold on the EPDS at first follow-up (RR 0.84; 0.53 to 1.34) and fewer said that they had been depressed in the previous few weeks (RR 0.77; 0.51 to 1.15); both were potentially chance findings. There were also no major differences for either the SHV first-time mothers or the CGS first-time mothers ($N = 80$) on the other two primary outcomes.

On secondary outcomes at first follow-up there were differences that were unlikely to be chance findings in the usage of health services, experience of motherhood and child use of medication by first-time mothers compared with others. The SHV index children used the GP less (–8%), but their mothers had greater contact with NHS health visitors on the telephone (+6%). The SHV first-time mothers had fewer worries than similar control group mothers about their child's health (–15%). CGS index children had greater use of NHS health visitors at home (+7%). Eight per cent fewer CGS women gave their child antibiotics in the previous week. None of the first-time mothers in either of the two intervention groups had given their children asthma medicine in the previous week, a 6% reduction.

Lone parents at baseline

For women who characterised themselves as a lone parent at baseline, there was little variation across the trial arms at baseline. SHV lone mothers ($N = 47$) were considerably less likely than lone

control mothers (N = 78) to be worried about the index child's health; this 21% reduction was unlikely to be a chance finding. For CGS lone mothers (N = 41) there were no notable differences compared with similar control group mothers.

Women whose first language is not English

There were 59 SHV women, 66 CGS women and 122 control women whose first language was not English. There were no differences between the trial arms in this subgroup on any of the primary outcomes at first follow-up that could not be attributed to the play of chance, and only a few on the secondary outcomes for the SHV group. These included differences in health service use: increased maternal use of NHS health visitors at home (+10%) and via the telephone (+9%), and increased use of social workers (+7%).

Chapter 7

Main outcomes at 18 months postrandomisation (second follow-up)

Response at second follow-up

The second follow-up questionnaire was sent to women to complete approximately 18 months postrandomisation, when the index children were about 21 months old. The questionnaire was completed by 601 women out of the 731 in the trial, a response rate of 82%. Three-quarters of the questionnaires (74%) were completed by the women and returned by post, 9% were filled in at the woman's home with the assistance of an interpreter and a researcher, 8% were completed in the woman's home with a researcher; and a further 9% were filled in over the telephone with a researcher.

When compared with other women in the study, a greater proportion of CGS women completed the second follow-up questionnaire. Fewer women in the control group completed the questionnaire with the assistance of a researcher. The average age of the index child at the time of questionnaire completion was similar across the trial arms (*Table 62*).

The number of non-responders was higher than at first follow-up because a shorter time was available at this late stage of the study to locate non-responders. At second follow-up a further 12 women chose to withdraw from the study, making 30 withdrawals in all (*Table 63*).

As at the first follow-up, the women who did not respond to the second follow-up questionnaire were more likely than the women who did respond to have a first language other than English. The responders and non-responders were broadly

TABLE 63 *Reasons for non-response to second follow-up questionnaire*

	n/N	%
Unable to contact	54/130	42
Moved, address unknown	37/130	28
Withdrew from study	30/130	23
Too busy at that time	3/130	2
Abroad at that time	3/130	2
Baby died	3/130	2

TABLE 62 *Response by trial arms to second follow-up questionnaire*

	SHV			CGS			Control			Total		
	n/N		%	*n/N*		%	*n/N*		%	*n/N*		%
Response rates												
Responded	145/183		79	158/184		86	298/364		82	601/731		82
Method of completion												
Postal	101/145		70	116/158		74	228/298		77	445/601		74
Interview with researcher and interpreter	16/145		11	20/158		13	20/298		7	56/601		9
Interview with researcher	17/145		12	10/158		6	22/298		7	49/601		8
Telephone interview	11/145		8	12/158		8	28/298		9	51/601		9
Timing of second follow-up												
	N	Mean	SD	*N*	Mean	SD	*N*	Mean	SD	*N*	Mean	SD
Age of index child (months)	145	21.42	(2.3)	158	21.65	(2.1)	298	21.34	(2.0)	601	21.4	(2.1)
	Mean difference (95% CI) SHV/control: 0.08 (–0.29 to 0.55)			Mean difference (95% CI) CGS/control: 0.30 (–0.05 to 0.70)								

TABLE 64 *Characteristics of responders and non-responders to second follow-up questionnaire*

	Responders			Non-responders		
	N	**Mean**	**SD**	***N***	**Mean**	**SD**
Age (years, at baseline)	601	30.0	5.8	130	28.8	6.0
Parity (at baseline)	601	1.9	1.1	130	2.1	1.2
	n/N		**%**	***n/N***		**%**
First language: not English	220/601		37	62/130		48

similar in terms of their age and parity levels at baseline (*Table 64*).

The next section of this chapter gives some of the data from the second follow-up for the SSFH Study women as a whole. As with Chapter 6 reporting the first follow-up, this provides a general context for the discussion, which follows outcomes in the three trial arms separately.

The context: life as a mother of a 21-month-old child

Maternal well-being

At second follow-up, just over half of the women described their lives as 'difficult'; this was a similar figure as at the first follow-up. Some women's lives were becoming easier as they settled into motherhood and their babies needed less attention:

> "I found it a struggle to adjust to a different lifestyle when I had R but then it was a doddle. I suppose my natural instinct just kicked in, but then I have had a lot of support …."

> "At 18 months B changed a bit and I began to get my life back. I feel a lot more in control of my own life now and that she is not as demanding as when she was a baby. I'm really enjoying her."

Overall, the proportion of women reporting high stress levels had risen to 39%, with 43% saying they had not enough or no control over their life. Just over one-quarter of the women reported that they had been depressed in the previous month (*Table 65*). The difficulties experienced when the baby was younger, such as exhaustion, ill health and loss of freedom, were still contributing to feelings of depression. Demands changed rather than eased as their babies grew from infants to toddlers, with competing priorities very much in evidence:

TABLE 65 *Maternal well-being at second follow-up*

	n/N	**%**
Last year rather/very difficult	314/597	53
Very high/quite high current level of stress	236/600	39
Not as much control as desired/no control over life	257/599	43
Self-reported depression in previous month	154/597	26
GHQ12 – score 12 or above	292/549	53
Pregnant since index child born	171/598	29
Physical health 'good'	410/598	69
Used health service	326/601	54

> "I feel I am never going to catch up with myself, nothing gets done properly. I rush everywhere – to work, home, collecting from school, homework – then when I get them all down by 9 o'clock, the house is a total mess, dishes to be washed and I just want to crawl into bed, and do sometimes."

Eleven per cent of women said that they had experienced physical violence in the previous year, and 28% had experienced verbal abuse. Half of the violent incidents described by women involved aggression from strangers or neighbours in the streets, on housing estates or while travelling; 10% of these appeared racially motivated. Over one-third of the women recounting violence had experienced physical or emotional abuse from a partner or an ex-partner. (These questions were not asked in the first follow-up.)

Eleven per cent of women had already had another baby, and the same proportion was pregnant at the time of the second follow-up. Four per cent of women had miscarried or had a stillbirth and a further 12% had had a termination since the study child was born. Many of these women were finding life particularly stressful:

> "Finding pregnancy, looking after my toddler and working very demanding."

TABLE 66 *Index child health and development at second follow-up*

	n/N	%
Generally healthy	562/598	94
Given medication in past week	376/601	63
Used health service in past month	302/601	50
Had injury in past 6 months	53/596	9
Easy to look after	421/587	72
Maternal worries about development	286/591	48
Maternal worries about eating habits	123/591	21

"During my second pregnancy I had [many health] problems. My husband and his parents really gave me a tough time. Those were the worst days of my life."

"I had [premature] twins when O was ten months … in hospital three and a half months. A strain on me and my partner. It has affected O very much and their arrival at home may be affecting his eating habits."

"… sad at losing my baby …."

"I have not had the chance to talk about [my termination]. It's had an effect on me, maybe that's the reason I've been so low recently. Being pregnant with my two very young children scared me terribly. I could not have coped with another baby."

Nearly one-third (31%) of the mothers rated their physical health in the previous month as 'not very good'. Headaches and back pain were the conditions experienced by the greatest proportions of women. Just over half of the women had used at least one health service for their own health needs in the previous month. Of the 154 women who said they had felt depressed, 42 (27%) reported that they had been receiving professional help for their depression in the past few weeks. One-quarter of the women reported that they smoked, on average ten cigarettes a day. Of those women who had a partner, 32% said that their partner smoked.

Index child's health

Ninety-four per cent of mothers said that their child was healthy at second follow-up (*Table 66*). Nearly two-thirds of the index children had been given medication in the previous week. Half of the index children had used at least one health service in the previous month. Nearly 9% of mothers reported that the index child had had an injury in the previous 6 months that required help from a health professional, most often for injuries to the head, general falls and burns. This was a reduction from the 14% who reported injuries at first follow-up.

Experiences of motherhood

At the time of the second follow-up questionnaire, when the index children were on average 21 months old, 72% of mothers found this child easy to look after (*Table 66*):

"She's beginning to want things the way she wants them … but generally she's very happy and loving."

"He's a full on, in your face baby, curious about his world … a full time baby who is a joy to be around but somewhat exhausting."

"Any toddler can be very active, inquisitive and difficult. She is a normal child with good and bad days."

Just over half of the mothers (52%) had no worries about their child's development. Developmental aspects that worried the greatest proportion of mothers were their child's eating habits (21%), speech development (13%) and sleeping habits (13%):

"Eats very little, drinks goat's milk and eats the odd grape or bit of apple, often won't eat breakfast, lunch or dinner. Doesn't seem interested in food."

"Takes two hours to eat a meal. Not eating solid food, have to blend it all."

"Very wakeful at night … wakes three or four times. Wakefulness is due, I think, [to him spending] three days a week at his grandparents, there he shares a double bed with his grandmother."

"He just points, doesn't want to speak at all, except mama, papa."

Household resources

The same proportion of women (35%) was in paid work at second follow-up as at first follow-up. Of these, 57% were in professional or managerial occupations, 21% in intermediate ones and 21% in routine or semi-routine occupations. Some women said that they were unable to work because of a lack of affordable child care. Overall, one-quarter of the women (26%) were financially worse off than they had been a year before. Forty-two per cent had a weekly household income of £200 or less, compared with 55% at baseline. Again, some women were employed through financial necessity when they would rather be at home caring for their children or enrolling in training or further education (*Table 67*). One-quarter of women, however, were currently studying, which was more than double the number at first follow-up:

TABLE 67 *Household resources at second follow-up*

	n/N	%
Women in paid work – full time	79/592	13
– part time	131/592	22
Currently studying	153/595	26
Weekly household income £150 or less	166/566	29
Financial situation worse than 1 year previous	155/594	26

TABLE 68 *Social support at second follow-up*

	n/N	%
Living with partner	427/601	71
No longer with father of index child	128/579	22
Partner 'rarely/never' looks after children	69/465	15
Partner 'rarely/never' helps with household tasks	176/464	38
Happy with relationship with partner	327/472	69
Receives not very much/no help from family	183/584	31
Has no close friends	50/598	8
Used community services for mothers and children aged under 5 years in previous month	227/601	38
Overall feelings of support: not at all supported	42/599	7

> "My life is good right now, better … because my husband has a job, steady work, and we can plan for the future …. L may get a nursery place soon. If she does I can go to work part time again. I really liked [my last] job, but it was long hours and L stopped eating and cried all the time. I realise that I won't be able to leave her to work until she's at nursery and having fun, then she won't miss me."

> "Returned to full time employment – job is demanding but not rewarding. Worry over the impact on daughter, quality of her childcare, keeping on top of everything – housework, laundry, bills."

> "I've been looking for work and been told by the job centre that I will be less better off. Yet I'm finding it hard to manage on income support and in constant debt, never enough money for food and clothes and basic needs. I am mentally and physically too tired to do any course and don't have the finances for it."

> "I'm overtired from working full time. Also worried about money as I'm having to pay £400–£460 for nursery, plus £205 on student loans, so money is very tight."

Overall, 40% of women were receiving housing benefit. Sixty four per cent of women were in rented housing, 3% in temporary accommodation and 3% living with relatives. The average household size was four, which was unchanged since baseline.

At second follow-up 45% of the women (265) said that they had been born outside the UK. Eleven per cent of the women (61) were at that time either asylum seekers or refugees, or had been granted exceptional leave to remain in the UK.

Support from partner, family and friends

The overall amount of support women reported at the first and second follow-up was similar. The same proportion of women (53%) felt well or totally supported, 39% felt fairly well supported and 7% felt not supported at all (*Table 68*). There were, however, changes in sources of support, with more women gaining most support from partners, and fewer gaining most support from family or friends. One interpretation of these changes is that friends and family rally round to help new mothers, but by the time the babies are 20 months old this wider support is beginning to fall away.

Nearly one in ten women said they had no close friends. By this stage 71% of the women had a live-in partner, 11% had a partner who lived elsewhere and 18% did not have a partner. Twenty-seven per cent of the women considered themselves to be lone parents and 22% were no longer together with the father of the index child. Of the women with a partner, more than two-thirds (69%) were happy with the relationship (an increase of 4% over first follow-up); 5% were unhappy. The number of lone parents feeling not at all supported had risen to 15%, whereas for women living with partners it was unchanged.

Around two-fifths of the women in the study sample as a whole (38%) had used local community services for mothers and children under 5 years old in the previous month.

Trial results: second follow-up

This section of the chapter examines the evidence of the effectiveness of each intervention separately for the primary and secondary trial outcomes at second follow-up. This is followed by sections on the economic evaluation, an analysis of the two intervention groups combined, a discussion of possible differential effectiveness among particular subgroups of study women, and a discussion of process findings.

TABLE 69 *Maternal depression at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/*N*	%	*n*/*N*	%	*n*/*N*	%		
Maternal assessment of mood in previous month								
Depressed	34/144	24	46/157	29	74/296	25	0.94 (0.66 to 1.35)	1.17 (0.86 to 1.60)
GHQ12 score								
Above depression threshold: ≥ 12	70/136	52	77/143	54	145/270	54	0.96 (0.79 to 1.17)	1.00 (0.83 to 1.21)
Mean GHQ12 score								
	N	**Mean (SD)**	***N***	**Mean (SD)**	***N***	**Mean (SD)**	**Mean difference (95% CI) SHV/control**	**Mean difference (95% CI) CGS/control**
GHQ12[a]	136	12.6 (6.08)	143	13.0 (6.54)	270	12.6 (5.65)	–0.06 (–1.36 to 1.06)	0.38 (–0.87 to 1.61)

[a] Fifty-two women did not complete the GHQ12. A further 23 missed items on the scale: 20 missed one item, two missed two items, and one missed four items. For this last group of 23, an average was taken of the scores of the completed items and this was added (proportionally) to their score to account for the missing item(s).

The three primary outcomes

Maternal depression

Two variables were used in the second follow-up questionnaire to measure maternal well-being: women's self-reported depression and the GHQ12.

Self-reported feelings of depression

Women were asked, among a list of other health problems, whether they had had depression in the past month. Although the risk of reporting depression was slightly greater among the CGS women than the control group women, this 4% difference was likely to be a chance finding. The proportions reporting depression in the SHV and control groups were similar (*Table 69*).

GHQ12 scores

When comparing the mean total scores from the 12 items on the GHQ12 scale, there was little difference between the SHV and control groups. As with self-reported depression, the CGS group had a higher mean score than the control group, but this was compatible with the play of chance (*Table 69*).

Although 2% fewer SHV women than control women had a score above the depression threshold (≥ 12) on the GHQ12, the difference could have been the result of chance (*Table 69*).

Child injury

There was little difference across the three trial arms in the risk of the index child having an injury requiring medical attention in the 6 months previous to the second follow-up questionnaire (*Table 70*).

Just fewer than one in five of the mothers reported that their child had had an injury requiring attention from a health professional in either of the two follow-up periods. When combining the results from the two 6-month periods, similar proportions in each of the trial arms had reported at least one injury (*Table 71*).

Maternal smoking

The percentage of women who reported smoking at the second follow-up was very similar between the two intervention groups and the control group (*Table 72*). Although the SHV group reported a slight reduction, compared with the control group, in the proportion smoking ten or more cigarettes per day, this was consistent with a chance variation (*Table 72*).

