Costs and effectiveness of community postnatal support workers: randomised controlled trial

Morrell C J, Spiby H, Stewart P, Walters S, Morgan A

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study compared usual care plus postnatal support in the community to usual care alone. The postnatal support intervention was defined as home visits in the first postnatal month (a maximum of 10 visits of up to 3 hours duration per visit) by a trained community postnatal support worker to help women rest and recover after childbirth and provide practical and emotional support. Usual care was defined as postnatal care at home by a community midwife.

Type of intervention
Treatment; Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population was women who lived in the recruitment area of the local hospital where the study was conducted. The women were aged 17 or over and delivered a live baby. Exclusion criteria were inability to give informed consent or communicate in English, or women whose baby was in the special care baby unit for more than 48 hours.

Setting
The setting in which the study intervention and comparator were delivered was the community. The authors implied that the study was conducted in their local setting, which was Sheffield, UK.

Dates to which data relate
The primary and secondary health outcome data, resource use and most unit cost (price) data were collected between 1996 and 1998. The unit costs of general practitioners, health visitors and social services were derived from national estimates, published in 1997.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
The resource use data used to estimate the costs for the study sample were prospectively collected from the trial participants and providers of the intervention and control services.

Study sample
The sample size calculation indicated that 360 women per group were required to detect a 5-point difference in Short
Form 36 (SF 36) general health perception scores, with 85% power at the 5% level of significance. The calculation assumed a standard deviation of 20 points on the SF 36 measure and 20% loss to follow up.

The study sample was recruited from postnatal wards at the recruiting hospital. A total of 623 women were recruited (311 intervention and 312 control).

A total of 3,102 confinements were identified during the recruitment period. Of these 34% were excluded. The three main reasons for exclusion were: lived outside the catchment area (70%), baby in special care baby unit or pre-term (15%), and language problem (9%). Of those who met the inclusion criteria, 82% were invited to participate and 37% of those invited gave informed consent.

Overall the trial sample represented 20% of the total number of confinements in the recruitment period. Statistically significant differences were reported (at the 5% level of significance) in the mean age, ethnic group and method of delivery between the sample recruited and those who refused to take part. The most common reason for refusal to participate was the availability of help at home.

**Study design**

The study used a single centre, randomised controlled trial design. The unit of randomisation was the woman who had delivered a baby. The study used a pre-prepared random digit allocation schedule and sequentially numbered, sealed opaque envelopes to allocate women to the intervention or control groups. The authors reported that allocation to the groups was concealed from all participants until after recruitment. No details were reported of whether the allocation was concealed from the investigators and analysts of allocation to groups.

The scheduled follow up period to collect data was 6 weeks and 6 months postnatally. The data were collected by postal questionnaire. Overall 88% of women returned the 6-week questionnaire, and 79% of women returned the 6-month questionnaire. There were some differences in the response rates between intervention and control groups at 6 weeks (90% intervention, 86% control) and 6 months (84% intervention, 74% control). The authors did not report reasons for non-return of the questionnaires.

**Analysis of effectiveness**

The authors stated that all analyses were conducted on an intention to treat basis. The analysis of health outcomes was based on completed questionnaire items returned by the trial participants, which was less than 100%. The analysis of cost data includes 12% of women allocated to the intervention group who declined all the postnatal community support visits.

The primary health outcome for the trial was general health, measured by the SF 36 general health perception domain score at 6 weeks. Measures of secondary health outcomes were the remaining SF 36 domains, Edinburgh postnatal depression scale, Duke functional social support scale and breast feeding rates.

The authors report that recruitment to the intervention and control arms was balanced. There were statistically significant differences between the intervention and control groups at recruitment. These were: use of transcutaneous electrical nerve stimulation (TENS) during labour (12% intervention, 7% control), incidence of twins (3% intervention, less than 1% control) and proportion of women with 1 or more adults living in the same home (87% intervention, 79% control). The authors did not report whether the analysis of data controlled for these differences.

**Effectiveness results**

At 6 weeks the mean difference in the primary outcome measure (SF 36 general health perception domain) was -1.6 (95% CI: -4.7 - 1.4, p=0.22), which was not statistically significant.

