A two-centred pragmatic randomised controlled trial of two interventions of postnatal support

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Objectives To establish whether providing additional postnatal support during the early postnatal months influences women's physical and psychological health and to identify health service benefits.

Design Pragmatic randomised controlled trial with a 2 × 2 factorial design with two interventions.

Setting Community centres, Ayrshire and Grampian, Scotland.

Population One thousand and four primiparous women, 83% completed the baseline questionnaire, 71% at six months.

Methods (1) An invitation to a local postnatal support group run weekly with a facilitator, starting two weeks postpartum. (2) A postnatal support manual, posted two weeks postpartum.

Main outcome measures Data regarding primary outcome postnatal depression (Edinburgh Postnatal Depression Scale, EPDS), secondary outcomes, general health measures (SF-36), social support (SSQ6), use of health services and women's views of interventions were collected at two weeks postpartum and at three and six months.

Results There were no significant differences in EPDS scores between the control and trial arms at three and six months, nor were there differences in the SF-36 and the SSQ6 scores. The 95% CI for the difference in EPDS effectively excluded a change in mean score of more than 10% with either intervention. There were no differences in health service attendances in primary or secondary care between the control and trial arms. Of those women who attended the groups, 40% attended six or more. Women reported favourably on the 'pack' with the majority reading it a few times and feeling that it was aimed at them.

Conclusions Wide-scale provision by the National Health Service of either support groups or self-help manuals is not appropriate if the aim is to improve measurable health outcomes.

INTRODUCTION

The importance of the postnatal care for the longer term health of women has been underlined by a number of policy documents on maternity care published over the last decade[1–4]. However, while this is acknowledged, there currently lacks a strong evidence base as to the effectiveness of different forms of care[5] and only within the last few years have randomised controlled trials been set up to examine in a rigorous manner alternative ways in which care can be provided[6]. What is evident in the above policy documents and elsewhere[7,8] is a concern about the existence of postnatal depression and the desire to develop effective interventions to ameliorate women's psychological distress. While the definition of 'postnatal depression' may remain debated[9], it is estimated that between 5% and 15% of women may suffer from this condition[10,11], although the proportion is seen to diminish after three months postpartum[12]. Others acknowledge that transition into motherhood may take its toll on women's mental and physical health[12,13].

Many investigators have noted the direct effects of social support on mental health[14,15], although few have studied this in relation to postnatal depression. The importance of the provision of social support for women in the postnatal period has been often argued (e.g. *Provision of Maternity Services in Scotland*[2] and *A Framework for Maternity Services in Scotland*[4]), but the term is complex and may be understood to have a wide range of definitions and meanings[16,17], and the range of possible interventions wide. Our study adopted a commonly accepted approach, that social support contains different components, namely informational, instrumental and emotional[16,18]; other postnatal trials have made similar assumptions [19,20]. Thus, the proposed interventions would offer support which would fall under two of the three headings, information and emotional, areas which women have reported are important to them (for example[21], *Provision of Maternity Services in Scotland*[2], which was based on extensive collaboration with consumer groups).

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A number of well conducted studies have provided evidence of positive benefits from social support during labour and delivery[22], although trials demonstrating an improvement in pregnancy have not shown an effect[17,23]. Those investigating social support effects on postnatal psychological health have been tended to be small scale and with methodological problems[24], while those with a good sample size showed no effect[19,20,24]. Thus, there remains uncertainty about the effectiveness of support in influencing postnatal psychological and physical health. The aim of this study was to ascertain the effects of providing additional postnatal support on women's psychological and physical health during the early postnatal months and to identify health service benefits from the provision of additional support measures.

METHODS

All primiparous women living in Ayrshire and attending the Ayrshire maternity hospital during the study period and women attending one Grampian maternity hospital and living within a 30 mile radius of Aberdeen were eligible. Ethical permission was granted by the Joint Ethical Committee (Grampian Health Board) and the Ayrshire and Arran Community Trust Ethics Committee.