The six secondary trial outcomes

Health service use

Maternal health service use in the past month

When comparing the proportions of women who had used at least one health service with those

TABLE 70 *Injuries requiring help from a health professional at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Injury in past 6 months								
Injury needing help	12/145	8	14/156	9	27/295	9	0.90 (0.47 to 1.73)	0.98 (0.53 to 1.81)
Mean no. of injuries								
	N	Mean (SD)	*N*	Mean (SD)	*N*	Mean (SD)	Mean difference (95% CI) SHV/control	Mean difference (95% CI) CGS/control
Injuries	145	0.08 (0.27)	156	0.10 (0.36)	295	0.10 (0.32)	–0.02 (–0.08 to 0.03)	0.004 (–0.06 to 0.08)

TABLE 71 *Injuries requiring help from a health professional at either first or second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Injury reported at either first or second follow-up								
Injury needing help	32/165	19	29/163	18	64/328	20	0.99 (0.68 to 1.45)	0.91 (0.61 to 1.36)

TABLE 72 *Maternal smoking at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Woman smokes								
Smoker	35/145	24	41/157	26	73/296	25	0.98 (0.69 to 1.39)	1.06 (0.76 to 1.47)
No. of cigarettes smoked per day								
10 or more	18/144	13	22/157	14	42/296	14	0.88 (0.52 to 1.47)	0.98 (0.61 to 1.59)

who had used none in the previous month, there was an 8% increase in usage among CGS women (*Table 73*).

When looking at use of specific services by SHV women compared with control women at the second follow-up, there was increased use of health visiting services (+1%), social work services (+1%) and GP visits at home (+2%). For all of these, the confidence intervals were wide. There was an 8% reduction in use of midwifery services in the previous month by SHV women, and in this case the reduced risk is unlikely to be a chance finding (*Table 73*).

For CGS women, compared with the control group, there was increased use of GPs (+8%), doctors in hospital (+4%) and at home (+1%), social workers (+1%) and telephone contacts with NHS health visitors (+2%). There was a small decrease in use of health visitors at clinic (–1%) or at home (–1%). These differences were compatible with the play of chance. As with the SHV women, CGS women were less likely than control group women to have used midwifery services in the previous month (–7%), and this was unlikely to be a chance finding (*Table 73*). (See below, *Table 77* on pregnancy status.)

TABLE 73 *Maternal use of health services in previous month at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Use of any health service	77/145	53	94/158	60	155/298	52	1.02 (0.85 to 1.23)	1.14 (0.97 to 1.35)
GP at clinic/surgery	64/145	44	84/158	53	135/298	45	0.97 (0.78 to 1.22)	1.17 (0.97 to 1.42)
Doctor in hospital	19/145	13	29/158	18	43/298	14	0.91 (0.55 to 1.50)	1.27 (0.83 to 1.95)
Doctor at home	4/145	3	3/158	2	2/298	1	4.11 (0.76 to 22.18)	2.83 (0.48 to 16.76)
NHS health visitor at clinic/surgery	4/145	3	2/158	1	5/298	2	1.64 (0.45 to 6.03)	0.75 (0.15 to 3.84)
NHS health visitor at home	6/145	4	3/158	2	8/298	3	1.54 (0.54 to 4.33)	0.79 (0.21 to 2.92)
NHS health visitor on telephone	3/145	2	5/158	3	3/298	1	2.06 (0.42 to 10.06)	3.14 (0.76 to 12.98)
Midwife	6/145	4	8/158	5	35/298	12	0.35 (0.15 to 0.82)	0.43 (0.20 to 0.91)
Social worker	4/145	3	5/158	3	5/298	2	1.64 (0.45 to 6.03)	1.89 (0.55 to 6.42)
Other health worker	10/145	7	10/158	6	16/298	5	1.28 (0.59 to 2.74)	1.19 (0.55 to 2.55)
Mean no. of episodes								
	N	Mean (SD)	*N*	Mean (SD)	*N*	Mean (SD)	Mean difference (95% CI) SHV/control	Mean difference (95% CI) CGS/control
GP at clinic/surgery	145	0.72 (1.01)	158	0.84 (1.25)	298	0.73 (0.99)	–0.01 (–0.23 to 0.18)	0.11 (–0.08 to 0.36)
Doctor in hospital	145	0.20 (0.63)	158	0.35 (1.17)	298	0.21 (0.76)	–0.01 (–0.15 to 0.12)	0.14 (–0.04 to 0.36)
Doctor at home	145	0.03 (0.16)	158	0.02 (0.14)	298	0.01 (0.18)	0.01 (–0.02 to 0.05)	0.01 (–0.03 to 0.03)
NHS health visitor at clinic/surgery	145	0.03 (0.16)	158	0.01 (0.11)	298	0.02 (0.13)	0.01 (–0.02 to 0.04)	–0.004 (–0.02 to 0.02)
NHS health visitor at home	145	0.07 (0.40)	158	0.02 (0.14)	298	0.04 (0.28)	0.03 (–0.03 to 0.12)	–0.02 (–0.06 to 0.01)
NHS health visitor on telephone	145	0.04 (0.35)	158	0.04 (0.26)	298	0.02 (0.25)	0.02 (–0.03 to 0.10)	0.02 (–0.02 to 0.08)
Midwife	145	0.13 (0.82)	158	0.20 (1.44)	298	0.21 (0.73)	–0.08 (–0.21 to 0.11)	–0.01 (–0.20 to 0.29)
Social worker	145	0.06 (0.41)	158	0.07 (0.52)	298	0.02 (0.16)	0.04 (–0.01 to 0.14)	0.05 (–0.01 to 0.16)
Other health worker	145	0.08 (0.29)	158	0.11 (0.54)	298	0.10 (0.61)	–0.03 (–0.12 to 0.05)	0.01 (–0.10 to 0.12)

TABLE 74 *Index child's use of health services in previous month at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Used health services								
Used any health service	70/145	48	86/158	54	146/298	49	0.99 (0.80 to 1.21)	1.11 (0.92 to 1.34)
GP at clinic/surgery	53/145	37	71/158	45	114/298	38	0.96 (0.74 to 1.24)	1.17 (0.94 to 1.47)
Doctor in hospital	13/145	9	20/158	13	33/298	11	0.81 (0.44 to 1.49)	1.14 (0.68 to 1.92)
Doctor at home	2/145	1	6/158	4	2/298	1	2.06 (0.29 to 14.44)	5.66 (1.16 to 27.71)
NHS health visitor at clinic/surgery	23/145	16	18/158	11	34/298	11	1.39 (0.85 to 2.27)	1.00 (0.58 to 1.71)
NHS health visitor at home	4/145	3	4/158	3	12/298	4	0.69 (0.22 to 2.09)	0.63 (0.21, 1.92)
Other health worker	6/145	4	2/158	1	7/298	2	1.76 (0.60 to 5.15)	0.54 (0.11 to 2.56)
Mean no. of episodes								
	N	Mean (SD)	*N*	Mean (SD)	*N*	Mean (SD)	Mean difference (95% CI) SHV/control	Mean difference (95% CI) CGS/control
Visits to GP at clinic/surgery	145	0.57 (0.88)	158	0.72 (1.20)	298	0.54 (0.82)	0.03 (–0.14 to 0.20)	0.18 (–0.001 to 0.46)
Doctor in hospital	145	0.11 (0.36)	158	0.18 (0.57)	298	0.14 (0.45)	–0.03 (–0.11 to 0.04)	0.03 (–0.06 to 0.15)
Doctor at home	145	0.01 (0.12)	158	0.05 (0.27)	298	0.01 (0.08)	0.01 (–0.01 to 0.03)	0.04 (0.01 to 0.09)
NHS health visitor at clinic/surgery	145	0.19 (0.48)	158	0.16 (0.70)	298	0.15 (0.51)	0.04 (–0.05 to 0.14)	0.01 (–0.09 to 0.16)
NHS health visitor at home	145	0.03 (0.22)	158	0.03 (0.16)	298	0.04 (0.20)	–0.01 (–0.04 to 0.04)	–0.01 (–0.05 to 0.02)
Other health professional	145	0.06 (0.34)	158	0.03 (0.33)	298	0.03 (0.21)	0.03 (–0.19 to 0.10)	0.001 (–0.04 to 0.08)

Index child's health service use

There was a 5% increase in use of at least one health service in the past month by CGS index children compared with the control group, but this risk was consistent with the play of chance. The SHV group and control group were very similar (*Table 74*).

Although differences in health service usage found at first follow-up were maintained when comparing use of services by SHV children and control children (decreased use of GP –1%, doctor in hospital –2%, and NHS health visitor at home –1%; increased use of NHS health visitor at clinic +5%), the differences were smaller at this stage, and could have been chance findings (*Table 74*).

CGS children were more likely than control group children to have seen a doctor at the surgery (+7%), in hospital (+2%) or at home (+3%) in the previous month. The increased use of GPs at home was a finding that was unlikely to be a result of chance (*Table 74*).

When comparing the use of *hospital services in past 6 months* by index children, there was little difference in the use of either inpatient or outpatient services between either of the two intervention groups and the control group. Three

TABLE 75 *Index child's use of hospital services in the previous 6 months at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Used hospital services								
Outpatient visits	24/144	17	26/157	17	52/296	18	0.95 (0.61 to 1.47)	0.94 (0.61 to 1.45)
A&E visits	28/144	19	35/157	22	56/296	19	1.03 (0.68 to 1.54)	1.17 (0.80 to 1.70)
Overnight stays	7/144	5	6/157	4	13/296	4	1.11 (0.45 to 2.70)	0.87 (0.34 to 2.25)
Mean no. of episodes								
	N	Mean (SD)	*N*	Mean (SD)	*N*	Mean (SD)	Mean difference (95% CI) SHV/control	Mean difference (95% CI) CGS/control
Outpatient visits	144	0.35 (1.01)	157	0.24 (0.63)	296	0.27 (0.72)	0.07 (–0.10 to 0.28)	–0.03 (–0.16 to 0.10)
A&E visits	144	0.22 (0.48)	158	0.29 (0.61)	296	0.23 (0.53)	–0.01 (–0.11 to 0.10)	0.06 (–0.05 to 0.18)
Inpatient episodes	143	0.06 (0.31)	157	0.05 (0.24)	296	0.04 (0.21)	0.01 (–0.04 to 0.06)	0.001 (–0.04 to 0.04)
No. of inpatient days	144	0.21 (1.35)	158	0.17 (1.04)	294	0.07 (0.42)	0.14 (–0.01 to 0.44)	0.10 (–0.03 to 0.32)

per cent more of the CGS than the control group children had attended A&E, but this difference was compatible with the play of chance (*Table 75*).

Maternal health

Rating of own health

Both SHV and CGS women were slightly less likely than control group women to rate their health as 'not very good' in the previous month. The differences were slight, and could be chance findings (*Table 76*).

Physical health problems

The women were asked whether they had had any of seven specific health problems in the past month (back pain, high blood pressure, anaemia, asthma, eczema, headaches and 'problems from giving birth – e.g. piles, incontinence, painful scar'). There were differences between SHV and control women in the problems experienced: 9% fewer SHV women experienced headaches, 6% fewer reported backache and 4% more said that they had been anaemic. All of these were potentially chance differences. There were similarities between the CGS group and the control group, but 8% more CGS women continued to experience problems as a result of giving birth, a finding that was unlikely to be a result of chance.

A composite variable was created that counts the number of physical health problems which a woman indicated that she had experienced in the previous month. Five per cent fewer of the SHV women than the control women had experienced three or more health problems. Conversely, 4% more CGS women than control women had experienced three or more problems. Both of these differences were compatible with the play of chance (*Table 76*).

Women's use of medication in the previous week

When comparing whether women had taken any medication in the previous week, little difference was found between the control group and either of the two intervention groups (*Table 77*).

Pregnancy status since birth of index child

Table 78 shows that proportionately fewer SHV than control group women were pregnant at the time the second follow-up questionnaires were completed or had been pregnant since the birth of the index child. CGS women were also less likely to have had a subsequent pregnancy.

TABLE 76 *Maternal health at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Physical health in previous month								
Not very good health	43/145	30	49/157	31	96/296	32	0.91 (0.68 to 1.23)	0.96 (0.72 to 1.28)
Health problems in previous month								
3 or more health problems	33/145	23	50/155	32	81/293	28	0.82 (0.58 to 1.17)	1.17 (0.87 to 1.57)
Back pain	66/145	46	84/155	54	151/293	52	0.88 (0.72 to 1.09)	1.05 (0.88 to 1. 26)
High blood pressure	6/145	4	8/155	5	11/293	4	1.10 (0.42 to 2.92)	1.37 (0.56 to 3.35)
Anaemia	21/145	15	21/155	14	32/293	11	1.33 (0.79 to 2.22)	1.24 (0.74 to 2.08)
Asthma	7/145	5	12/155	7	23/293	8	0.61 (0.27 to 1.40)	0.99 (0.50 to 1.93)
Eczema	15/145	10	13/155	8	35/293	12	0.87 (0.49 to 1.53)	0.70 (0.38 to 1.29)
Headache/migraine	62/145	43	78/155	50	152/293	52	0.82 (0.66 to 1.03)	0.97 (0.80 to 1.17)
Problems resulting from giving birth	17/145	12	32/155	21	39/293	13	0.88 (0.52 to 1.50)	1.55 (1.01 to 2.37)

TABLE 77 *Maternal use of medication at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Taken medication in previous week								
Any form of medication[a]	82/145	57	91/158	58	166/298	56	1.02 (0.85 to 1.21)	1.03 (0.87 to 1.22)
Painkillers	70/145	48	78/158	49	141/298	47	1.02 (0.83 to 1.25)	1.04 (0.86 to 1.27)
Vitamins	42/145	29	51/158	32	78/298	26	1.11 (0.80 to 1.52)	1.23 (0.92 to 1.66)
Decongestants	16/145	11	27/158	17	37/298	12	0.89 (0.51 to 1.54)	1.38 (0.87 to 2.17)
Alternative remedies	13/145	9	15/158	10	30/298	10	0.89 (0.48 to 1.66)	0.94 (0.52 to 1.70)
Antibiotics	11/145	8	11/158	7	16/298	5	1.41 (0.67 to 2.97)	1.30 (0.62 to 2.73)
Antidepressants	5/145	3	3/158	2	17/298	6	0.60 (0.23 to 1.61)	0.33 (0.10 to 1.12)
Sleeping pills	1/145	1	3/158	2	4/298	1	0.51 (0.06 to 4.56)	1.41 (0.32 to 6.24)
Tranquillisers	0/145	0	1/158	1	1/298	0		1.89 (0.12 to 29.95)
Other medication	18/145	12	17/158	11	22/298	7	1.68 (0.93 to 3.03)	1.46 (0.80 to 2.66)

[a] Excludes women who took only vitamins or alternative remedies.

TABLE 78 *Pregnancy status since birth of index child*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Pregnant at second follow-up	10/145	7	17/158	11	40/295	14	0.51 (0.26 to 0.99)	0.79 (0.47 to 1.35)
Has been pregnant since birth of index child (including currently pregnant)	36/145	25	43/158	27	92/295	31	0.80 (0.57 to 1.11)	0.87 (0.64 to 1.19)

TABLE 79 *Index child's health and use of medication at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Physical health in previous month								
Not very healthy	9/144	6	9/157	6	18/297	6	1.03 (0.48 to 2.24)	0.95 (0.44 to 2.06)
Taken medication in previous week								
Any form of medication[a]	89/145	61	101/158	64	186/298	62	0.98 (0.84 to 1.15)	1.02 (0.88 to 1.19)
Painkillers	68/145	47	68/158	43	113/298	38	1.24 (0.99 to 1.55)	1.13 (0.90 to 1.43)
Skin ointment	22/145	15	44/158	28	78/298	26	0.58 (0.38 to 0.89)	1.06 (0.78 to 1.46)
Vitamins	33/145	23	42/158	27	58/298	20	1.17 (0.80 to 1.71)	1.37 (0.97 to 1.93)
Cough medicine	29/145	20	27/158	17	60/298	20	0.99 (0.67 to 1.48)	0.85 (0.56 to 1.28)
Decongestants	13/145	9	22/158	14	36/298	12	0.74 (0.41 to 1.36)	1.15 (0.70 to 1.89)
Antibiotics	13/145	9	13/158	8	25/298	8	1.07 (0.56 to 2.03)	0.98 (0.52, 1.86)
Alternative remedies	9/145	6	8/158	5	19/298	6	0.97 (0.45 to 2.10)	0.79 (0.36 to 4.39)
Diarrhoea medicine	2/145	1	4/158	3	6/298	2	0.69 (0.14 to 3.35)	1.26 (0.36 to 4.39)
Asthma medicine	2/145	1	4/158	3	10/298	3	0.41 (0.09 to 1.85)	0.75 (0.24 to 2.37)
Other medication	6/145	4	2/158	1	9/298	3	1.37 (0.50 to 3.78)	0.42 (0.09 to 1.92)

[a] Does not include children who were only given vitamins or alternative remedies.