The authors reported statistically significant differences in the following SF 36 domains: Physical function -2.2 (95% CI: -4.6 - 0.5, p=0.01), social function -3.8 (95% CI: -7.7 - 0.3, p=0.03), Role limitation, physical -7.9 (95% CI: -14.6 - 0.9, p=0.008) and health change -3.00 (95% CI: -6.9 - 1.1, p=0.08) and the Edinburgh postnatal depression scale 0.7 (95% CI: -0.2 - 1.6, p=0.05). These differences were in favour of the control group.
There was no evidence of differences between the groups on any of the measures at 6 months.

Clinical conclusions
The authors concluded that there were no differences in the primary outcome (as measured by the general health domain, SF 36) between the interventions. The differences in the secondary outcomes found at the 6-week follow up were not present at the final 6-month evaluation.

Measure of benefits used in the economic analysis
A summary measure of health benefit was not defined in the paper. There were no statistically significant differences in health outcomes between the intervention and control groups. The economic analysis compared the costs of the two groups (cost minimisation analysis).

Direct costs
The direct costs of health and social care services and patient expenses were estimated from measures of resource use for each trial participant multiplied by the unit cost or price of those resources. The authors present resource use data and the costs of that resource use (i.e., resource use multiplied by unit cost).

Resource use for the intervention and control service was calculated from the number and duration of visits made by the postnatal community support workers and/or midwives. Travel costs, education, training and equipment was added to staff time to generate the total cost of the intervention and control service. The authors did not report the source of these items. The use of other services was estimated from trial participant reports of numbers of service contacts. These contacts included primary care services (GP's and health visitors), secondary and community care services (hospitals, mental health care services and social services), and patient’s personal expenditure.

Local cost data were used to estimate most unit costs. The authors did not report the methods used to derive these unit costs, or whether they were average or marginal costs. The unit costs of general practitioners (GP’s), health visitors and social services were estimated from published national estimates. The costs were based on 1996 unit cost or price values. The authors do not report whether any adjustment of the unit costs to reflect different price years was necessary.

The costs were estimated for the 6-week and 6-month follow-up periods only. Discounting of costs was not necessary. The authors did not report whether any adjustments were made to the observed levels of resource use to control for the impact of the trial on usual care (e.g., impact of postnatal support worker on midwifery practice in the intervention or control arms).

Statistical analysis of costs
A statistical analysis was used to compare the costs of the intervention and control group at 6-week and 6-months follow-up. Differences in each resource use and cost variable and total costs were tested with non-parametric tests (Mann-Whitney test). The authors did not report the level of significance used to determine whether there were statistically significant differences in costs. Confidence intervals (95%) were estimated for mean differences between groups using non-parametric bootstrap centile methods. The authors did not report the rationale for using these statistical methods on the data collected in the trial (e.g. the data were not normally distributed or the distributions of data differed between groups). The authors did not report whether the sample size of the study was sufficient to detect a difference if it existed. The authors did not report methods used to reduce the impact of multiple hypotheses testing on the chance of detecting a statistically significant difference where it did not exist.

Indirect Costs
Indirect costs were not included in this study.

Currency
Sensitivity analysis
The authors suggest that the costs of implementing and running the postnatal community support service may evolve over time. A one-way sensitivity analysis was used to assess the implications of different levels of activity and throughput on the costs of the postnatal community support service and total costs.

Estimated benefits used in the economic analysis
See Effectiveness results above.

Cost results
At 6 weeks the mean (sd) total costs were 635 (325) for the postnatal community support group compared to 456 (291) for the usual care group. The mean difference in costs was 180 (95% CI: 126 - 232, p=0.001), in favour of the control group.

At 6 months the mean (sd) total costs were 815 (565) for the postnatal community support group compared to 639 (500) for the usual care group. The mean difference in total costs was 179 (95% CI: 80 - 272, p=0.001), in favour of the control group.

There were no statistically significant differences in the use and costs of services other than the intervention (postnatal community support service and usual care) and control (usual care) service.

The costs included use of a range of primary, secondary and community health care services with which the women had contact.

The authors did not report whether women were asked to record all services used or only contacts with the services listed in the paper.

Synthesis of costs and benefits
There were no significant differences in the health outcomes measured, which meant that synthesis of costs and benefits was not necessary.

Authors’ conclusions
The authors concluded that there was no difference between the two groups in the primary health outcome measured, and no improvement in self perceived health status in the intervention group. They also concluded that there was little difference in the use and costs of NHS services, and that the postnatal community support service was an additional cost.