Midwives from the two study hospitals agreed to recruit primiparous women who attended antenatal clinics between 34 and 37 weeks of pregnancy between October 1997 and June 1998. Women were approached when they were 34–37 weeks pregnant and asked for their consent to be included in the study. All women signed a consent form at this point and their hospital number was faxed to the trial co-ordinator based at Glasgow University. Randomisation was carried out postnatally by the trial co-ordinator once a live delivery had been confirmed, using a computer generated scheme with randomised permuted blocks, stratified by centre. Women whose infant subsequently died or was admitted to the Special Care nursery for more than two weeks were excluded from the study.

The study tested two postnatal interventions, the first, a self-help manual ('pack') and the second, an invitation to attend a support group ('group'), both sent to women two weeks postpartum. The pack, the *New Lives Magazine*, was produced by the Maternity Alliance and provides supportive information and advice geared to new mother and baby (mother's health, sleep and support needs, baby crying *etc*). The packs were devised in collaboration with women and piloted with multiethnic and social class readerships in mind. Information is presented in a 'woman-friendly' format with illustrations, quizzes and so on.

The groups were run on a weekly basis in six central locations in each health board. One facilitator per health board was trained to run the groups. The two facilitators came from a midwifery background and had experience with group work. A training session was run at the start of the study with the facilitators; the premise of the group work was that the agenda of the groups should be drawn up with the attendees; pilot sessions indicated that topics tended to centre on those associated with the baby; however women were also encouraged to talk about issues that related to their own health and wellbeing. Feedback from the group facilitators (the subject of a further paper) suggests that they did so. Facilitators ran each group for a two hour period. Women were encouraged to attend with a colourful invitation with the date and venue of their nearest group; this was re-sent to inform them of the date of the next group session in their locality. Women did not receive any additional incentives relating to the pack.

Three standardised tests were used to assess physical and mental health and social support. These included the Edinburgh Postnatal Depression Scale (EPDS)[25], a screening tool for postnatal depression (a score of 12 or more indicating potential depression and the need to investigate further), the SF-36[26], which rates mental and physical wellbeing along eight dimensions of health, and the SSQ6[27], a well validated measure of social support, providing two scores, a numerical score of the number of supports identified by the individual, and the degree of satisfaction with supports of 1–6 (6 = *high satisfaction*). Women completed three postal questionnaires at baseline (pre-intervention) and at three (post-intervention) and six months (follow up). The baseline questionnaire included the first two measures and the three and six month questionnaires included all three. Questionnaires 2 and 3 also enquired about health service usage while women in the relevant trial arms completed sections relating to their perceptions of the intervention(s). Non-respondents were followed up after two weeks with a reminder.

Demographic data were collected from the records of all participating (and non-participating) women. In Ayrshire data were abstracted manually from medical records while the Aberdeen Maternity and Neonatal Databank computerised data-base provided the data for Grampian. Queries in both centres were checked from medical records by MR and CG. Data were collected on age of mother, occupation of mother and partner if known, mode of delivery and birth outcome. Social class was allocated by MR to each parent using the Registrar General's Classification of Occupations, and a Depcat score[28] was derived from postcodes in Ayrshire and Grampian (Depcat is a Scottish wide deprivation score based on postcode sectors, originally derived by Carstairs and Morris from four factors reported in the national census, over-crowding, male unemployment, low social class and no car; the score can be calculated for any individual with a Scottish address from their postcode). Analysis of social class was subsequently re-grouped into 'middle class' (SC 1,11, and 111NM) and 'working class' (SC 111M, 1V and V). Depcat analysis was carried out by three categories, 1–2 (affluent), 3–5 (intermediate) and 6–7 (deprived). Information was not collected on ethnicity; Ayrshire has the greater population of ethnic minority

women (0.5% of the total population of the board, 1997 figures); language barriers are not reported as a difficulty with this generation of women in either health board. The facilitators of the support groups completed a short questionnaire which included questions about attendance numbers, length and time of day of the groups, activities carried out and topics discussed. Economic analysis of the costs to women was carried out (but not presented here).