Index child's health

Mother's assessment of child's health

Mothers were asked whether they thought the index child was generally 'healthy' or 'not very healthy'. Similar proportions of women in the control group and both of the intervention groups categorised their child as being 'not very healthy' (*Table 79*).

Child's use of medication in previous week

There were small variations between the two intervention groups and the control group on the use of medication in the previous week. All of these were likely to be chance findings, except for the 11% decrease in use of skin ointment on SHV children compared with control children (*Table 79*).

TABLE 80 *Experience of motherhood and child development at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Mother's perception of ease of looking after index child								
Not easy	39/144	27	43/153	28	84/290	29	0.94 (0.68 to 1.30)	0.96 (0.71 to 1.32)
Mother's particular worries about index child's development								
Speech	9/142	6	26/156	17	40/293	14	0.46 (0.23 to 0.93)	1.22 (0.78 to 1.92)
Eating habits	21/142	15	45/156	29	57/293	20	0.76 (0.48 to 1.20)	1.48 (1.06 to 2.08)
Sleeping	16/142	11	23/156	15	36/293	12	0.92 (0.53 to 1.60)	1.20 (0.74 to 1.95)
Toilet training	13/142	9	14/156	9	32/293	11	0.84 (0.45 to 1.55)	0.82 (0.45 to 1.49)
Behaviour	10/142	7	14/156	9	28/293	10	0.74 (0.37 to 1.47)	0.94 (0.51 to 1.73)
Hearing	2/142	1	3/156	2	7/293	2	0.59 (0.12 to 2.80)	0.80 (0.21 to 3.07)
Weight	13/142	9	16/156	10	28/293	10	0.96 (0.51 to 1.79)	1.07 (0.60 to 1.92)
Height	2/142	1	6/156	4	6/293	2	0.69 (0.14 to 3.37)	1.88 (0.62 to 5.73)
General development	0/142	0	2/156	1	5/293	2		0.75 (0.15 to 3.83)
Something else	7/142	5	9/156	6	19/293	7	0.76 (0.33 to 1.77)	0.89 (0.41 to 1.92)

Mean no. of worries about index child's development

N	Mean (SD)	*N*	Mean (SD)	*N*	Mean (SD)	Mean difference (95% CI) SHV/control	Mean difference (95% CI) CGS/control
142	0.65 (0.88)	156	1.01 (1.21)	293	0.88 (1.17)	–0.23 (–0.42 to –0.01)	0.13 (–0.10 to 0.36)

Experiences of motherhood

Looking after the index child

Slightly fewer women in the two intervention groups than the control group said that they did not find the index child 'easy' to look after. The differences were small and compatible with the play of chance (*Table 80*).

Mother's views about index child's development

Women were asked whether they were worried about any of nine aspects of their child's development: speech, hearing, eating habits, sleeping habits, toilet training, height, weight, behaviour and general development. When comparing the SHV group with the control group, fewer SHV women were worried about each of the nine aspects of the child's development. For example, the percentage worrying about the child's speech development was reduced by 8% for SHV women compared with control women, a difference that did not appear to be as a result of chance (*Table 80*). In addition to the lower proportion of SHV mothers being worried about individual aspects of development, the mean number of worries a SHV mother had about her child's development was reduced compared with the control women (*Table 80*).

A greater proportion of CGS women than control women had concerns about five aspects of child

TABLE 81 *Financial resources at second follow-up*

	SHV		CGS		Control		RR (95% CI)	RR (95% CI)
	n/N	%	*n/N*	%	*n/N*	%	SHV/control	CGS/control
Financial situation compared with a year before								
Worse off	44/144	31	40/157	26	71/293	24	1.26 (0.23 to 1.73)	1.05 (0.54 to 1.47)
Paid employment status								
Mother not in paid work	90/143	64	99/156	64	191/293	65	0.99 (0.85 to 1.14)	0.97 (0.84 to 1.13)
Partner not in paid work	29/115	25	25/126	20	50/224	22	1.13 (0.76 to 1.68)	0.89 (0.58 to 1.36)
Weekly household income (including all benefits)								
£0–150 per week	36/133	27	43/154	28	87/279	31	0.87 (0.62 to 1.21)	0.90 (0.66 to 1.22)

development: speech, eating habits, sleeping habits, height and weight. The proportion of women who were worried about their child's eating habits was 9% greater for the CGS women than for control group women. This was unlikely to be a chance finding. The average number of worries per CGS woman was also higher than that for control group women (*Table 80*).

Household resources

Current financial situation

The women were asked whether their financial situation was better than, worse than or the same as it was a year before. Women in the SHV group had a greater risk of being 'worse off' than the control group women did: 7% more SHV women said they were now in a worse financial position. Conversely, the SHV group also had a greater proportion who were now 'better off' than in the control group. These differences were consistent with the play of chance. The degree of change in financial situation was similar for control group and CGS women (*Table 81*).

Paid employment

The groups were similar with respect to the risk of the women not being in paid employment (*Table 81*). For women with partners, a greater proportion of partners of SHV women than control women were not in paid employment. This finding was compatible with the play of chance.

Household income

The risk of being on a weekly household income of less than £150 per week was reduced for women in both intervention groups compared with the control group women, but this reduction of risk was likely to be a chance finding (*Table 81*).

Support of partner

The proportion of women without a partner at the time of the second follow-up questionnaire was lower for women in the SHV group than in the control group, but this 3% difference could have been a chance finding. For women with partners, composite scores of support given by partners over six aspects of support (looking after the children, bathing them, feeding them, shopping for food, doing household tasks and cooking for the family) were compiled. The risk was increased for women in both intervention groups compared with control group women of having a partner who on average helped 'rarely' or' never' (a composite score of 12 or less), but the difference in each case was likely to be a chance finding (*Table 82*).

DUFSS

In the DUFSS, the higher the mean score, the less satisfactory the social support received by the woman. Control group and CGS women had similar mean scores just above 18.50, whereas SHV women had a mean of 18. Although SHV women were more likely to have received satisfactory support than the control group, the difference was compatible with the play of chance (*Table 82*).

Self-reported views of overall support

Both of the intervention groups had greater proportions than the control group of women who felt 'not at all' or only 'fairly well' supported over the previous 6 months. The differences were small, however, and potentially chance findings (*Table 82*).

Summary of results from 18-month postrandomisation follow-up

Second follow-up questionnaires were received from 601 of the participants (82% response rate).

TABLE 82 *Social resources at second follow-up*

	SHV		CGS		Control		RR (95% CI) SHV/control	RR (95% CI) CGS/control
	n/N	%	*n/N*	%	*n/N*	%		
Current partner status								
Does not have partner	23/145	16	28/158	18	57/298	19	0.83 (0.53 to 1.29)	0.93 (0.62 to 1.39)
Level of support from partner (women with partners, *N* = 495)								
Score 12 or less[a]: partner rarely or never gives support	20/118	17	21/121	17	30/224	13	1.27 (0.75 to 2.13)	1.30 (0.78 to 2.16)
Overall feelings of support								
Not at all/fairly well supported	66/144	46	75/157	48	135/298	45	1.01 (0.81 to 1.26)	1.05 (0.86 to 1.30)
DUFSS score								
Score 19 or above: Less satisfactory social support	54/132	41	68/145	47	122/273	45	0.92 (0.72 to 1.17)	1.05 (0.84 to 1.30)
Mean DUFSS score								
	N	Mean (SD)	*N*	Mean (SD)	*N*	Mean (SD)	Mean difference (95% CI) SHV/control	Mean difference (95% CI) CGS/control
DUFSS score	132	18.00 (7.27)	145	18.51 (7.46)	273	18.55 (7.81)	–0.55 (–1.98 to 1.04)	–0.04 (–1.59 to 1.38)

[a] Thirty-two women with partners did not answer these questions about partner support.

Primary outcomes

For the primary outcomes of maternal depression, childhood injury and maternal smoking there were no differences between the SHV women and the control group. There were also no differences between the CGS group or the control group on any of the three primary outcome measures.

Secondary outcomes

For the secondary outcomes, both maternal and child health service usage were similar between control and SHV women. SHV women were less likely to have used midwifery services in the previous month. The trend was for better maternal health (self-reported health and number of health problems in previous month) among the SHV women, but the differences could have been due to chance. There were similarities in the descriptions that mothers gave of the index children's health in both the SHV and control groups.

There were also differences between the control group and the SHV on the outcome of mother–child interaction. SHV mothers had significantly fewer worries about their child's development. They were less worried on all of nine developmental questions than were control group mothers, and particularly worried less about issues to do with their child's speech development. Household resources, both financial and social, were similar between the SHV and control groups.

CGS women reported more continuing problems than control women with health as a result of having given birth. In general, maternal health was similar between the two groups, as were measures of the index child's health.

Health service use was also similar between the CGS and control groups, but there were two differences: a reduction in maternal use of midwifery services in the previous month and an increase in child use of doctors at home for the CGS groups. When considering the outcome of mother–child interaction, CGS women were more worried about their child's eating habits than were control group women. There were no significant differences on other developmental worries. Household resources remained similar between the CGS and control group women.

Economic evaluation

Cost of health and social service use in the previous month at 18 months

At the time of second follow-up, use of health and social services was not obviously different between the SHV group and the control group (*Table 83*). However, mean total healthcare costs in the previous month for the CGS group were higher by £26, compared with the control group, with 95% confidence limits between 0 and £63. This increase was noted in both the primary and secondary healthcare sectors, but at this level, the confidence intervals for cost differences include possible net reduction in costs in both sectors.

A minority of women in each arm of the trial made use of community support services other than those used by women allocated to the CGS arm. The costs of community service use were similar across the three arms. The mean cost per woman was around £30 in the previous month; however, the median cost was zero in each group, reflecting the very skewed distribution of use of these groups (*Table 84*).

Personal costs of medications and travel for mothers in the previous month at 18 months

Estimated personal costs for women in the trial based on imputed travel and reported use of medications at 18 months were similar to those at 12 months, at over £35 per woman in the previous month (*Table 85*). Women also reported the fees paid to community groups, which had zero median and a mean that did not differ between trial arms.

Overall costs

Estimated costs of the intervention and health, social care and community service use per woman over the 18-month period are shown in *Table 86*. These are based on the costs reported at 12 and 18 months (from January 2000 to June 2001) with assumptions made about the trends in service use between baseline and follow-up points. The table shows costs calculated for the 'base case analysis', in which it was assumed that costs incurred in the previous month are typical of the period since the previous survey, that costs of volunteer input have zero value and that the discount rate for future costs is 6%.

In this analysis, the SHV intervention emerged as a relatively expensive intervention to implement compared with the CGS intervention. This is unsurprising given that the SHV intervention included the employment and specialist training of professional health visitors, whereas the CGS intervention was provided by existing community groups. Although the SHV intervention also produced more substantial cost savings in health and social care and out-of-pocket expenses by trial women, these savings were not sufficient to offset the cost of the intervention. The costs over 18 months for the CGS arm were also higher overall, but with very wide 95% confidence intervals including the possibility of a net cost reduction. Bootstrap confidence intervals for the mean difference in costs between each intervention group and the control group show that the estimated differences in overall cost in both groups are consistent with chance variation.

Table 87 shows the results of changing the assumptions of the base case. The change in discount rate had little effect, since only a small part of the overall cost was discounted. Inclusion of replacement valuation of volunteer time in community groups also had relatively little effect on overall cost, because volunteer input represented a relatively small proportion of the overall staff time in the CGS service costs.

The overall cost results were highly sensitive to the assumption about health and social care service use outcomes in the intervening periods between follow-up points for which data were not collected in the trial. In the base case, it was assumed that service use at each follow-up month was typical of use in the months preceding. For the sensitivity analysis, health and social care service use outcomes at 12 and 18 months were averaged and the result used as a typical month to calculate costs over the 18-month study period. The results in *Table 87* show a larger estimated cost increase for the SHV intervention group, which would vary if different assumptions about service use over time were made.

A cost–utility analysis was initially planned on health status measures, but because there was no clear difference in any of the three primary outcomes (maternal depression, child injury and maternal smoking) it was concluded that there would not be any difference in utility between groups either. As a result, this aspect was not explored further in the economic evaluation. Differences were found in satisfaction and other outcomes which suggest that if a valid sensitive preference-based instrument had been available, a small difference between groups might have been found. That is, there was some apparent benefit from the SHV intervention, but not in the form of measured health gain.

TABLE 83 *Cost of reported use of NHS and social care services in the previous month by women in the SSFH study at second follow-up (£)*

	SHV intervention			CGS intervention			Control group			Mean difference SHV – control (95% CI)	Mean difference CGS – control (95% CI)
	N	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)		
Primary and social care services at 18 months	145	75.98 (92.19)	39.71 (0–127.00)	158	96.01 (160.28)	55.80 (39.33–119.13)	298	74.45 (86.11)	39.71 (0–119.13)	1.53 (–13.96 to 20.12)	21.56 (–1.62 to 51.84)
Hospital contact at 18 months	142	17.04 (76.92)	0 (0–11.13)	157	15.98 (80.62)	0 (0–11.3)	293	10.79 (29.41)	0 (0–11.13)	6.25 (–3.77 to 20.90)	5.19 (–3.64 to 16.21)
Total healthcare services at 18 months	142	92.34 (121.95)	52.46 (0–140.81)	157	112.61 (188.56)	72.40 (39.62–128.71)	293	85.97 (93.04)	56.31 (11.13–129.68)	6.37 (–14.27 to 29.02)	26.64 (–0.00 to 62.65)

Bootstrap confidence intervals.

TABLE 84 *Cost of community support services use by women in the SSFH study at second follow-up (£)*

	SHV intervention			CGS intervention			Control group			Mean difference SHV – control (95% CI)	Mean difference CGS – control (95% CI)
	N	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)		
Community support services used at 18 months	140	31.15 (68.10)	0 (0–40.22)	158	26.56 (51.70)	0 (0–25.1)	294	31.72 (59.86)	0 (0–44.22)	–0.78 (–14.21 to 12.21)	–5.16 (–17.11 to 2.74)

Bootstrap confidence intervals.

TABLE 85 *Personal costs of medications and travel for mothers at second follow-up (£ at 2000 prices)*

	SHV intervention			CGS intervention			Control group			Mean difference SHV – control (95% CI)	Mean difference CGS – control (95% CI)
	N	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)		
Total costs	140	34.52 (24.27)	27.99 (17.22–52.49)	158	38.37 (26.65)	37.85 (20.88–56.76)	294	34.65 (24.34)	34.16 (18.50–47.10)	–0.13 (–5.12 to 5.17)	3.72 (–1.35 to 8.39)
Travel costs	140	1.65 (1.94)	1.04 (0.50–2.43)	158	1.79 (2.15)	1.08 (0.50–2.50)	294	1.66 (1.73)	1.08 (0.50–2.50)	0.00 (–0.37 to 0.39)	0.13 (–0.26 to 0.44)
Medications	144	32.75 (23.67)	26.80 (13.96–49.72)	158	36.58 (26.16)	35.76 (19.80–54.96)	297	32.96 (23.92)	31.96 (18.00–46.52)	–0.21 (–4.83 to 4.32)	3.62 (–1.72 to 7.84)
Fees paid to community groups	140	2.71 (5.66)	0 (0–3.13)	158	2.52 (5.32)	0 (0–3.13)	294	2.80 (5.42)	0 (0–3.13)	–0.09 (–1.24 to 1.06)	–0.28 (–1.26 to 0.82)

Bootstrap confidence intervals.

