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The research reported in this issue of the journal was commissioned by the HTA programme as project number 99/33/51. The contractual start date was in April 2003. The draft report began editorial review in August 2006 and was accepted for publication in October 2008. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Psychological interventions for postnatal depression: cluster randomised trial and economic evaluation. The PoNDER trial

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Objectives: To investigate outcomes for postnatal women attributed to special training for health visitors (HVs) in systematically identifying postnatal depression and delivering psychologically informed interventions, and to establish the cost-effectiveness of the intervention.
Design: A pragmatic randomised cluster trial with clusters allocated to experimental HV training arms or control, with an 18-month follow-up.
Setting: GP practices in the former Trent Regional Health Authority.
Participants: Women registered with participating GP practices who became 36 weeks pregnant during the recruitment phase of the trial, had a live baby and were on a collaborating HV's caseload for 4 months postnatally.
Intervention: HV training in the assessment of postnatal women, combined with either cognitive behavioural approach (CBA) or person-centred approach (PCA) sessions for eligible women, plus the option of a selective serotonin reuptake inhibitor if indicated.
Main outcome measures: The primary outcome was the proportion of at-risk women with a 6-month Edinburgh Postnatal Depression Scale (EPDS) score ≥ 12. The primary comparison was between at-risk women in the combined clusters randomised to HV training and women in practices randomised to provide HV usual care. The secondary comparison was to determine any differences between the proportions of women with a 6-month EPDS score ≥ 12 in the CBA and PCA groups.
Results: HVs in 101 clusters in 29 primary care trusts collaborated in the study. From 7649 eligible women 4084 (53.4%) consented to take part: 17.3% (595/3449) of women who returned a 6-week questionnaire had a 6-week EPDS score ≥ 12 and were at-risk women; 70.3% (418/595) of at-risk women had a 6-month EPDS score available. In total, 45.6% (67/147) of control group (CG) at-risk women had a 6-month EPDS score ≥ 12 versus 33.9% (93/271) of intervention group (IG) women ($p = 0.036$). A total of 32.9% (46/140) of at-risk women in the CBA group versus 35.1% (46/131) in the PCA group had a 6-month EPDS score ≥ 12 ($p = 0.74$). The CG mean 6-month EPDS score for at-risk women was 11.3 (SD 5.8) versus 9.2 (SD 5.4) for the IG ($p = 0.002$) and this remained statistically significant after adjusting for 6-week variables ($p = 0.001$). In total, 16.4% (150/914) of all women in the CG had a 6-month EPDS score ≥ 12 compared with 11.7% (205/1745) in the IG ($p = 0.003$). The CG mean 6-month EPDS score for all women was 6.4 (SD 5.2) compared with 5.5 (SD 4.7) for the IG ($p < 0.001$). The economic analysis results showed a consistent pattern of psychological approaches being cost-effective at funding levels used by the National Institute for Health and Clinical Excellence.
Conclusions: HV training was effective compared with HV usual care in reducing the proportion of at-risk women with a 6-month EPDS score ≥ 12, with a

wide confidence interval for the estimated intervention effect, suggesting that the true treatment effect may be small. The effect remained for 1 year. The economic evaluation demonstrated that the HV intervention was highly likely to be cost-effective compared with the control. There was no difference in outcomes between the CBA and the PCA groups.
Trial registration: Current Controlled Trials ISRCTN92195776.

Contents

List of abbreviations

ARM	Agnew Relationship Measure
BAC	British Association of Counselling
BacReN	Barnsley Research Network
BDI	Beck Depression Inventory
BSQ	Behaviour Screening Questionnaire
CBA	cognitive behavioural approach
CBA-F	cognitive behavioural approach face-to-face group
CBA-P	cognitive behavioural approach postal group
CBC	cognitive behavioural counselling
CBT	cognitive behavioural therapy
CCTR	Cochrane Controlled Trials Register
CDSR	Cochrane Database of Systematic Reviews
CG	control group
CINAHL	Cumulative Index to Nursing and Allied Health Literature (health database)
CORE-OM	Clinical Outcomes in Routine Evaluation Outcome Measure
CPHVA	Community Practitioners' and Health Visitors' Association
CPN	community psychiatric nurse
CRN	collaborative research network
DAS	Dyadic Adjustment Scale
DocReN	Doncaster Research Network
DSM-IV	*Diagnostic and Statistical Manual of Mental Disorders version IV*
DSM-III-R	*Diagnostic and Statistical Manual of Mental Disorders version III*
EPDS	Edinburgh Postnatal Depression Scale
GFC	general facilitative conditions
GHQ-12	12-item General Health Questionnaire
GIS	geographical information systems
HADS	Hospital Anxiety and Depression Scale
HTA	health technology assessment
HV	health visitor
ICC	intracluster correlation coefficient