The pragmatic randomised trial of the two interventions used a 2 × 2 factorial design and was analysed by 'intention-to-treat'. For the power calculation, the 'threshold approach' was used. Using the 15% incidence of postnatal depression described by Cox *et al.*[11], then a total sample size of 1350 women will give 80% power to detect a reduction from 15% to 10% at the 5% significance level. By setting appropriate thresholds, this is appropriate to the EPDS. Test scores at three months were used as the primary end point when ascertaining efficacy. An explicit rate of uptake of the intervention was not built into power calculations because with a pragmatic trial the rate is subsumed into the estimated effect size.

The data were analysed by pooling the four intervention groups as 'pack *versus* no pack' and 'group *versus* no group'. Interaction effects were explored but are not reported here as such analyses lacked statistical power. χ^2 tests were used to compare proportions and analysis of covariance (ANCOVA) was used to analyse the raw EPDS and SF-36 scores at three and six months, adjusting for the baseline measurements. Medians were not found useful. We recognise that the distributions are skewed, especially for EPDS, but with the sample sizes involved, the ANCOVA would be expected to produce robust results.

RESULTS

Of 1173 women approached antenatally by midwives, 1004 women agreed to participate and 169 (14%) refused. Participants differed from the non-participants, being older (mean ages: participants 26.5 years, non-participants 25.1 years, $P = 0.004$, 95% CI for difference = 0.5–2.3) and more likely to have a higher Depcat score. Of the 1004