TABLE 86 *Estimated cost per woman over 18 months: base case analysis (£)*

	SHV intervention			CGS intervention			Control group			Mean difference SHV – control (95% CI)	Mean difference CGS – control (95% CI)
	N	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)		
Intervention costs	183	543 (377)	512 (137–913)	184	33.2 (151.7)	3.8 (0.6–49.7)	364	0 (0)	0 (0–0)	543 (488 to 598)	33.2 (11 to 55)
Health and social care costs	130	1503 (1449)	1023 (476–1968)	131	2007 (3126)	993 (476–2285)	260	1672 (1947)	1212 (579–2202)	–169 (–555 to 121)	335 (–190 to 1006)
Costs of Community Support Services' costs	140	550 (1202)	0 (0–710)	158	469 (912)	0 (0–443)	294	560 (1057)	0 (0–780)	–10 (–140 to 144)	–91 (–212 to 47)
Out-of-pocket costs to women	136	631 (388)	590 (314–868)	144	700 (376)	662 (415–1022)	277	685 (389)	660 (379–986)	–54 (–135 to 26)	14 (–60 to 92)
Total 18 month costs	123	3255 (2253)	2661 (1749–4277)	125	3231 (3323)	2303 (1359–3908)	250	2915 (2349)	2434 (1450–3866)	340 (–137 to 829)	315 (–294 to 980)

Bootstrap confidence intervals.

TABLE 87 *Sensitivity analysis for 18-month costs*

	SHV intervention			CGS intervention			Control group			Mean difference SHV – control (95% CI)	Mean difference CGS – control (95% CI)
	N	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)		
Base case analysis (mean costs, zero volunteer costs, constant use of resources over time)	123	3255 (2253)	2661 (1749–4277)	125	3231 (3323)	2303 (1359–3908)	250	2915 (2349)	2434 (1450–3866)	340 (–137 to 829)	315 (–294 to 980)
Total cost undiscounted	123	3306 (2295)	2667 (1780–4347)	125	3286 (3373)	2346 (1398–3974)	250	2964 (2374)	2465 (1475–3897)	342 (–184 to 858)	322 (–343 to 1028)
Total cost discounted at 8%	123	3238 (2241)	2658 (1733–4258)	125	3212 (3304)	2289 (1344–3896)	250	2900 (2342)	2423 (1442–3830)	339 (–117 to 847)	312 (–313 to 952)
Total costs valuing volunteers' time	123	3310 (2348)	2661 (1776–4286)	125	3276 (3328)	2477 (1372–3955)	250	2961 (2388)	2443 (1488–3880)	349 (–143 to 867)	315 (–299 to 1043)
Based on interpolated trends in resource use	123	2905 (2102)	2302 (1657–3718)	125	2721 (2841)	1869 (1211–3162)	250	2445 (2186)	1910 (1215–3078)	460 (37 to 940)	276 (–248 to 858)

Bootstrap confidence intervals.

Comparison of results at second follow-up between the control group and the combined intervention groups

Additional analysis of the main outcome variables was carried out that compared a combination of the two intervention groups with the control group at the second follow-up stage. Tables with the results of this analysis can be found in Appendix 5.

Primary outcomes

For the outcome of maternal depression, more women in the combined intervention group than the control group reported being depressed (+2%), but fewer had a high score (≥ 12 indicating greater risk of depression) on the GHQ12 (–1%). Similarly, there was a reduction for the intervention group compared with the control group in the proportion of mothers who smoked (–2%). The number of children who had had an accident that required medical attention in the previous 6 months was very similar between the two groups. For all three of these primary outcomes, any differences may have been a result of chance.

Secondary outcomes

Maternal health service use was slightly greater for the combined intervention group than for the control group in all services except for midwifery. These differences were compatible with the play of chance. Similarly, children in the combined intervention groups were more likely than those in the control group to have used health services in the past month; these increases may have been the result of chance in all except for visits from GPs at home (mean difference 0.03; 0.004 to 0.05).

When considering the outcome of maternal health, similar proportions of mothers in the combined intervention and control groups rated their own health as 'not very good' in the previous month. More women in the intervention than the control group had experienced problems with anaemia, high blood pressure and problems relating to having given birth, but fewer had suffered from asthma or eczema during the previous month. All of these differences were compatible with the play of chance. The use of medication by the mothers in the previous week was broadly comparable between the two groups. As at first follow-up, the mothers in the two groups assessed the health of the index children similarly, as well as the reporting of medication use in the last week.

Similar proportions of the mothers in the combined intervention and control groups did not find the experience of looking after the index child to be an easy one. The mothers' concerns about specific aspects of child development were also broadly similar between the two groups, with all differences potentially being chance findings.

As at first follow-up, similar proportions of women in the two groups were in paid work, but at second follow-up 4% more intervention mothers than control mothers said that their financial situation was worse than it had been a year previously. Of the women with partners, more intervention women than control women said that their partner helped rarely or never (+4%). Overall support given by all sources was judged to be poor ('not at all supportive' or 'fairly supportive') by 2% more intervention mothers than control mothers. Similar proportions of women from the two groups had a high score on the DUFSS (less satisfactory social support), although the control group had a higher mean score on this scale. All of these variations in household resources were compatible with the play of chance.

Comparison of results at second follow-up between the SHV group and the combined control and CGS groups

Primary outcomes

Similar to the findings at first follow-up, there was a 3% reduction in the incidence of self-reported depression in SHV women compared with the combined control and CGS groups, but this was potentially a chance finding (RR 0.89; 0.64 to 1.24). Smoking and child injury levels were very similar between the groups.

Secondary outcomes

Worries about their child's development on speech and eating were reduced for SHV mothers compared with the combined control/CGS mothers (speech 0.43; 0.22 to 0.84; eating 0.65; 0.42 to 1.00). Except for a decreased usage of skin ointment by SHV children, all other differences on secondary outcomes were potentially chance findings.

Subgroup analysis: second follow-up

Women who received medium or high SHV intervention

At second follow-up, the proportions of women in the SHV high/medium intervention group

(N = 106) and control group (N = 298) were similar for depression, smoking and child injury. In addition, few differences were found between the groups on secondary outcomes. Fewer women in the SHV high/medium intervention group than control women had seen a midwife in the previous month (RR 0.40; 1.16 to 1.00).

Women who had used the CGS intervention

When comparing the women who had used the CGS intervention (N = 32) with control group women (N = 298), no major differences were apparent on any of the primary outcomes. More of those who used the CGS intervention than those in the control group were concerned about child development issues; notably, more were worried about their child's eating habits (RR 1.77; 1.04 to 3.01).

Socially excluded women

When comparing socially excluded SHV women (N = 81) with similar control women (N = 155), 7% fewer of the SHV women scored above the risk threshold of the GHQ12; this reduction was compatible with the play of chance. There were no major differences across the trial arms on the other primary outcomes. With secondary outcomes, the only differences that were unlikely to be chance findings were found in health service use by socially excluded CGS mothers (N = 84). These included increased maternal use of GPs (+12%) and hospital doctors (+8%), as well as a greater risk of having used any health services in the previous month (RR 1.25; 1.00 to 1.55).

First baby

The trial groups were broadly similar on all of the primary outcomes at second follow-up. In terms of secondary outcomes, fewer first-time mothers in the SHV group (N = 68) than first-time mothers in the control group (N = 142) were pregnant at the time of the second follow-up: 3% versus 20% (RR 0.27; 0.08 to 0.88). This led to a reduction among the SHV group of use of midwifery services in the previous month (RR 0.15; 0.04 to 0.61). SHV first-time mothers were also less likely than control mothers to have used skin ointment medication on their children in the previous week. CGS first-time mothers (N = 79) were more likely than first-time mothers in the control group to have had a GP see their child at home in the previous month (RR 8.89; 1.06 to 74.78), to be worried about their child's eating habits (RR 1.63; 1.03 to 2.58) and to have given their child painkillers in the previous week.

Lone parents at baseline

For women who had considered themselves to be lone parents at baseline, more CGS women (N = 37) than control women (N = 66) said that they had been depressed in the previous month. This 24% increase was unlikely to be the result of chance (RR 1.78; 1.11 to 2.86). These two groups had similar proportions who had high scores on the GHQ12, however. The lone-parent SHV women (N = 42) had a reduced risk of a high score on the GHQ12 (RR 0.82), but this was compatible with the play of chance. On the secondary outcomes, the proportion of women in the SHV group compared with the control group who had a partner at second follow-up was greater; the risk of not having a partner was RR 0.60 (0.38 to 0.95), a finding unlikely to be the result of chance.

Speakers of a first language other than English

Although a smaller proportion of non-English first-language speakers in both of the intervention groups than the control group had high scores on the GHQ12, the differences in depression levels were compatible with the play of chance. The groups were similar on the other primary outcomes of smoking and child injury.

Women from the SHV group who spoke a first language other than English (N = 52) were more likely than similar control group women (N = 108) to have DUFSS scores under the threshold of 19: lower scores are an indication that the social support received was favourable (RR 0.51; 0.31 to 0.83). Similarly, fewer SHV women than control women said that the overall support given to them was poor (RR 0.65; 0.43 to 1.01). The only difference on secondary outcomes between non-English first-language speakers in the CGS group (N = 60) and the control group was greater use of vitamins among CGS index children.

Process data

In addition to the process data presented in Chapters 4 and 5 and the context sections in Chapter 6 and this chapter, the section below describes some of the information collected in interviews with SHV women about parenting issues, and qualitative data from all the trial women on their views relating to community services and participation in the trial.

The interviews conducted with the SHV intervention women revealed a number of common

themes about the social contexts of mothers' lives, which may well have acted to limit the benefits of additional social support across both intervention arms. The first was the frustration of bringing up children in disadvantaged material circumstances. For example, one mother living on the fourth floor of a block of flats and suffering from depression talked about the problem of the lift breaking down:

> "I was constantly phoning the council, saying 'look you've got to get it fixed' … I had to go out and put her into a small buggy and bump her up and down the stairs … I had to make two or three trips to and back from the shops, because I had to get food and nappies and stuff for her … I think it's just frustration … . It's forever breaking down."

Second, there were frequent comments about the child-unfriendly nature of public transport in London; difficulties that made women feel confined to home or very local areas only:

> "People don't care, you're struggling with a pushchair … it's just really, really terrible."

> "If you haven't got a car it's difficult … to get them out and about and to get your shopping done and to take them to places … . If you've got one you can get on a bus, but you can't do bus journeys with two."

Another mother recounted a story of trying to get on a bus with two small children and a pushchair. She put one child on and turned round to get the pushchair and the other child; meanwhile, the bus drove off:

> "I was running along trying to stop the bus, I was in a right state … It was awful, a really horrible experience."

The general lack of public amenities for children was a third common theme:

> "… places that are more … baby friendly … that would be nice … I think it would be nice if there were more places that you could go with babies that were set up better for babies … as they do have in other countries more … so it wasn't so difficult to go out with babies … I wish that there were more things that I could actually do with her … because it's hard to be in all day … ."

> "… it would be lovely to have a nice clean park at the end of every road for children to play on, but I can't think that, you know, being in the world as it is … ."

A fourth frequently mentioned theme in these accounts was the assumption built into much health and social care provision that mothers' time is an endless and unvalued commodity:

> "… in terms of the whole palaver of the baby clinic it's quite a long thing, and sometimes you think, well is it really worth it for that question?"

These difficulties happen in a context in which for many women motherhood is described as a responsible, anxious and generally socially unrewarded condition. As one mother of twins said:

> "… it's a lot more worry, you don't consider the worry at all … it doesn't occur to you that you're going to worry as much as you do … it seems such a huge massive responsibility being a mother to two babies."

And as another put it:

> "I think that's the hardest thing, you can work really, really hard and no one ever says, 'Oh! You did well'."

The comments that women wrote at the end of the questionnaires were sometimes fairly desperate and indicated an ongoing need for support:

> "I just have to get back onto the council about moving, I haven't heard nothing from them since I filled out a transfer form … I've been pretty down about a number of things … . I would like to know if you can give me any advice on moving and of doing any voluntary work to get me out of the house."

> "Life is very difficult and I don't know what to do … I am homeless in a hostel and it isn't clean. I share a bath with five other families … . We don't have enough money to buy things for the baby … ."

> "Hard to be a single mother on income support, there is never enough money. I feel very lonely sometimes. I really, really want to go back to study, but my son hurt himself at the school crèche and I just think it is not good to have him there, so I've withdrawn from school for now, until he is older."

It was particularly hard for some ethnic minority women, who found the situation of mothers in the UK very isolating:

> "Looking after a baby in this country is very difficult as you have to do everything on your own. In my country, other people will look after the baby for you and do housework and help in every way."

> "In this country we live between four walls. I don't go out. I don't know the area. In my country there are separate gardens and places for women to go – without men there where I can relax."

Some women made positive suggestions about ways in which the situation of mothers with young children could be improved:

> "… meeting up with other mums and 'getting out' is vital. When you feel down the last thing you feel like

doing is going out, even though you know it's the best thing you could do. Could the Health Authority supply each new mum with a list of baby and toddler groups and activities (both council and private) and perhaps opportunities for more parenting courses, or a parenting helpline?"

"Housing – when people complain to the housing department they don't listen and act quickly … Islington school charges money for after school club – can't afford it … Would like some help with kids so I can help my eldest son learn to read … Should have spent the money from the Dome on us poor people."

The women were asked in the second follow-up questionnaire, 'How have you felt about taking part?' (in the study). Most (71%) of the women who answered this question (N = 460) were positive:

"I'm glad I was able to participate. I hope the study can help other mums. I enjoyed taking part, [the SHV] helped keep me sane over the first year, I miss her."

"Interested to see what questions are being asked, keen to give any help in gathering information about the effect having a baby has on your life."

"I enjoyed it. In my position [single parent] it was nice to have that support, advice and regular visits."

"Interesting. Made me feel valuable as a mother."

"I felt better expressing my feelings and able to share it with someone else, hoping that it may help to change or be useful to help other people."

"Pleased, like someone cared how I felt."

"I have felt quite honoured to have been involved with this study."

"Without my SHV I wouldn't be here today."

Some women had found time a problem:

"Just don't have lots of time to take calls or difficult to get time to fill this in. Have to do it on the train."

"I don't have enough time to fill in all the forms, please don't send it again."

For others, the experience of being part of the study was a mix of the positive and the negative:

"Very good overall. But the HV visits wasn't enough. She only came for four visits, I wish it continued."

Overall 3% (12) were more negative:

"Regarding the telephone line I was supposed to get, I was disappointed."

"It has made me realise some of the problems I have."

"Questions about financial status and child's health are intrusive."

'Taking part in this experiment hasn't changed anything."

A total of 154 women had something to say in answer to a question concerning the 'worst bits' about taking part in the research. These comments included:

"Using up valuable time."

"Having to admit when you are not coping as well as you would expect from yourself."

"Filling in forms which made me realise how little support I have with childcare."

"Addressing issues I'd rather not acknowledge."

"It might make no difference."

"I wasn't in the group who had help."

"Would have preferred to have chosen form of community support."

And simply:

"It ended."

More women (261) answered a question about the 'best bits' about the research:

"Knowing someone is funding research on childcare."

"Being forced to consider questions and learning through that."

"Realising that I have had more support and help than I thought (I only realised this through answering the questions)."

"Having someone to come round and talk to."

"The questions were well laid out and made filling out the study easy."

"Being able to be honest about problems in my life. Even though I'm not speaking to someone it is good to write it down."

"Feeling it may help others."

"Offloading to an anonymous group of people."

"Being put in touch with Parents & Co."

The second follow-up questionnaire also asked women how they thought the study could have been improved. Among the 105 answers to this question were the following:

"Less paperwork."

"A study into the user-friendliness of public transport for people with prams and shopping!"

"Because we are foreigners … we need an interpreter to ask for things from the health service and other services in order to go forward in our life."

"I wonder if it would have been useful to ask more questions about mother's paid work … you didn't ask if women would like to work more if more childcare were available …"

"Maybe ask people who had problems if they knew what the root cause of this was."