continued

ICD-10	International Classification of Diseases
ICP	integrated care pathway
IG	intervention group
IMD	Index of Multiple Deprivation
IPT	interpersonal psychotherapy
ITT	intention to treat
LC	local co-ordinator
LEQ	Life Events Questionnaire
LOCF	last observation carried forward
LREC	Local Research Ethics Committee
MMR	measles, mumps and rubella immunisation
MRC	Medical Research Council
MREC	Multicentre Research Ethics Committee
MSR	Measure of Social Relationships
NDC	non-directive counselling
NICE	National Institute for Health and Clinical Excellence
NSF	National Service Framework
NUD*IST	Non-numerical Unstructured Data by Indexing, Searching and Theorizing (software)
NVivo	qualitative software package capable of handling rich text records
OPP	Opinions on Psychological Problems
PCA	person-centred approach
PCA-F	person-centred approach face-to-face group
PCA-P	person-centred approach postal group
PCDI	parent–child dysfunctional interaction
PCT	primary care trust
PND	postnatal depression
PPDSQ	Punjabi Postnatal Depression Screening Questionnaire
PSE	Present State Examination
PSI	Parenting Stress Index
PsycINFO	database covering international literature in psychology and related fields
RCT	randomised controlled trial
RIL	research information leaflet
SCAN	Schedules for Clinical Assessment in Neuropsychiatry
SCID	Structured Clinical Interview for DSM-IV Disorders
SD	standard deviation
SF-36	36-item Short-Form Health Survey Questionnaire
SF-12	12-item Short-Form Health Survey Questionnaire

SF-6D	a classification for describing health, derived from a selection of SF-36 items
SI	SCAN interviewers
SIGN	Scottish Intercollegiate Guidelines Network
ShefReN	Sheffield Research Network
SOAs	super output areas
SPSS	Statistical Package for Social Scientists
SSRI	selective serotonin reuptake inhibitor
STAI	State–Trait Anxiety Inventory
TAG	Trial Advisory Group
TCA	tricyclic antidepressants
TG&DQ	Toddler Growth and Development Questionnaire
TRG	Training Reference Group
QALY	quality-adjusted life-year
UKCP	United Kingdom Council for Psychotherapy
WHO	World Health Organization

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 in the notes at the end of the table.

Executive summary

Background

About 12.9% of women may have depression during the first postnatal year. There are problems in the identification of postnatal depression (PND) and the Edinburgh Postnatal Depression Scale (EPDS) has been used in the UK, with a clinical interview, to help assess postnatal women's mood and identify depressive symptoms and suicidal thoughts.

In the short term PND has been found to be amenable to treatment but not prevention. Antidepressants are effective but compliance is not good and it is not known which class is most helpful. Psychologically informed interventions offer a practical alternative and the potential role for health visitors (HVs) in PND has been promoted. The trial aimed to build upon evidence and address the limitations of previous research in PND and to examine the role of HVs in this context.

Aim and objectives

The primary trial aim was to estimate any differences in outcomes for postnatal women, families and infants attributed to special training for HVs in the intervention groups (IGs), delivered at GP practice (cluster) level, in systematically identifying depressive symptoms and delivering psychologically informed sessions, based on either cognitive behavioural principles or person-centred principles in primary care, compared with the HV usual care control group (CG). The secondary aim was to establish the relative cost-effectiveness of the intervention from an NHS perspective, relative to control.