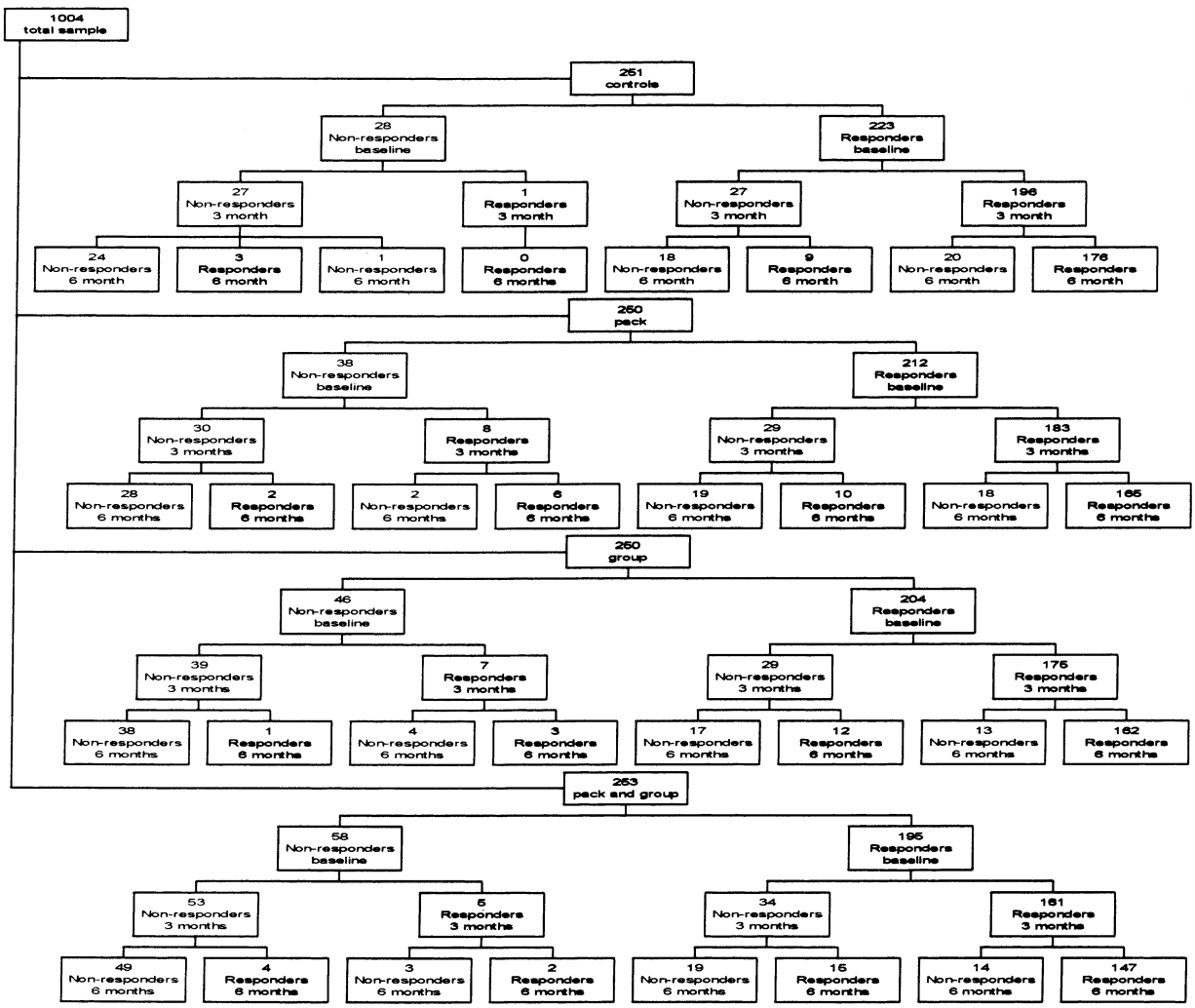

Fig. 1. Responders and non-responders by four trial arms.

Table 1. Baseline characteristics of sample by pooled groups. Values are given as *n* (%) and mean [SD].

	Pack		Group	
	Yes	No	Yes	No
Centre				
Grampian	249	245	248	246
Ayrshire	254	256	255	255
Age	26.4 [5.71]	26.5 [5.50]	26.3 [5.62]	26.6 [5.59]
Social class*				
1–111NM	222 (44.1)	230 (45.9)	209 (41.6)	243 (48.5)
111M–1V	234 (46.5)	231 (46.1)	253 (50.3)	212 (42.3)
Depcat*				
1–2	156 (31.0)	168 (33.5)	171 (34.0)	153 (30.5)
3–5	289 (57.5)	282 (56.3)	281 (55.9)	290 (57.9)
6–7	49 (9.7)	41 (8.2)	45 (8.9)	45 (9.0)
Delivery				
Spontaneous	271 (53.9)	298 (59.5)	289 (57.5)	280 (55.9)
Assisted	114 (22.7)	102 (20.4)	106 (21.1)	110 (22.0)
Caesarean	114 (22.7)	99 (19.8)	103 (20.5)	110 (22.0)
EPDS $\geq$ 12	61 (15.2)	71 (16.8)	65 (16.5)	67 (15.6)
SF-36				
Physical functioning	85.2 [17.78]	85.1 [18.16]	86.0 [18.08]	84.5 [17.85]
Role physical	52.4 [42.62]	57.2 [40.43]	56.6 [41.72]	53.2 [41.40]
Bodily pain	59.7 [25.17]	63.0 [24.92]	61.8 [25.66]	61.0 [24.56]
General health	79.5 [15.79]	79.0 [17.45]	78.9 [17.42]	79.5 [15.93]
Vitality	48.2 [18.80]	48.5 [19.34]	48.1 [19.58]	48.6 [18.60]
Social functioning	72.7 [23.24]	72.2 [23.53]	72.1 [24.31]	72.8 [22.50]
Role emotional	73.9 [37.51]	74.7 [36.90]	73.9 [37.36]	74.7 [37.05]
Mental health	72.5 [16.60]	73.0 [15.49]	72.2 [16.97]	73.3 [15.13]

* Depcat categories 1–7 regrouped into three groups: 1–2 (affluent), 3–5 (intermediate) and 6–7 (deprived).

participants, 834 (83%) women completed the baseline questionnaire, 736 (73%) the three month questionnaire and 717 (71%) women the six month questionnaire (Fig. 1). Response rates from baseline to six months did not differ by trial group: 84% (control), 86% (pack), 87% (group) and 86% (pack and group). Not all women who responded at three months had completed the baseline survey and not all six month responders had completed the baseline and three month questionnaire. The groups were well balanced at baseline (Table 1).