"To take more account of other people's cultures, e.g. not all men help with things in my culture …"

"Maybe have a website."

"It's good but it could ask about how we cope or how we feel about how we cope."

"Send a free mother's help!"

Chapter 8
Discussion and conclusions

Main findings

The interventions

The SSFH study tested two different approaches to providing support for mothers with young babies living in a disadvantaged urban area of the UK, one using specially trained health professionals (the SHV intervention) and the other using existing voluntary sector community organisations (the CGS intervention). These two approaches were designed to reflect aspects of current statutory and voluntary provision. The standard against which both interventions were compared was the services routinely available for new mothers. The two SHV and CGS interventions were defined as the 'offer' of support.

Uptake of the offered SHV intervention was high, with 172 of the 183 women allocated having at least one visit (94%). The women *allocated* to the SHV intervention received an average of 603 minutes of support provided in seven home visits and additional telephone contacts with the SHVs over a 10-month period. When considering only the women who used the SHV intervention, the average amount of time spent per woman increased to 644 minutes. Most women were positive about the SHV intervention. Of the women allocated, 87% said that the number of visits was 'just right', and 85% that they found their SHV either 'very helpful indeed' or that she had given 'the right amount of help'. Most (97%) said their SHV had listened to them, 85% that she had given them good advice, and 52% that she had done 'practical things' to help. The SHV were very positive about working in this manner. There was some evidence at first follow-up that first-time mothers found the SHV intervention more useful than more experienced mothers.

The picture with the CGS intervention was more complex. The groups were asked to take the initiative in contacting the women assigned to them, but otherwise to provide their normal service. Uptake of the service was low: only 35 women out of the 184 allocated (19%). Where the women did not immediately take up the offer of support, all but one of the groups repeated their attempts at contacting at least some of the women, often trying a different form of communication. The groups that had the most success in supporting women were those that tried more than one means of contacting them and offering support. On average, the women *allocated* to the CGS intervention received 86 minutes of support. The 35 women who *used* the services received on average 484 minutes of support through home visiting, drop-in activities and/or support over the telephone. Of the women who used the CGS services, 48% who answered a question about satisfaction said that the support group had given 'the right amount of help' or had been 'very helpful indeed'.

These findings suggest that the SHV intervention was a more appropriate strategy, as measured by uptake and women's satisfaction, than the CGS intervention for providing support to the target population. However, these findings also reflect the fundamental differences between the two interventions: one was created and supported centrally, with the research intervention being the providers' only professional focus, and effort made to synchronise practice; the other intervention was made up of eight different groups, all of which offered different services in disparate locations, and for all of these providers, the research was an addition to their already overstretched services.

Outcomes

Results of the SSFH study in terms of outcomes for mothers and children suggest that the offer of visits from health visitors trained to focus exclusively on supporting mothers results in some limited benefit over routinely available services, but not for the primary outcomes of depression, smoking and child injury. SHV women had different patterns of health service use and had less anxious experiences of motherhood. The offer of support from community organisations did not appear to confer the same limited additional benefit.

Maternal depression

At first follow-up, the mean EPDS score was lower for both interventions compared with the control group; 4% fewer SHV women and 2% fewer CGS women scored above the depression threshold. Similar proportions of women in the three groups reported having recently felt depressed.

At second follow-up, the SHV group and control group had similar mean GHQ12 scores; the CGS group had a higher mean score. Four per cent more CGS women than control women said that they had been depressed in the previous month; there was little difference between SHV and control women. All differences found on maternal depression at both follow-up stages were compatible with the play of chance.

Child injury

At first follow-up, the proportion of index children who had sustained an injury in the previous 6 months that had required medical attention was 3% less for the CGS group than for the control group. Similar proportions of injuries were sustained in the SHV and control groups.

At second follow-up, there was little difference found in injury rates between the arms of the trial; there was a 1% reduction among SHV index children compared with the control group children. These minor differences found at the two follow-ups were likely to be chance findings.

Maternal smoking

At first follow-up, 4% fewer SHV women and 1% fewer CGS women than control women reported that they smoked.

At second follow-up, the proportions smoking were similar among the three groups, with 1% fewer SHV women and 1% more CGS women than control group women reporting that they did so. These differences were consistent with chance variation.

Health service use

At first follow-up, patterns of health service use for both mothers and index children were broadly similar in the CGS and control groups. However, there were differences when comparing the SHV group with the control group. SHV women and children had fewer visits in the previous month than those in the control group to GPs at surgeries and to hospital doctors. A higher proportion of SHV compared with control group women had made use of NHS health visitor services for their own health needs, had talked to health visitors on the telephone and had seen a social worker. These three were unlikely to be chance differences. As regards children's overall use of services, 7% fewer SHV than control group children had used at least one health service in the previous month. Of these children, 11% fewer had attended GP surgeries than control children; a difference that is unlikely to be due to chance.

This increased use of NHS health visitors and social workers could be a result of referrals instigated by the SHVs. It may also be a reflection of the 'deprivation effect' suffered by some women following the end of the SHV intervention, where they sought out others to fill the support gap.

At second follow-up, the use of health services was generally similar between the intervention and control groups, with many of the differences found in the first follow-up no longer being apparent. However, both SHV and CGS women were less likely to have used midwifery services in the previous month, differences unlikely to be a result of chance. Overall, CGS children were more likely to have used at least one health service in the previous month, and 3% more had used a GP at home, a finding that is unlikely to be due to chance. Hospital service use by index children in the previous 6 months was very similar across the three trial arms.

Maternal physical health

At first follow-up there were 8% fewer SHV women and 7% fewer CGS women who said that their health had been 'not very good' in the past month. These differences may have been the result of chance. There was a 3% reduction in maternal use of medication in the CGS group compared with the control group, but this was likely to be a chance finding.

At second follow-up the self-reported ratings of physical health were similar in the three groups, with 2% fewer SHV women reporting not very good/mixed health. Five per cent fewer SHV women and 4% more CGS women than control women had experienced three or more health problems over the previous month. Little difference was found in use of medication in the previous week. These differences at second follow-up were compatible with the play of chance. However, two differences were unlikely to be the result of chance: 8% more CGS women than control women continued to experience problems as a result of giving birth, and 7% fewer SHV women were pregnant at the time of the second follow-up.

Child health

At first follow-up, 3% fewer SHV mothers than control group mothers reported that their child's health was 'not very good'; the proportions were similar for CGS and control children. Fewer CGS children were reported to have suffered from colic. Similar proportions of children in the three groups had been given at least one form of

medication in the previous week. There was only slight variation in immunisation levels across the three groups. The above differences could be chance findings. Although mothers' reporting of the index child's health does not in general seem to differ between the groups, 5% fewer children in both of the intervention groups were taking asthma medication and 12% fewer SHV children had had skin ointment medication; these were unlikely to be chance findings.

At second follow-up when comparing the health of the index child over the previous month, the three groups were very similar. There was little variation in the proportions of index children who had been given at least one medication in the previous week. When comparing use of specific medications, there were differences that were, on the whole, compatible with the play of chance. Eleven per cent fewer SHV children than control children had been given skin ointment, which was, again, unlikely to be a chance finding.

Experiences of motherhood

At first follow-up there were slightly greater proportions of SHV and CGS women than control women who did not find their baby 'easy' to look after. The two intervention groups were both less likely than the control group to worry about the index child's development. The differences on these two aspects could have been due to chance. However, both intervention groups were also considerably less worried about the index child's health, and the reduction of 11% for SHV women was unlikely to be a chance difference.

At second follow-up there was little difference between the groups in the ease of looking after the index child. When comparing SHV women with control women, fewer SHV women were worried about each of nine aspects of child development. The percentage worrying about the child's speech development was reduced by 8% for SHV women, a difference that did not appear to be as a result of chance. The average number of worries an SHV mother had about her child's development was reduced compared with control women. Conversely, a greater proportion of CGS mothers than control women was worried about five aspects of child development. Nine per cent more CGS mothers than control group mothers were worried about their child's eating habits; this finding was unlikely to be a result of chance. The average number of worries per CGS woman was higher than that for control group women.

Infant feeding

More of the women in the SHV and CGS groups than in the control group who initiated breast-feeding stopped before 26 weeks. Similarly, more women from both intervention groups had introduced solid foods before the baby was 16 weeks old. For both of these infant-feeding variables, the differences were compatible with the play of chance.

Household resources

At first follow-up, fewer women in both intervention arms than control women said that their financial situation was worse than at the time when the baby was born, but these differences could have been due to chance. Slightly fewer women in both interventions compared with the control group were in paid employment. The level of partner support was broadly similar in the three arms of the trial. The risk of having a partner who offered support rarely or never was reduced for women in both intervention arms compared with control women. The risk of having poor support from all sources was also lower in both intervention arms: a 7% difference between SHV and control groups. The differences in both partner support and overall support could have been chance findings.

At second follow-up more women in both intervention groups than in the control group rated their financial situation as worse than it had been a year before: 7% more SHV women said that they were worse off. These differences were consistent with the play of chance. The groups were similar with respect to the risk of not being in paid employment. The risk of being on an income of less than £150 per week was less for women in both interventions than in the control group, but this may have been a chance finding. The risk was increased for women in both intervention groups compared with the control group of having a partner who helped rarely or never with domestic work, and of feeling poorly supported from all sources over the previous 6 months. The differences in both cases were potentially chance findings. Scores from the DUFSS scale were broadly similar between the CGS women and the control women; SHV women had a lower average DUFSS score, an indication of more satisfactory support, but this difference was compatible with the play of chance.

Outcomes for combined intervention groups versus control group

When the analysis was rerun combining the two intervention groups, intervention women reported

at first follow-up better physical health, fewer worries about their children and less use of asthma medication for the index child than control group women. These differences were unlikely to be due to chance. At second follow-up, any differences between the combined intervention group and the control group could have been chance findings. Because of the low uptake of CGS services, it is unsurprising that analysis with the greater power of combined intervention still did not show much impact.

Subgroup analysis

There were some differences in outcomes at first follow-up between subgroups of women in the SSFH study. In the SHV intervention group, high and medium users of the intervention used GPs for their children less, but there was an increased use of NHS health visitors and social workers. Also in this group, first-time mothers compared with others had fewer worries about their children, used GPs less and made more telephone contact with their NHS health visitors. In the SHV intervention group, women who did not speak English as a first language made more use than others of NHS health visitors and social workers. Dividing the study women into lone parents and others resulted in lone mothers in the SHV intervention group having less worry about their child's health. Socially excluded SHV mothers were more likely than similar control mothers to have used NHS health visitors and social workers, but also to be more satisfied with the support received from their partners and less worried about the baby's health. None of these differences was likely to be due to chance.

At second follow-up, high and medium users of the SHV intervention were less likely than others to have seen a midwife. Users of the CGS intervention were more likely to be worried about their child's eating habits. Socially excluded CGS women used health services more than others. In the SHV group, fewer first-time mothers were pregnant, and as such used midwifery services less than others. CGS first-time mothers were more likely than others to have taken their child to the GP and to have worries about child development issues. Among women who had considered themselves to be lone parents at baseline, more SHV women had a partner by second follow-up. More CGS women who had been lone parents said that they had been depressed in the previous month, although their GHQ12 scores were similar to others. Among women whose first language was not English, a higher proportion of SHV women had low DUFSS scores, an indication of favourable social support, and more of these women were satisfied with the overall support that they had received. None of these differences was likely to be chance findings.

Economic value of the intervention

Estimated costs were higher for women in the SHV and CGS arms at 18 months, and when extrapolated over the period of the trial. The increased costs of the SHV intervention itself was offset by reduced costs for other health service and personal costs. These estimated costs have a very wide confidence range and are sensitive to assumptions about patterns of service use between data points in the study. The additional societal costs per woman in the SHV and the CGS arms were consistent with chance, and are consistent with no overall cost change, although there would be some shift in the balance of costs between types of resource.

Given that there is no clear gain in any of the three primary outcomes (maternal depression, child injury and maternal smoking), cost-effectiveness was not estimated. It would be concluded from this analysis that there is no net economic cost or benefit of choosing either of the interventions or, alternatively, that either intervention would be as socially efficient as the current pattern of care.

Strengths and limitations of the study

Strengths

RCT with integral economic and process evaluations

The SSFH study makes an important contribution to the research evidence in the area of social support and health by responding to the recommendation that rigorous experimental designs are needed to examine the effectiveness of different types of support in improving different measures of outcome in different target groups. The study used an RCT design to compare two interventions with standard services in three randomly allocated groups of women. The design of the SSFH study incorporated an evaluation of economic costs and benefits. This is increasingly being recommended as best practice in trial design.[137] The SSFH study was designed to collect data on the *processes* involved in implementing the two interventions, as well as assessing their relationship to *outcomes*, again following current guidance about best methodological practice. For example, interview data were collected from the SHVs at two time-points, and also from the community groups, about their experiences of

providing services to SSFH study women. In both intervention arms of the trial detailed data were kept in a standardised format about the uptake and the nature of the intervention as provided to study women.

Inclusivity

An important issue explored in existing research in only a limited way is the appropriateness and effectiveness of supportive interventions in different population groups. Recruiting non-English-speaking women to the SSFH study resulted in a more culturally diverse population than is found in many trials where language is used (explicitly or implicitly) as an exclusion criterion. In the SSFH study at baseline 42% of the women said they were from BME groups and 39% did not have English as their first language. At second follow-up, 2% were asylum seekers and 8% either had refugee status or had been granted exceptional leave to remain in the UK (this information was not collected at baseline). This profile of the women in the SSFH study compares with that in the recent trial by Morrell and colleagues,[68] where 8% of participants were from BME groups and women who were unable to understand and speak English were excluded from participation. The trial in Bristol by Grant and colleagues[55] of referrals between the primary care and the voluntary sectors did not report ethnicity of participants, but acknowledged that the exclusion of people who do not speak or read English may limit the generalisability of the trial findings.

Informed consent

All eligible and contactable women were given a full explanation of the design and purposes of the study in a face-to-face interview, using interpreters where necessary (for 14% of the women). The 731 women who agreed to take part represented 58% of the 1263 eligible women who were asked to do so. A further 311 women were ineligible to take part in the study; most of these (294) could not be traced, had moved or were moving imminently. On average, two recruitment visits were made to eligible women, up to a maximum of ten visits. The two biggest single reasons the women gave for declining to take part were that they were 'not interested' (24%) or 'too busy' (24%); only 13 women (2%) refused because they did not want to be allocated to either intervention. A further 17 women (3%) said they already had enough support.

Reliability

Postal questionnaires were chosen as the most cost-effective, methodologically appropriate and reliable way of collecting outcome data in this kind of study. Response rates to the questionnaires were high: 90% for the questionnaire designed for completing 12 months after randomisation, and 82% for the second follow-up questionnaire at 18 months (92% of those women responding at first follow-up). Similar proportions of women responded at follow-up across the three arms of the study. Non-responders were more likely than responders to have a first language other than English, but were similar in terms of their age and parity. Because of the cultural and linguistic diversity of the study women, some of the questionnaires could not be completed by mail but required the help of researchers and/or interpreters. These were also used to chase non-responders to postal reminders about questionnaire completion. At the first follow-up 12%, and at the second follow-up 9%, of questionnaires were completed with the help of researcher–interpreter teams; 20% of the questionnaires at first follow-up and 17% at second follow-up were completed with the help of researchers alone.

Validated tools

Three standardised instruments were included: the Edinburgh Postnatal Depression Scale (first follow-up questionnaire), the Duke Functional Social Support Scale and the General Health Questionnaire (second follow-up questionnaire). These three instruments were selected as the most appropriate available. (But see below for lack of validation in different cultural groups.)

Standardisation of practice

The SHV intervention was standardised as far as possible; the SHVs were all provided with the same training in non-judgemental listening and were supported with protocols about how to respond to particular situations and how to make their services available to women assigned to them. Regular team meetings with the researchers over the course of the intervention helped to standardise the level and extent of support offered by the five SHVs. The CGS was necessarily less standardised, as the intention here was to explore the usefulness of 'naturally occurring' services in the local community.