CRD COMMENTARY - Selection of comparators
The authors compared usual care with and without a postnatal community support service. Usual care was defined in the paper as postnatal care at home provided by community midwives in the local setting for the study. You, as a user of this database, need to assess whether this type of service and the level of care reported in the results are available in your setting.

Validity of estimate of measure of effectiveness
The study used an open randomised trial design, with outcomes measured with self-completion postal questionnaires. The addition of a new service to usual care made it difficult to mask patients to the allocation group. However, the analysis of data could have been masked to treatment allocation. The authors do not report whether this was done.
Approximately one third of women in the available recruitment population were excluded from the trial. Over 50% of women invited to participate in the trial refused to do so. The authors reported differences in mean age (mean difference 1 year, 95% CI: 0.5 - 1.6), proportion who were white, (p=0.001) and caesarean section, (p=0.02), between the study sample and the women eligible for the trial who refused to participate. The authors reported that the difference in mean age was statistically significant but not clinically important. The authors suggested that there might have been some self-selection in the trial based on perceived need for additional help. The reader should assess whether these factors and the exclusion criteria of being able to communicate in English affect the representativeness of the study sample and the generalisability of the health outcomes to non-trial participants.

The authors report differences in the characteristics of the groups at baseline (higher use of TENS, incidence of twin births, proportion living with 1 or more adults in the intervention group). These factors may have biased the results if they affected the need for, or use of, services or health outcomes. The authors reported that a balanced randomisation was achieved but did not report the methods used to control for these potentially confounding factors. There was a higher response rate in the intervention group than in the control group. Although an intention to treat analysis was planned, the actual analysis was carried out for questionnaire responders only. This may have biased the results if there were important differences in health outcomes between responders and non-responders.

The recruitment to the trial and the number of women who responded to the postal questionnaires to measure health outcomes and service use were lower than suggested by the power calculation for the study. It is not clear whether the lack of difference in effectiveness was due to equivalence or to insufficient observations to detect a difference.

**Validity of estimate of costs**
The authors listed the services for which utilisation was recorded but did not report whether this was a limited list selected by the study team as relevant for measurement or whether it comprised all services used by the trial participants. The reader should consider whether there are other relevant services, the inclusion of which could have affected the results of this study or the transfer of the results to a different setting.

The issues discussed above (recruitment, allocation between groups, response rates and final sample size for analysis) could also affect the measures of resource use and costs and the validity of the results.

**Other issues**
The authors discussed a number of limitations to the study and compared the results with evaluations of similar interventions in different health/disease areas. Overall, the results appear to have been consistent with studies of similar types of intervention. The authors suggested that the instruments used to measure health outcomes might not have been sensitive to small but important differences.

The authors reported in the discussion, that whilst there was no difference in health outcomes, 75% of women in the intervention group thought the additional postnatal support service was better than expected. The authors suggested that this might indicate benefits not valued within the trial.

The study was conducted in the UK, using a randomised controlled trial design. Self-selection into the study means that the costs and effects found in the intervention and control groups may differ in the population of women who could benefit from a postnatal support service. The reader should assess whether there are important differences in the study setting, and processes of care that would affect the generalisability of the results to their own setting.

**Implications of the study**
The authors suggest that additional research is required to identify appropriate measures of outcome for postnatal support services. The problems with the outcome measures used and the limitations of the evaluation noted above indicate that the evidence from this study is uncertain. Further evaluation may be necessary to inform health care policy.
Source of funding
Funded by the NHS Research and Development, Health Technology Assessment programme.

Bibliographic details

PubMedID
10977833

Original Paper URL
http://bmj.com/cgi/content/full/321/7261/593?maxtoshow=&amp;HITS=10&amp;hits=10&amp;RESULTFORMAT=&searchid=1012317125392_11127&amp;stored_search=&amp;FIRSTINDEX=0&amp;volume=321&amp;firstpage=593

Indexing Status
Subject indexing assigned by NLM

MeSH
Adolescent; Adult; Allied Health Personnel /economics; Breast Feeding; Community Health Nursing /economics; Cost-Benefit Analysis; Depression, Postpartum /prevention & control; Female; Follow-Up Studies; Great Britain; House Calls; Humans; Nurse Midwives /economics; Patient Satisfaction; Postnatal Care /economics; Pregnancy; Treatment Outcome

AccessionNumber
22000008262

Date bibliographic record published
31/01/2002

Date abstract record published
31/01/2002