Regarding postnatal depression, there were no statistically significant differences in EPDS scores between intervention and corresponding control women either with the proportion scoring $\geq$12 (Table 2) or for mean EPDS scores (Tables 3 and 4). The confidence intervals for the differences in mean EPDS scores were tight, effectively excluding the possibility of a difference of greater than 10% with either intervention. Scores for all eight dimensions of health from the SF-36 were not significantly different between the two groups and showed no effect of the pack or the group (Tables 3 and 4). What is evident is that for some dimensions (notably for vitality, role physical and social functioning) mean scores at baseline were low (i.e. poorer health) in comparison with a UK community

Table 2. Women with EPDS score of 12 and over, by pooled groups, at three and six months. Values are given as *n* (%) (denominators are the number of women who had a valid EPDS score at three and six months) and OR [95% CI].

	Pack			Group		
	No	Yes	OR [95% CI]	No	Yes	OR [95% CI]
3 months	53/376 (14.1)	48/356 (13.5)	1.05 [0.63, 1.47)	46/388 (11.9)	55/344 (16.0)	0.71 [0.28, 1.13]
6 months	45/364 (12.4)	50/345 (14.5)	0.83 [0.40, 1.27]	46/370 (12.4)	49/339 (14.5)	0.84 [0.41, 1.27]

EPDS = Edinburgh Postnatal Depression Scale.

Table 3. SF-36, EPDS and SSQ6 at three months by pooled groups. Means calculated from those that have baseline and three month data. Values are given as mean (SD) and difference [95% CI].

	Pack			Group		
	No	Yes	Difference [95% CI]*	No	Yes	Difference [95% CI]*
EPDS	6.0 (4.64)	5.8 (5.01)	0.1 [−0.50, 0.72]	5.8 (4.49)	6.1 (5.17)	0.0 [−0.62, 0.60]
SF-36						
Physical functioning	90.5 (14.03)	91.0 (13.86)	−0.6 [−2.40, 1.17]	90.8 (13.45)	90.8 (14.49)	0.6 [−1.19, 2.39]
Role physical	83.3 (29.78)	83.0 (31.84)	−1.1 [−5.36, 3.24]	83.6 (30.68)	82.7 (30.92)	1.9 [−2.43, 6.17]
Bodily pain	82.3 (22.03)	82.6 (21.21)	−1.0 [−4.02, 1.94]	82.3 (21.91)	82.7 (21.32)	0.1 [−2.90, 3.05]
General health	79.3 (17.75)	79.6 (17.04)	−0.2 [−1.95, 1.61]	79.2 (16.59)	79.8 (18.30)	−1.3 [−3.12, 0.45]
Vitality	58.0 (18.75)	59.2 (19.76)	−1.2 [−3.63, 1.16]	58.5 (18.40)	58.6 (20.17)	−0.3 [−2.70, 2.10]
Social functioning	85.4 (19.13)	85.5 (20.34)	−0.1 [−2.78, 2.55]	85.9 (19.11)	84.9 (20.37)	0.9 [−1.77, 3.58]
Role emotional	83.2 (30.44)	79.5 (36.01)	3.4 [−1.20, 8.08]	82.7 (31.92)	79.9 (34.71)	2.2 [−2.47, 6.86]
Mental health	75.8 (15.12)	76.5 (16.71)	−0.9 [−2.84, 0.97]	76.6 (15.07)	75.6 (16.80)	0.1 [−1.79, 2.06]
SSQ6						
Average number of supports	2.5 (1.20)	2.4 (1.09)	0.1 [−0.06, 0.28]	2.4 (1.14)	2.4 (1.16)	0.0 [−0.19, 0.15]
Average satisfaction	5.3 (0.77)	5.2 (0.82)	0.1 [−0.07, 0.18]	5.3 (0.82)	5.3 (0.76)	0.0 [−0.16, 0.09]

EPDS = Edinburgh Postnatal Depression Scale.