Limitations

Uptake of the CGS intervention

Initially, this trial was conceived with only one support intervention: the SHV intervention. This was developed following the piloting of the method in the earlier SSPO trial[2–5] and the results of the process work that accompanied that early trial. The funding body requested that an

additional intervention be added, to allow for comparison between professional and non-professional support. This request was made because the funders considered this to be an issue of key policy importance about which there was limited evidence in this country. This trial was funded at the advent of government initiatives (e.g. Sure Start) that had as a key component the support of lay groups. The late addition of this trial arm meant that the best practice for designing trials, which involves exploratory work to develop interventions,[138] was not possible for the CGS arm. Pilot work was not carried out; had it been, then it is likely that the low uptake of the CGS intervention would have been detected, and this intervention would have been either abandoned or significantly modified.

As it was, uptake of the two interventions was significantly different: 94% of the women allocated to the SHV intervention group had at least one visit from their SHV, but only 19% of the women allocated to the CGS arm made any use of the service to which they were assigned. These results appear not to be unusual; a recently published Scottish trial which also had an intervention of postnatal group support found that only 18% of women invited to take part in a group actually took up this offer.[139]

The most common reason given by the women in the SSFH study for not using the community groups providing drop-in or home visiting services was that they were too busy. The most common reason for women not using the telephone help-line (87% of those referred to it) was that they 'had no problems'. Women in the CGS arm had to be proactive to participate in the intervention, even if it was just to lift the telephone receiver. They had to work much harder to use services that did not fit in with their babies' timetables, or that were more than a pram push away, than the SHV women, whose support came to them. It may well be that offering these kinds of community group services to mothers with very young babies in this way is perceived as an inappropriate form of 'support'. However, it is important to note that women in the study as a whole did not reject community services: 47% of them had used at least one community service by the time their baby was 14 months old, and 38% had used a community service in the month before the second follow-up. It is also notable that the most successful community groups in terms of uptake in the CGS arm were those offering at least some home-visiting services. The CGS workers felt that the low uptake of services occurred for a combination of reasons: 'inappropriate referrals', for example women who had different needs or different expectations than their service could provide; problems with making initial contact with some women; or the children being too young for mothers to want to access drop-in services. Other studies have shown that referrals to community groups by health visitors or social workers can be an inefficient way of encouraging women to use community group support.[77]

Although the study team considered a number of strategies for trying to improve the uptake of the CGS arm, it was agreed that all of these would alter, half way through the trial, the nature of the intervention being measured and modify the agreement that had been made with the participants when they were recruited into the study.

Since outcome data about effects of the two interventions were analysed on an intention-to-treat basis, results for the CGS arm are likely to have been significantly diluted by the women's lack of use of the services offered by community groups. Although it is unfortunate in terms of measuring effectiveness that fewer women utilised the CGS intervention, it is still interesting in policy terms that this was the result of such an endeavour.

Power calculation and predictive capabilities

The main weakness of this study is the imprecision of the estimated intervention effects. The revised recruitment targets inevitably meant the study had less power to detect treatment effects of the magnitude that had been postulated. In addition, having two interventions instead of one cut the power dramatically. This became especially acute when one of the two interventions was so poorly utilised. Because of this low uptake, combining in analysis the 'supported' women (women from both intervention arms), the option with the greatest power to display change, became less viable. With hindsight, it would have been more appropriate to have carried out a trial with only one of the two interventions.

However, it is important to emphasise that the information from the present trial will ultimately be considered in the context of the totality of evidence from all relevant randomised trials in a systematic review. All relevant randomised evidence will contribute to reducing uncertainty about the effect of the support interventions, and since this trial is one of the largest trials in this area it will make a substantial and important contribution.

Recruitment biases

Women who declined to take part in the study were more likely than those who were recruited to belong to an ethnic minority group (56% of those who declined compared with 42% of those recruited). In 15 cases (3%) the woman's family refused on her behalf. Over half (seven) of the 12 women whose partners refused on their behalf were from the Indian subcontinent, two were other Asians, one was African, one Middle Eastern and one of 'other' BME origin. This 'proxy' refusal raises issues about the ways in which different cultural values concerning autonomy challenge the model of individualised consent underlying the standard research recruitment process.[140]

There may also have been an element of 'gatekeeping' in the behaviour of some of the interpreters who helped to recruit women to the study. Some of these may (unknown to the researchers) have expressed their own views about the desirability of taking part in the study to the women they were recruiting, and hence may have affected the pattern of recruitment.

Operational biases

Since the women could not be blinded to allocation, some dissatisfaction with actual group allocation may have affected their responses, particularly among women who wanted the SHV intervention but were not allocated to this group. Although preferences for type of community group support within the CGS arm were matched as far as possible with the types of group support available, some women did not get their first choice. For some women, the group to which they were assigned was not as local as they would have wished (nine women said the group was too far away). It is impossible to quantify the ways in which this dissatisfaction among women with the intervention offered might have affected their participation in the study and the trial outcomes.

Because of language and literacy problems or non-response to postal questionnaires, some data were collected by researcher–interpreter teams or by researchers alone (see above). In these cases, the possibility of knowledge about group allocation influencing the data collected cannot be ruled out.

Appropriateness of the interventions

There was a lower uptake of both interventions among women whose first language was not English. A low level of use of the SHV intervention (four or fewer home visits) was more likely among this group of women. Within the CGS group, contact with non-English-speaking women was hampered by some groups having no staff or volunteers with the appropriate language skills, or the funds to pay for interpreters. One of the reasons for the low take-up was the failure of some of the groups to make that first contact, and another was because the means of contacting some women were inappropriate. For example, leaving answerphone messages does not seem to be an appropriate or effective way of contacting women whose first language is not English. Cultural inappropriateness in terms of what the groups offered (e.g. drop-ins for women who were shy about going out and meeting strangers, or for whom this was culturally unacceptable) was one reason for lack of uptake. Despite choosing a range of community groups, many of which had components of specialised services tailored for specific cultural groups, the services available did not always reflect the diversity of the communities that the groups were serving, and thus some women were offered a 'community' service that did not reflect their cultural or language background.

The individualised model of support underlying the SHV intervention, with intensive face-to-face contact between the health visitors and the women, may also have conflicted with dominant cultural values, and thus have been received as inappropriate, for some of the ethnic minority women. Equally, offering supportive listening through the filter of an interpreter may not have been a sufficient means of providing this support. Although some women were delighted to have access to an interpreter and flattered that the project valued their needs and experiences enough to provide one, others were wary about issues of confidentiality and were constrained by the interpreter's presence.

Appropriate tools

None of the standardised instruments used (EPDS, DUFSS and GHQ12) has been validated for all the cultural groups included in the SSFH study. The EPDS has been validated in Punjabi, but there was only one Punjabi woman in the study, and she spoke fluent English so no Punjabi-speaking interpreter was necessary. The DUFSS has been validated mainly with 'white' married women aged under 45 in the USA.[103] The GHQ12 has been validated only for the general population.[133] A culture-specific version called the Chinese Health Questionnaire has been devised,[141] but was not used with the very small numbers of Chinese-speaking women in this study.

The use of instruments such as the EPDS and GHQ12 is problematic for populations such as Asian and African–Caribbean women, for whom the 'meanings' and prevalence of outcomes such as depression and health service use are known to be different from those in the groups for whom these instruments were originally developed.[142,143] In 50 cases (16 SHV, nine CGS, 25 control) the EPDS was not completed; these were all women who needed help filling in the questionnaire because of language or literacy problems. Although there was no significant difference between the study arms in EPDS completion rates, those women who did not complete it were significantly more likely to self-report (in answer to a separate question) being 'low' or 'depressed'.

In addition, the use of self-report tools may have resulted in some under-reporting among all participants, regardless of cultural background, of depression or other outcomes perceived to be negative. The extent to which this self-report bias may have affected the findings cannot be gauged.

Limited outcome data

The challenge of collecting accurate and complete data from research samples is greater when these are socially disadvantaged, and when providing research data is just another task to be fitted into difficult and stressful lives. In these circumstances, aiming for as many data as possible has to be balanced against what it is feasible and reasonable to request. In the SSFH study the data on economic inputs and outcomes, in particular, were more limited than the researchers would have liked, and keeping questionnaire length down by not repeating the same questions between the two outcome time-points resulted in a certain loss of comparability. This is recognised as a common problem in economic evaluation alongside clinical trials.[144]

There were also difficulties in collecting data from such a complex, highly mobile population. In retrospect, it may have been a more efficient use of resources to have concentrated on one data collection sweep, instead of two. This would have allowed more time for additional recruitment and additional qualitative interviews to inform the results.

Other limitations to the economic evaluation

The overall cost results were highly sensitive to the assumptions made about health and social care service use outcomes in the intervening periods between follow-up points for which data were not collected in the trial. The conclusion reached from the sensitivity analysis is that in future studies resource use variables should be captured over the whole study period, rather than estimated on the basis of 'snapshot' views, especially in the postnatal and early years period where health and social care use are likely to change fairly rapidly over time.

Morrell and colleagues[68] comment that the costs of providing support interventions are inflated when women's satisfaction is not valued as an outcome. The implication for future economic evaluation of similar interventions is that methods of either contingent valuation (willingness to pay) or conjoint analysis should be considered for assessing women's preferences and values for services and outcomes.

Findings of the SSFH study in the context of other research evidence

The SSFH study was planned and implemented against the background of a number of systematic reviews, which have highlighted the need for well-designed experimental studies capable of answering important unanswered questions about the relationship between social support and health. The specific research gaps (discussed in Chapter 1) are:

- The lack of well-designed RCTs carried out in the UK, compared with other countries.
- The failure of many support trials to include culturally and ethnically diverse samples.
- The lack of evidence from existing research about the appropriateness and effectiveness of professional versus non-professional support.
- The need to answer questions about the effectiveness of support interventions in altering different health and welfare outcomes.
- Lack of evidence from existing studies about the economic costs of different interventions.

As a trial carried out with a culturally and ethnically diverse sample in a UK setting, the SSFH study offers limited evidence for the effectiveness of offering additional support services to women with young children. The two interventions tested compared the offer of the 'professional' strategy of supportive home visiting by specially trained health visitors and the offer of a 'non-professional' strategy involving referral to a community support group with the services routinely available to new mothers. There was no evidence of effect of either intervention on the three main trial outcomes: child injury, maternal

depression and maternal smoking. There was some evidence of mixed pattern of effect on service use. There was enhanced use 12 months postrandomisation of NHS health visitor and social work services by women offered the SHV intervention and less use of GPs by their children. At 18 months postrandomisation, there was less use of midwifery services among women in both intervention groups and more use of health services, particularly GP services, among children in the CGS group. The trial results also suggest a real effect at both follow-up points on mothers' worries about their children's health and development, and on the use of specific medications for children, which were lower among SHV women and higher among CGS women compared with women in the control group.

While the SSFH study fills some of the research gaps identified above, it does not satisfactorily answer the question about professional versus non-professional support, since uptake of the offer of community group support was so low. The enthusiasm of many of the women allocated to the SHV intervention for a personalised home-visiting service repeats the findings of other studies;[2] as does the combination of satisfaction with a lack of identifiable effect on depression and other primary study outcomes.[68,145] It is difficult to compare the extent of social disadvantage and ethnic diversity in the SSFH study sample with samples included in other trials of social support, since relatively few provide sufficient details on the nature of their samples. However, it seems likely that the SSFH study sample was more highly socially disadvantaged, especially with regard to the high levels of refugees and asylum seekers and linguistic diversity within the target population.

Implications for service providers and policy makers

The SSFH study provides no evidence that either of the two models of support tested (non-judgemental listening provided by specially trained health visitors and the support available from local community organisations) is appropriate or effective enough to offer clear-cut benefits over existing services for the primary trial outcomes of maternal depression, child injury and maternal smoking. Nor do they appear to influence household resources: current financial situation, maternal employment status or maternal view of social support.

With respect to health service use and experiences of motherhood and perceptions of child health and development, the results are more favourable for the SHV intervention, and become more clearly so when the economic evaluation is taken into account. In the SHV group there was some evidence of a changed and more appropriate use of services. In the control group nearly half of the children had been taken to a GP in the month preceding the first follow-up; this was substantially reduced to 38% of children in the SHV group. It seems probable that SHVs were able to advise and reassure mothers about some health and developmental issues, as well as advising women that social work and statutory health visitor services could be useful to them. SHV mothers also had significantly fewer worries than the control group about their child's development. This suggests that SHVs were able to encourage women and possibly to improve their self-confidence and their confidence in their ability to care for their children. It is worth noting that this intervention was created as an additional separate service to the normal NHS health visiting service; it is not known what the service would look like if it was integrated completely into standard health visiting practice.

The apparent inability of either intervention significantly to improve major health outcomes is consonant with the views stated in the process evaluation by the providers of both interventions. The view was expressed that social support alone, whether given by health visitors or by community services, is unlikely to be able to counteract the health-damaging effects of social and material disadvantage, including the stresses and difficulties that are a normal part of many mothers' lives in countries such as the UK today.

Beyond the main trial outcomes, there were some interesting findings that have implications for service providers and policy makers. These include the low uptake of community group services, the use of standard services by non-English-speaking women, and issues of transport and accessibility of services for new mothers. These additional findings will be discussed further in subsequent articles.

Unanswered questions and recommendations for future research

Parenting has been described as "the most important public health issue facing our society".[146] Identifying effective interventions for parents with young children, especially disadvantaged parents, is therefore a research priority.

The summary in this chapter of the results of the SSFH study may either overestimate or underestimate the 'real' effects of providing additional social support to parents living in disadvantaged circumstances. It is important to take into account here both the methodology of the study (its external and internal validity) and the data collected as part of the process evaluation, which describe how the interventions were implemented and received by the study women.

Recommendations for research

The limitations of the study in the context of other research suggest a number of specific issues for future research.

- This study is one of many recent trials of social support and its effect on health. The authors recommend that the results of these trials now be synthesised in a systematic review.
- The researchers recommend that future research on postnatal support match more closely appropriate models of support with the age of babies and the changing pattern of mothers' needs. For example, it might be more appropriate for health visitors and community groups to offer home visits sooner after the child was born (instead of, as in this trial, beginning at 10 weeks postpartum) and to have these visits focused until 6 months after the baby was born. Alternatively, the intervention could be offered throughout pregnancy and the first 6 postnatal months. The home visits could be offered at more frequent intervals (weekly or fortnightly) during this period.
  Conversely, community services offering support *outside the home* may be more appropriate if targeted to women when the child is 6–18 months old. Uptake might be improved by regular reminders of the services on offer.
- Research is still needed that directly compares the acceptability of professional and non-professional provision of postnatal support to mothers. The authors recommend that work be carried out which explores two home visiting interventions that are identical except for the professional credentials of the supporters. Although some studies have found it possible to recruit volunteer supporters, this was found to be extremely problematic, and would suggest that comparisons should be between paid supporters with and paid supporters without health qualifications.
- The researchers recommend the design and testing of a more culturally sensitive intervention or set of interventions for use with target populations of the kind included in the SSFH study. These should include the training and use of supporters from the relevant communities. Participation of members of these communities in the development of such interventions would be essential. Consideration should be given to bringing some language supporters from outside the study area to provide an intervention, because of fears about confidentiality within small communities.
- Other recent trials of postnatal social support[68,139] have questioned the suitability of established outcome tests of health and psychological well-being in measuring small changes gained from the offer of support. This study team supports Reid and colleagues' contention that: "*'Hard' measures are difficult to use and 'soft' measures remain imperfect assessments*".[139] This was especially true when using standardised instruments with women whose first language was not English. There is a strong need for more culturally appropriate standardised measures of outcomes than are currently available. Further development is recommended of appropriately sensitive tools for the measurement of changes in health and well-being.
- Although the SSFH study had a longer period of follow-up than many others, the follow-up at 18 months postrandomisation only allowed for collection of data 6 months after the planned end of the intervention. It is possible that the women who were enthusiastic about either the SHV or CGS intervention were experiencing withdrawal symptoms at this time-point; they could therefore have reported more negative outcomes than they did earlier or would have done had they been asked later. It is possible that longer term follow-up might show either more or less difference between outcomes in the three trial groups than has been detected so far. The authors recommend that longer term follow-up be built into future trials of social support.
- There was a trend among the women in the SHV arm of the trial to delay the birth of subsequent children. The theory that social support can influence delay in subsequent pregnancy should be considered as an aspect of additional future research on postnatal social support.

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Appendix 1

Community groups considered for participation in the trial

General Information

Information Unit, Islington Council
Information Unit, Camden Council (Cindex)
Islington Voluntary Action Council
Camden & Islington GHC
Camden & Islington Health Authority
Healthy Islington 2000
Exploring Parenthood
Maternity Alliance
Association for Post Natal Illness
Camden & Islington Advocacy Service
Camden Health & Race Group
Cry-sis
www.babyonline.com.yelpages
Chinese Health Resource Centre
NHS free-phone help line (pre-NHS Direct)
Education Department Early Years Service (North East, North West, South)
Family Welfare Association
National Childbirth Trust
NSPCC

Group Information

African Association for Maternal and Child Care International
African Women's Welfare Association
Anna Freud Center Parent Infant Project
Camden Black Sisters Umoja Group
Camden Chinese Community Centre Nursery
Coram Fields Drop-in
Finsbury Park Homeless Families and Refugees Centre
Holborn Community Association
Home-Start Islington
Home-Start Camden
Hopscotch Asian Women Centre
Islington Chinese Association
Islington Somalia Community
Kentish Town Health Centre Post Natal Group
King's Cross Neighbourhood Centre
Meet-a-Mum (MAMA)
National Childbirth Trust – Hackney and Islington Branch
Pakistan Women's Welfare Association
Parents & Co.
Parentline
Somali Welfare Centre
1A Family Centre

Appendix 2

Unit costs of health and social services used by women and children in the SSFH study

Unit costs of health and social services used by participants in SSFH trial (£, year 2000 prices)

	Base case unit cost	Source	Comments
Child (cost per contact)			
GP at surgery or clinic	17.46	PSSRU (2000)[126]	Assumes consultation lasting 9.36 minutes. Including direct care staff costs and qualification costs
Doctor in hospital (outpatient attendance)	31.49	PSSRU (2000)	Consultant medical, consultation lasting 20 minutes
GP at home	38.00	PSSRU (2000)	Assumes home visit lasting 13.2 minutes, includes 12 minutes travel time
Health visitor at clinic or surgery	10.55	SSFH costing study	Own costing exercise carried out in April 2001, using financial data for 1999 and 2000 from NHS Camden & Islington community services
Health visitor at home (per hour)	49.16	SSFH costing study	Own costing exercise carried out in April 2001, using financial data for 1999 and 2000 from NHS Camden & Islington community services
Night in hospital	318.37	PSSRU (2000)	Paediatric inpatient day
A&E overnight	289.61	PSSRU (2000)	
A&E day case	46.22	PSSRU (2000)	
A&E outpatient	66.76	PSSRU (2000)	
Cost per course of medication	16.53	PSSRU (2000)	Prescription costs per consultation
Mother			
Doctor at surgery/clinic	23.62	PSSRU (2000)	Clinic consultation lasting 12.6 minutes, including direct care staff and excluding qualification costs
Doctor in hospital (outpatient attendance)	31.49	PSSRU (2000)	Consultant medical, consultation lasting 20 minutes
GP at home	38	PSSRU (2000)	Assumes home visit lasting 13.2 minutes, including 12 minutes travel time
GP telephone contact	19.51	PSSRU (2000)	Assumes telephone contact for 10.8 minutes, includes direct care staff
Health visitor at the clinic/surgery	12.96	SSFH costing study	Own costing carried out in April 2001, using 1999–2000 financial data (NHS Camden & Islington community services)
Health visitor at home (per hour)	49.16	SSFH costing study	Hourly cost of home visit: average time per visit from time sheets was 48 minutes
Health visitor over the telephone	4.15	SSFH costing study	Assumes average time of 6 minutes
Midwife home visit	87.27	PSSRU (2000)	Assumes home visit lasting 60 minutes
Prescription cost per consultation	16.53	PSSRU (2000)	Average prescription costs per consultation

Appendix 3

First follow-up results: intervention group versus control group

	Intervention			Control			RR (95% CI)
	n/*N*		%	*n*/*N*		%	
Maternal depression							
Self-reported: depressed or low spirited	114/327		35	121/325		37	0.94 (0.76 to 1.15)
EPDS score ≥ 12	81/304		27	90/303		30	0.90 (0.70 to 1.16)
	N	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
Mean EPDS score	149	8.37	(5.7)	303	8.98	(5.3)	–0.61 (–1.48 to 0.25)
	n/*N*		%	*n*/*N*		%	**RR (95% CI)**
Child injury requiring medical attention							
Injury in past 6 months	43/325		13	48/326		15	0.90 (0.61 to 1.32)
Maternal smoking							
Smokes	83/329		25	90/327		28	0.92 (0.71 to 1.18)
Maternal health service use in previous month							
Use of any health service	171/327		52	175/326		53	0.98 (0.85 to 1.13)
No. of visits to:	***N***	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
GP at clinic/surgery	329	0.67	(1.0)	328	.83	(1.3)	–0.15 (–0.34 to 0.02)
Doctor in hospital	329	0.20	(0.7)	326	.29	(1.4)	–0.09 (–0.30 to 0.06)
Doctor at home	329	0.04	(0.3)	328	0.02	(0.1)	0.02 (–0.02 to 0.06)
Health visitor at clinic/surgery	329	0.10	(0.5)	328	0.04	(0.3)	0.06 (0.01 to 0.12)
Health visitor at home	329	0.05	(0.3)	328	0.02	(0.2)	0.03 (–0.01 to 0.06)
Health visitor on telephone	329	0.07	(0.4)	328	0.09	(0.01)	0.06 (0.02 to 0.12)
Midwife	328	0.09	(0.5)	327	0.17	(1.1)	–0.07 (–0.23 to 0.04)
Social worker	328	0.05	(0.4)	328	0.02	(0.2)	0.03 (–0.01 to 0.07)
	n/*N*		%	*n*/*N*		%	**RR (95% CI)**
Index child's health service use in previous month							
Use of any health service	212/327		65	220/326		68	0.96 (0.86 to 1.07)
No. of visits to:	***N***	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
GP at clinic/surgery	327	0.70	(1.1)	326	0.80	(1.1)	–0.11 (–0.27 to 0.06)
Doctor in hospital	327	0.17	(0.5)	326	0.25	(1.7)	–0.09 (–0.34 to 0.05)
Doctor at home	327	0.02	(0.2)	326	0.04	(0.3)	–0.02 (–0.06 to 0.02)
Health visitor at clinic/surgery	327	0.41	(0.9)	326	0.41	(0.8)	–0.01 (–0.12 to 0.12)
Health visitor at home	327	0.09	(0.7)	326	0.03	(0.2)	0.06 (0.003 to 0.15)
Index child's use of hospital services: previous 6 months							
Outpatient visits	317	0.44	(1.2)	319	0.30	(0.8)	0.13 (–0.11 to 0.30)
A&E visits	309	0.37	(0.7)	314	0.36	(0.7)	0.01 (–0.10 to 0.12)
Inpatient episodes	326	0.07	(0.3)	326	0.07	(0.3)	0.003 (–0.04 to 0.05)

continued

	Intervention		Control		RR (95% CI)
	n/N	%	*n/N*	%	
Maternal health and medication use in last week					
Not very good/mixed health	60/323	19	85/326	26	0.71 (0.53 to 0.95)
Had any form of medication	175/327	54	176/324	54	0.99 (0.85 to 1.14)
Painkillers	155/327	47	157/324	49	0.98 (0.83 to 1.15)
Vitamins	82/327	25	87/324	27	0.93 (0.72 to 1.21)
Decongestants	36/327	11	40/324	12	0.89 (0.58 to 1.36)
Alternative remedies	31/327	10	40/324	12	0.77 (0.49 to 120)
Antibiotics	25/327	8	22/324	7	1.13 (0.65 to 1.96)
Antidepressants	15/327	5	15/324	5	0.99 (0.49 to 1.99)
Sleeping pills	7/327	2	8/324	3	0.87 (0.32 to 2.36)
Tranquillisers	1/327	1	5/324	2	0.20 (0.02 to 1.69)
Other medication	28/327	9	36/324	11	0.77 (0.48 to 1.23)
Child health and medication use in last week					
Not very good/mixed health	15/329	5	22/321	7	0.67 (0.35 to 1.26)
Any form of medication	216/329	66	203/328	62	1.06 (0.95 to 1.19)
Painkillers	171/328	52	154/325	47	1.11 (0.95 to 1.29)
Skin ointment	62/328	19	83/325	26	0.74 (0.56 to 1.00)
Vitamins	67/328	20	71/325	22	0.94 (0.70 to 1.27)
Cough medicine	55/328	17	54/325	17	1.02 (0.72 to 1.43)
Decongestants	49/328	15	45/325	14	1.09 (0.75 to 1.58)
Antibiotics	32/328	10	35/325	11	0.91 (0.58 to 1.44)
Alternative remedies	19/328	6	25/325	8	0.72 (0.40 to 1.28)
Diarrhoea medicine	9/328	3	16/325	5	0.98 (0.86 to 1.11)
Asthma medicine	4/328	1	18/325	6	0.22 (0.08 to 0.65)
Other medication	13/329	4	9/328	3	1.44 (0.62 to 3.32)
Had colic	147/320	46	153/320	48	0.88 (0.75 to 1.03)
Has been immunised	306/324	94	305/321	95	0.99 (0.96 to 1.03)
Experience of motherhood					
Child 'not easy' to look after	88/323	27	80/324	25	1.10 (0.85 to 1.43)
Worries about child health	83/326	26	112/324	35	0.74 (0.58 to 0.94)
Worries about child development	15/318	4	18/322	6	0.73 (0.36 to 1.47)
Infant feeding					
Stopped breast-feeding by 26 weeks	153/280	55	135/277	49	1.12 (0.95 to 1.32)
Solids given before 16 weeks	82/319	26	70/317	22	1.16 (0.88 to 1.54)
Household resources					
Financially worse off than at birth of baby	136/324	42	151/323	47	0.90 (0.76 to 1.07)
Mother not in paid work	215/327	66	209/328	64	1.03 (0.92 to 1.16)
Overall supported 'not at all/fairly well'	144/326	44	163/328	50	0.89 (0.75 to 1.05)
Partner rarely or never gives support	29/265	11	39/267	15	0.75 (0.48 to 1.17)

Appendix 4

First follow-up results: SHV group versus combined control and CGS group

	SHV			Control + CGS			RR (95% CI)
	n/*N*		%	*n*/*N*		%	
Maternal depression							
Self-reported: depressed or low spirited	58/164		35	177/488		36	0.98 (0.77 to 1.24)
EPDS score ≥ 12	38/149		26	133/458		29	0.88 (0.64 to 1.20)
	N	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
Mean EPDS score	149	8.23	(5.4)	458	8.82	(5.5)	–0.58 (–1.58 to 0.41)
	n/*N*		%	*n*/*N*		%	**RR (95% CI)**
Child injury requiring medical attention							
Injury in past 6 months	24/164		15	67/487		14	1.06 (0.69 to 1.64)
Maternal smoking							
Smokes	39/165		24	134/491		27	0.87 (0.64 to 1.18)
Maternal health service use in previous month							
Use of any health service	87/165		53	258/492		52	1.01 (0.85 to 1.19)
No. of visits to:	***N***	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
GP at clinic/surgery	165	0.65	(0.9)	492	0.78	(1.3)	–0.13 (–0.31 to 0.04)
Doctor in hospital	165	0.17	(0.5)	490	0.27	(1.3)	–0.10 (–0.24 to 0.04)
Doctor at home	165	0.02	(0.2)	492	0.03	(0.3)	–0.01 (–0.04 to 0.03)
Health visitor at clinic/surgery	165	0.12	(0.5)	492	0.07	(0.3)	0.07 (–0.01 to 0.15)
Health visitor at home	165	0.07	(0.3)	492	0.03	(0.2)	0.05 (–0.00 to 0.10)
Health visitor on telephone	165	0.13	(0.6)	492	0.01	(0.1)	0.13 (0.04 to 0.21)
Midwife	165	0.13	(0.6)	492	0.13	(0.9)	–0.00 (–0.12 to 0.12)
Social worker	164	0.07	(0.4)	490	0.02	(0.3)	0.05 (–0.02 to 0.11)
	n/*N*		%	*n*/*N*		%	**RR (95% CI)**
Index child's health service use in previous month							
Use of any health service	100/165		61	332/488		68	0.89 (0.78 to 1.02)
No. of visits to:	***N***	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
GP at clinic/surgery	165	0.60	(0.9)	488	0.81	(1.1)	–0.21 (–0.38 to –0.04)
Doctor in hospital	165	0.15	(0.4)	488	0.23	(1.4)	–0.8 (–0.22 to 0.06)
Doctor at home	165	0.02	(0.2)	488	0.03	(0.3)	–0.01 (–0.5 to 0.3)
Health visitor at clinic/surgery	165	0.40	(0.7)	488	0.41	(0.9)	–0.01 (–0.14 to 0.11)
Health visitor at home	165	0.07	(0.3)	488	0.06	(0.5)	0.01 (–0.05 to 0.08)
Index child's use of hospital services: previous 6 months							
Outpatient visits	161	0.48	(1.4)	475	0.33	(0.8)	0.15 (–0.8 to 0.38)
A&E visits	165	0.37	(0.7)	485	0.32	(0.7)	0.05 (–0.07 to 0.17)
Inpatient episodes	164	0.08	(0.4)	488	0.07	(0.3)	0.01 (–0.05 to 0.07)

continued

	SHV		Control + CGS		RR (95% CI)
	n/N	%	*n/N*	%	
Maternal health and medication use in last week					
Not very good/mixed health	30/163	18	115/486	24	0.78 (0.54 to 1.12)
Had any form of medication	88/164	54	263/487	54	0.99 (0.84 to 1.17)
Painkillers	81/164	49	231/487	47	1.04 (0.87 to 1.25)
Vitamins	40/164	24	129/487	27	0.92 (0.68 to 1.25)
Decongestants	15/164	9	61/487	13	0.73 (0.43 to 1.25)
Alternative remedies	17/164	10	54/487	11	0.93 (0.56 to 1.57)
Antibiotics	11/164	7	36/487	7	0.91 (0.47 to 1.74)
Antidepressants	8/164	5	22/487	5	1.09 (0.49 to 2.38)
Sleeping pills	3/164	2	12/487	3	0.74 (0.21 to 2.60)
Tranquillisers	1/164	1	5/487	1	0.59 (0.07 to 5.05)
Other medication	11/164	7	53/487	11	0.62 (0.33 to 1.15)
Child health and medication use in last week					
Not very good/mixed health	6/165	4	31/485	6	0.61 (0.26 to 1.43)
Any form of medication	109/165	66	310/492	63	1.05 (0.92 to 1.19)
Painkillers	89/165	54	236/492	48	1.12 (0.95 to 1.33)
Skin ointment	23/165	14	122/492	25	0.56 (0.37 to 0.85)
Vitamins	35/165	21	103/492	21	1.01 (0.72 to 1.42)
Cough medicine	25/165	15	84/492	17	0.89 (0.59 to 1.34)
Decongestants	22/165	13	72/492	15	0.91 (0.58 to 1.42)
Antibiotics	17/165	10	50/492	10	1.01 (0.60 to 1.71)
Alternative remedies	11/165	7	33/492	7	0.99 (0.51 to 1.92)
Diarrhoea medicine	3/165	2	22/492	5	0.41 (0.12 to 1.34)
Asthma medicine	2/165	1	20/492	4	0.30 (0.07 to 1.26)
Other medication	5/165	3	17/492	4	088 (0.33 to 2.34)
Had colic	76/160	48	224/480	47	1.02 (0.84 to 1.23)
Has been immunised	152/164	93	459/481	95	0.97 (0.93 to 1.02)
Experience of motherhood					
Child 'not easy' to look after	46/163	28	122/484	25	1.12 (0.84 to 1.49)
Worries about child health	39/162	24	156/488	32	0.75 (0.58 to 1.02)
Worries about child development	8/162	5	23/478	5	1.03 (0.47 to 2.25)
Infant feeding					
Stopped breast-feeding by 26 weeks	77/140	55	211/417	51	1.09 (0.91 to 1.30)
Solids given before 16 weeks	42/160	26	110/476	23	1.14 (0.84 to 1.54)
Household resources					
Financially worse off than at birth of baby	67/164	41	220/483	46	0.90 (0.73 to 1.10)
Mother not in paid work	107/165	65	316/490	65	1.01 (0.88 to 1.15)
Overall supported 'not at all/fairly well'	70/163	43	237/491	48	0.89 (0.73 to 1.09)
Partner rarely or never gives support	14/132	11	54/400	14	0.79 (0.45 to 1.37)