* Adjusted for baseline using ANCOVA for EPDS and SF-36.

based scores for women (data not shown), while the scores rose by six months to become comparable to the community samples[29].

For measures of social support, the SSQ6 scores at three months between the trial arms were not significantly different in the mean number of supports or with degree of satisfaction with supports (Tables 3 and 4).

There were no statistically significant differences between the trial groups with all measures of use of the health services including contact with health professionals at home and in the surgery and in and out patient attendances for mother and baby.

Only 92 (18%) of the 503 who were invited to attend did so. The majority of support groups had fewer than four attending and 89/309 sessions had no attendees. The main reasons for non-attendance were lack of convenience of the group (either through timing or location) and women not wishing to attend on their own, either because they felt shy or they might not know anyone at the group. However, of those who reported attending, the majority attended three or more meetings with over 40% attending six or more. When asked about whether they would pay for a group, 71% responded positively. There was an association between social class and attendance at the groups, with a higher

Table 4. SF-36, EPDS and SSQ6 at six months. Means calculated from those that have baseline and six month data. Values are given as mean (SD) and difference [95% CI].

	Pack			Group		
	No	Yes	Difference [95% CI]*	No	Yes	Difference [95% CI]*
6/12 EPDS	5.3 (4.88)	5.4 (5.35)	−0.0 [−0.72, 0.68]	5.3 (4.84)	5.3 (5.40)	0.1 [−0.59, 0.81]
6/12 SF-36						
Physical functioning	92.7 (14.36)	93.6 (11.28)	−1.0 [−2.78, 0.81]	92.7 (14.04)	93.7 (11.69)	−0.6 [−2.36, 1.23]
Role physical	85.8 (28.17)	89.8 (23.56)	−4.3 [−8.15, −0.54]	87.9 (26.21)	87.6 (26.00)	1.1 [−2.67, 4.95]
Bodily pain	86.1 (19.28)	87.1 (17.96)	−1.5 [−4.24, 1.22]	85.9 (19.32)	87.3 (17.90)	−1.0 [−3.77, 1.68]
General health	79.9 (18.09)	80.0 (16.24)	−0.2 [−2.11, 1.72]	79.5 (17.02)	80.4 (17.42)	−1.4 [−3.32, 0.50]
Vitality	59.1 (19.82)	60.3 (20.29)	−1.4 [−4.05, 1.28]	58.6 (20.20)	60.9 (19.84)	−2.4 [−5.03, 0.31]
Social functioning	88.1 (18.92)	88.1 (19.29)	−0.1 [−2.80, 2.61]	87.9 (18.76)	88.4 (19.45)	−0.7 [−3.38, 2.02]
Role emotional	85.4 (30.25)	87.2 (29.03)	−2.1 [−6.41, 2.21]	86.3 (29.82)	86.1 (29.52)	−0.2 [−4.49, 4.14]
Mental health	75.9 (15.92)	76.5 (16.56)	−0.9 [−3.06, 1.18]	76.0 (15.53)	76.5 (16.96)	−1.1 [−3.19, 1.05]
6/12 SSQ6						
Average number of supports	2.4 (1.18)	2.3 (1.13)	0.1 [−0.08, 0.27]	2.4 (1.17)	2.4 (1.15)	−0.0 [−0.21, 0.14]
Average satisfaction	5.3 (0.71)	5.3 (0.66)	−0.0 [−0.13, 0.09]	5.3 (0.71)	5.3 (0.66)	−0.1 [−0.17, 0.05]

EPDS = Edinburgh Postnatal Depression Scale.

* Adjusted for baseline using ANCOVA for EPDS and SF-36.

proportion of women from 'middle class' than 'working class' backgrounds reporting attending the groups (38% *versus* 17%, $\chi^2 = 18.45$, $df = 1$, $P < 0.001$) and owning rather than renting their house (33% *versus* 12%, $\chi^2 = 17.78$, $df = 1$, $P < 0.001$).