Appendix 5

Second follow-up results: intervention group versus control group

	Intervention			Control			RR (95% CI)
	n/*N*		%	*n*/*N*		%	
Maternal depression							
Self-reported: depressed or low spirited	80/301		27	74/296		25	1.09 (0.81 to 1.40)
GHQ12: score ≥ 12	147/279		53	145/270		54	0.98 (0.84 to 1.15)
	N	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
Mean GHQ12 score	279	12.78	6.31	270	12.62	5.65	0.17 (–0.84 to 1.07)
	n*/*N		**%**	***n*/*N***		**%**	**RR (95% CI)**
Child injury requiring medical attention							
Injury in past 6 months	26/301		9	27/295		9	0.94 (0.56 to 1.58)
Maternal smoking							
Smokes	76/302		25	73/296		25	1.02 (0.77 to 1.35)
Maternal health service use in previous month							
Use of any health service	171/303		56	155/298		52	1.09 (0.94 to 1.26)
	N	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
GP at clinic/surgery	303	0.78	1.14	298	0.73	0.99	0.05 (–0.12 to 0.23)
Doctor in hospital	303	0.28	0.95	298	0.21	0.76	0.07 (–0.08 to 0.19)
Doctor at home	303	0.02	0.15	298	0.01	0.18	0.001 (–0.02 to 0.03)
Health visitor at clinic/surgery	303	0.02	0.14	298	0.02	0.13	0.003 (–0.02 to 0.03)
Health visitor at home	303	0.04	0.30	298	0.04	0.28	0.01 (–0.04 to 0.05)
Health visitor on telephone	303	0.04	0.31	298	0.02	0.25	0.02 (–0.02 to 0.06)
Midwife	303	0.17	1.18	298	0.21	0.73	–0.04 (–0.18 to 0.13)
Social worker	303	0.07	0.47	298	0.02	0.16	0.05 (0.002 to 0.12)
	n*/*N		**%**	***n*/*N***		**%**	**RR (95% CI)**
Index child's health service use in previous month							
Use of any health service	156/303		52	146/298		49	1.05 (0.90 to 1.23)
No. of visits to:	***N***	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
GP at clinic/surgery	303	0.65	1.06	298	0.54	0.82	0.11 (–0.04 to 0.27)
Doctor in hospital	303	0.15	0.48	298	0.14	0.45	0.001 (–0.10 to 0.07)
Doctor at home	303	0.03	.21	298	0.01	0.08	0.03 (0.004 to 0.05)
Health visitor at clinic/surgery	303	0.17	0.60	298	0.15	0.51	0.02 (–0.06 to 0.11)
Health visitor at home	303	0.03	0.19	298	0.04	0.20	–0.01 (–0.04 to 0.02)
Index child's use of hospital services: previous 6 months							
Outpatient visits	301	0.29	0.84	296	0.27	0.72	0.02 (–0.11 to 0.13)
A&E visits	302	0.25	0.55	296	0.23	0.53	0.03 (–0.06 to 0.11)
Nights in hospital	301	0.19	1.20	294	0.07	0.42	0.12 (–0.01 to 0.28)

continued

	Intervention		Control		RR (95% CI)
	n/*N*	%	*n*/*N*	%	
Maternal health in last month					
Not very good/mixed health	92/302	31	96/296	32	0.94 (0.74 to 1.19)
Headaches/migraines	140/300	47	152/293	52	0.90 (0.76 to 1.06)
Backpain	150/300	50	151/293	52	0.97 (0.83 to 1.14)
Problems remaining from giving birth	49/300	16	39/293	13	1.23 (0.83 to 1.81)
Anaemia	42/300	14	32/293	11	1.28 (0.83 to 1.97)
Eczema	28/300	9	35/293	12	0.78 (0.49 to 1.25)
Asthma	19/300	6	23/293	8	0.81 (0.45 to 1.45)
High blood pressure	14/300	5	11/293	4	1.24 (0.57 to 2.69)
Other problems	81/300	27	83/293	28	0.95 (0.73 to 1.24)
Three or more problems	83/300	28	81/293	28	0.97 (0.74 to 1.25)
Maternal medication use in last week					
Had any form of medication	173/303	57	166/298	56	1.02 (0.89 to 1.18)
Painkillers	148/303	49	141/298	47	1.03 (0.87 to 1.22)
Vitamins	93/303	31	78/298	26	1.17 (0.91 to 1.51)
Decongestants	43/303	14	37/298	12	1.14 (0.76 to 1.72)
Alternative remedies	28/303	9	30/298	10	0.92 (0.56 to 1.50)
Antibiotics	22/303	7	16/298	5	1.35 (0.72 to 2.52)
Antidepressants	8/303	3	17/298	6	0.46 (0.20 to 1.06)
Sleeping pills	4/303	1	4/298	1	0.98 (0.25 to 3.90)
Tranquillisers	1/303	0	1/298	0	0.98 (0.06 to 15.65)
Other medication	35/303	12	22/298	7	1.55 (0.93 to 2.58)
Child health and medication use in last week					
Not very good/mixed health	18/301	6	18/297	6	0.99 (0.52 to 1.86)
Any form of medication	190/303	63	186/298	62	1.00 (0.89 to 1.14)
Painkillers	136/303	45	113/298	38	1.18 (0.98 to 1.43)
Skin ointment	66/303	22	78/298	26	0.83 (0.63 to 1.11)
Vitamins	75/303	25	58/298	20	1.27 (0.94 to 1.72)
Cough medicine	56/303	19	60/298	20	0.92 (0.66 to 1.27)
Decongestants	42/303	14	36/298	12	1.15 (0.76 to 1.74)
Antibiotics	26/303	9	25/298	8	1.02 (0.60 to 1.73)
Alternative remedies	17/303	6	19/298	6	0.88 (0.47 to 1.66)
Asthma medicine	6/303	2	10/298	3	0.59 (0.22 to 1.60)
Experience of motherhood; worries about child development					
Child 'not easy' to look after	82/297	28	84/290	29	0.95 (0.74 to 1.23)
Worries about eating	66/298	22	57/293	20	1.14 (0.83 to 1.56)
Worries about sleep	39/298	13	36/293	12	1.07 (0.70 to 1.63)
Worries about speech	35/298	12	40/293	14	0.86 (0.56 to 1.31)
Worries about weight	29/298	10	28/293	10	1.02 (0.62 to 1.67)
Worries about toilet training	27/298	9	32/293	11	0.83 (0.51 to 1.35)
Worries about child behaviour	24/298	8	28/293	10	0.84 (0.50 to 1.42)
Worries about height	8/298	3	6/293	2	1.31 (0.46 to 3.73)
Worries about hearing	5/298	2	7/293	2	0.70 (0.23 to 2.19)
Worries about general development	2/298	1	5/293	2	0.39 (0.08 to 2.01)
Worries about something else	16/298	5	19/293	7	0.83 (0.43 to 1.58)
Household resources					
Financially worse off than 1 year previously	84/301	28	71/293	24	1.15 (0.88 to 1.51)
Mother not in paid work	191/299	64	191/293	65	0.98 (0.87 to 1.10)
Weekly household income ≤ £150/week	79/287	28	87/279	31	0.88 (0.57 to 1.22)
Partner rarely or never gives support	41/239	17	30/224	13	1.28 (0.83 to 1.98)
Overall supported 'not at all/fairly well'	141/301	47	135/298	45	1.03 (0.87 to 1.23)
Duke score ≥ 19	122/277	44	122/273	45	0.99 (0.82 to 1.19)

	N	Mean	(SD)	*N*	Mean	(SD)	Mean difference (95% CI)
Mean Duke score	277	18.27	7.36	273	18.55	7.81	–0.28 (–1.51 to 1.04)

Appendix 6

Second follow-up results: SHV group versus combined control and CGS group

	SHV			Control and CGS			RR (95% CI)
	n/*N*		%	*n*/*N*		%	
Maternal depression							
Self-reported: depressed or low spirited	34/144		24	120/453		27	0.89 (0.64 to 1.24)
GHQ12: score ≥ 12	70/136		52	222/413		54	0.96 (0.79 to 1.15)
	N	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
Mean GHQ12 score	136	12.56	(6.1)	413	12.75	(6.0)	–0.19 (–1.40 to 1.01)
	n*/*N		**%**	***n*/*N***		**%**	**RR (95% CI)**
Child injury requiring medical attention							
Injury in past 6 months	12/145		8	41/451		9	0.91 (0.49 to 1.68)
Maternal smoking							
Smokes	35/145		24	114/453		25	0.96 (0.69 to 1.33)
Maternal health service use in previous month							
Use of any health service	77/145		53	249/456		55	0.97 (0.82 to 1.16)
No. of visits to:	***N***	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
GP at clinic/surgery	145	0.72	(1.0)	456	0.77	(1.1)	–0.05 (–0.25 to 0.15)
Doctor in hospital	145	0.20	(0.6)	456	0.26	(0.9)	–0.06 (–0.19 to 0.07)
Doctor at home	145	0.03	(0.2)	456	0.02	(0.2)	0.01 (–0.02 to 0.04)
Health visitor at clinic/surgery	145	0.03	(0.2)	456	0.02	(0.1)	0.01 (–0.02 to 0.04)
Health visitor at home	145	0.07	(0.4)	456	0.03	(0.2)	0.04 (–0.03 to 0.11)
Health visitor on telephone	145	0.04	(0.4)	456	0.03	(0.3)	0.01 (–0.05 to 0.07)
Midwife	145	0.13	(0.8)	456	0.20	(1.0)	–0.07 (–0.23 to 0.08)
Social worker	145	0.06	(0.4)	456	0.04	(0.3)	0.02 (–0.05 to 0.10)
	n*/*N		**%**	***n*/*N***		**%**	**RR (95% CI)**
Index child's health service use in previous month							
Use of any health service	70/145		48	232/456		51	1.05 (0.90 to 1.23)
No. of visits to:	***N***	**Mean**	**(SD)**	***N***	**Mean**	**(SD)**	**Mean difference (95% CI)**
GP at clinic/surgery	145	0.57	(0.9)	456	0.60	(1.0)	–0.04 (–0.21 to 0.13)
Doctor in hospital	145	0.11	(0.4)	456	0.16	(0.5)	–0.05 (–0.12 to 0.03)
Doctor at home	145	0.01	(0.1)	456	0.02	(0.2)	–0.01 (–0.03 to 0.02)
Health visitor at clinic/surgery	145	0.19	(0.5)	456	0.15	(0.6)	0.04 (–0.05 to 0.13)
Health visitor at home	145	0.04	(0.2)	456	0.04	(0.2)	–0.00 (–0.04 to 0.04)
Index child's use of hospital services: previous 6 months							
Outpatient visits	144	0.35	(1.0)	453	0.26	(0.7)	0.08 (–0.09 to 0.26)
A&E visits	144	0.22	(0.5)	454	0.25	(0.6)	–0.03 (–0.12 to 0.07)
Nights in hospital	144	0.21	(1.4)	451	0.10	(0.7)	0.11 (–0.12 to 0.34)

continued

	SHV		Control and CGS		RR (95% CI)
	n/*N*	%	*n*/*N*	%	
Maternal health in last month					
Not very good/mixed health	43/145	30	145/453	32	0.93 (0.70 to 1.23)
Headaches/migraines	62/145	43	230/448	51	0.83 (0.68 to 1.03)
Backpain	66/145	46	235/448	53	0.87 (0.71 to 1.06)
Problems remaining from giving birth	17/145	12	71/448	16	0.74 (0.45 to 1.21)
Anaemia	21/145	15	53/448	12	1.22 (0.77 to 1.96)
Eczema	15/145	10	48/448	11	0.97 (0.56 to 1.67)
Asthma	7/145	5	35/448	8	0.62 (0.28 to 1.36)
High blood pressure	6/145	4	19/448	4	0.98 (0.40 to 2.40)
Other problems	39/145	27	125/448	28	0.96 (0.71 to 1.31)
Three or more problems	42/144	29	163/448	36	0.80 (0.60 to 1.06)
Maternal medication use in last week					
Had any form of medication	82/145	57	257/456	56	1.00 (0.85 to 1.18)
Painkillers	70/145	48	219/456	48	1.01 (0.83 to 1.22)
Vitamins	42/145	29	129/456	28	1.02 (0.76 to 1.37)
Decongestants	16/145	11	64/456	14	0.79 (0.47 to 1.32)
Alternative remedies	13/145	9	45/456	10	0.91 (0.50 to 1.64)
Antibiotics	11/145	8	27/456	6	1.28 (0.65 to 2.52)
Antidepressants	5/145	3	20/546	4	0.82 (0.31 to 2.15)
Sleeping pills	1/145	1	7/456	2	0.45 (0.06 to 3.62)
Tranquillisers	0/145	0	2/456	0.4	1.04 (0.11 to 9.91)
Other medication	18/145	12	39/456	9	1.45 (0.86 to 2.46)
Child health and medication use in last week					
Not very good/mixed health	9/144	6	27/454	6	1.05 (0.51 to 2.18)
Any form of medication	89/145	61	287/456	63	0.98 (0.84 to 1.13)
Painkillers	68/145	47	181/456	40	1.18 (0.96 to 1.45)
Skin ointment	22/145	15	122/456	27	0.57 (0.37 to 0.86)
Vitamins	33/145	23	100/456	22	1.04 (0.73 to 1.47)
Cough medicine	29/145	20	87/456	19	1.05 (0.72 to 1.53)
Decongestants	20/145	14	58/456	13	1.08 (0.68 to 1.74)
Antibiotics	13/145	9	38/456	8	1.08 (0.59 to 1.96)
Alternative remedies	9/145	6	27/456	6	1.05 (0.50 to 2.18)
Asthma medicine	2/145	1	14/456	3	0.45 (0.10 to 1.95)
Experience of motherhood; worries about child development					
Child 'not easy' to look after	39/143	27	127/444	29	0.95 (0.70 to 1.29)
Worries about eating	21/142	15	102/449	23	0.65 (0.42 to 1.00)
Worries about sleep	16/142	11	59/449	13	0.86 (0.51 to 1.44)
Worries about speech	9/142	6	66/449	15	0.43 (0.22 to 0.84)
Worries about weight	13/142	9	44/449	10	0.93 (0.52 to 1.68)
Worries about toilet training	13/142	9	46/449	10	0.89 (0.50 to 1.61)
Worries about child behaviour	10/142	7	42/449	9	0.75 (0.39 to 1.46)
Worries about height	2/142	1	12/449	3	0.53 (0.12 to 2.33)
Worries about hearing	2/142	1	10/449	2	0.63 (0.14 to 2.85)
Worries about general development	0/142	0	7/449	2	0.39 (0.05 to 3.10)
Worries about something else	7/142	5	28/449	6	0.79 (0.35 to 1.77)
Household resources					
Financially worse off than 1 year previously	44/144	31	111/450	25	1.24 (0.92 to 1.66)
Mother not in paid work	90/143	63	279/449	62	1.01 (0.88 to 1.17)
Weekly household income ≤ £150/week	36/133	27	130/433	30	0.90 (0.66 to 1.23)
Partner rarely or never gives support	20/118	17	57/351	16	1.04 (0.66 to 1.66)
Overall supported 'not at all/fairly well'	66/144	46	210/455	46	0.99 (0.81 to 1.22)
Duke score ≥ 19	54/132	41	190/418	46	0.90 (0.71 to 1.13)

	N	Mean	(SD)	*N*	Mean	(SD)	Mean difference (95% CI)
Mean Duke score	132	18.00	(7.3)	418	18.54	(7.7)	–0.54 (–1.98 to 0.91)

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We look forward to hearing from you.

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