A total of 313 (62%) out of 503 women reported that they received the pack. Less than a tenth of them reported that they did not read at the magazine at all (9%), the remainder 'a few times' (77%), 'quite often' or 'many times' (13%). Just over a third (37%) said that they were willing to pay for it. By six months, over half of the responders ($n = 237$, 57%) reported reading the pack 'a few times or quite often'. Forty-one of those who received the pack said that it helped with health problems or worries about themselves or their baby without seeing a health professional. There was no evidence of an interaction between group and pack allocations among women randomised to receive both (not shown) and there was no evidence of an association between social class and those who reported reading the pack.

DISCUSSION

The trial was set up as a pragmatic trial in communities where other postnatal support options were available. The sample size was good and the trial obtained a high response rate. Nevertheless, the trial did not demonstrate any effect of either intervention on psychological, physical or social wellbeing. The low take-up rate for the interventions, in particular the support groups, reduced the likelihood of finding an effect. The findings of the study suggest, therefore, that while there is concern about the degree and form of postnatal support offered to women, wide-scale provision by the National Health Service of either intervention is not appropriate in the early puerperium if the aim is to improve measurable health outcomes.

While the findings are clear, the study leaves some questions unanswered. One interpretation of the lack of effect could be that the invitation to the support group is not perceived of as providing benefit to women at this stage in their lives. Support takes a number of forms[16,30] and it could be that predominantly emotional and informational supports are not appropriate at this time. More controversially, critics of the concept have suggested that support may not always be perceived as positive and that the notion that 'more is better' should be challenged. The feature in this trial and others[14] of the control group's comparatively good scores vis-à-vis those of the trial arms could be taken to reinforce the negative role of support.

Although it was demonstrated that women who attended a group were likely to return (and responses to open-ended questions about the groups were positive), a significant number of women did not take up the invitation to the support group, resulting in a lack of power to the analysis. One striking feature of the study was the high proportion of women who consented into the study, compared with the low numbers who took up the offer of attending postnatal groups. Although the nature of the study and its interventions were clearly explained to women, women were consented into the study antenatally and at a time when they had not yet experienced the impact of a new infant and its demands. The trial authors felt that to attempt to gain consent in the immediate postnatal hospital period was not good practice and that thereafter approaching women in their homes had practical difficulties. Nevertheless, the question remains about how appropriate it is to ask women to become involved with a study at a time when they may not realistically be able to judge how willing they may feel once the infant is born.

There are two further issues to be addressed. First, the marked social class bias of attendees might be explained by better resources and/or greater social confidence of middle class women. Such interventions therefore pose more problems to working class women who, for reasons of convenience (or lack of it) and social diffidence, find the notion of attending a group less attractive. Secondly, the impact of the trial structure may have affected the response rate to the invitation. Alternative forms of the randomised controlled trial are not conventionally used although they have been proposed in the literature[31,32]. A more flexible trial structure, for example, allowing women to choose the intervention that appeals or inviting women to attend with a friend rather than by themselves might accommodate those women who had concerns about this particular form of support.

At the more general level, postnatal interventions seldom show an effect if the study involves women from a community based, as opposed to a selected, sample. Thus, those interventions that demonstrate a reduction in postnatal depression (e.g. see Elliott[33]) have been carried out with a group of women already screened as potentially depressed. One could argue that the fairly dilute impact of the intervention is only felt where there is clear need and a very targeted population. This would reinforce the lack of generalisability of the small scale studies with targeted samples, but also makes it difficult to achieve any effect with larger community samples.

While this and other trials[19,23] have incorporated established outcome measures of psychological wellbeing and social support, it could be that these tests do not identify the small changes in wellbeing, which may result from the offer of support. Additionally, although the EPDS has been incorporated into routine practice in some areas in the UK[34], there is evidence that health visitor description of women's mood in the first two months has a better positive predictive value than the EPDS[35]. Psychological tests and tests associated with lifestyle changes such as those experienced in the postnatal period require greater exploration in the future. 'Hard' measures are difficult to use and 'soft' measures remain imperfect assessments.

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