The cluster level objective was to prepare the HVs to provide the individual level intervention, which was clustered within the wider training for the cluster-level intervention. The individual level objectives were to:

- identify at-risk women with a 6-week EPDS score ≥ 12
- identify IG at-risk women with an 8-week EPDS score ≥ 12 eligible for the HV psychological sessions
- identify any differences in the proportion of IG and CG at-risk women with a 6-month EPDS score ≥ 12 at 6 months postnatally
- monitor differences in secondary outcomes at 6, 12 and 18 months postnatally
- identify any differences in costs for use of services
- examine outcomes for women's infants and partners to 18 months postnatally.

A further set of secondary study objectives for all women who consented to take part in the study were to:

- identify any differences by group in the proportion of all women with a 6-month EPDS score ≥ 12
- monitor differences by group in secondary outcomes in all women at 6, 12 and 18 months postnatally
- monitor differences by group in the health of all women's partners at 6, 12 and 18 months postnatally
- monitor differences by group in infant development for all women to 18 months postnatally
- identify any differences in costs for use of services for all women in the intervention versus control groups.

Methods

The study was a pragmatic randomised cluster trial with clusters allocated to experimental HV training arms or control. This pragmatic trial of the effectiveness of an intervention provided under normal conditions aimed to answer a clinical question in a real-life clinical situation, excluding as few women as possible.

Eligible consenting women were sent a postal questionnaire at 6 weeks postnatally. All women with a 6-week EPDS score ≥ 12 were at-risk women and were included in the main trial of the two

approaches, the cognitive behavioural approach (CBA) or the person-centred approach (PCA), compared with control. The IG at-risk women with a 6-week EPDS score ≥ 12 were interviewed using the Schedule for Clinical Assessment in Neuropsychiatry (SCAN). Women classified as moderately or severely depressed were asked to state their preference for the psychological sessions or a selective serotonin reuptake inhibitor (SSRI), or both.

The IG at-risk women were reassessed at 8 weeks postnatally by a face-to-face HV administration of the EPDS. At-risk women with an 8-week EPDS score ≥ 12 were eligible for psychological sessions.

The cluster level intervention therefore comprised the package of HV training in the assessment of postnatal women, combined with providing either the CBA or the PCA sessions for women eligible for them, according to the HV's management protocol, plus the option of a SSRI if indicated.

All women in the three main arms of the study, the CBA IG, the PCA IG and the CG, were followed up at 6, 12 and 18 months postnatally by postal questionnaires. The primary outcome was the proportion of at-risk women with a 6-month EPDS score ≥ 12.

The primary comparison was between those at-risk women in the combined clusters randomised to HV training and those women in practices randomised to provide HV usual care (control) to identify any differences attributable to providing the HV training. The secondary comparison was to determine any differences between the proportion of women with a 6-month EPDS score ≥ 12 in the two main psychological approach groups (CBA and PCA) to identify any differences attributable to training in one or other of the two approaches.

Results

Health visitors in 101 clusters in 29 primary care trusts collaborated in the 3-year study. From 7649 eligible women 4084 (53.4%) consented to take part: 17.3% (595/3449) of women who returned a 6-week questionnaire had a 6-week EPDS score ≥ 12 and were at-risk women; 70.3% (418/595) of at-risk women had a 6-month EPDS score available. In total, 45.6% (67/147) of CG at-risk women had a 6-month EPDS score ≥ 12 versus 33.9% (93/271) of IG women. The absolute difference of 11.7% (95% CI 0.4 to 22.9%) was statistically significant ($p = 0.036$). This difference suggests that the odds of an IG woman having a 6-month EPDS score ≥ 12 was 0.62 (95% CI 0.40 to 0.97) times the odds for a CG woman. After adjusting for covariates, the odds ratio for the IG effect was relatively unchanged at 0.60 (95% CI 0.38 to 0.95) and this effect remained statistically significant ($p = 0.028$).

A total of 32.9% (46/140) of at-risk women in the CBA group versus 35.1% (46/131) in the PCA group had a 6-month EPDS score ≥ 12 (difference 2.2%, 95% CI –14.2% to 10.1%, $p = 0.74$). This difference suggests that the odds of a PCA group woman having a 6-month EPDS score ≥ 12 is 1.09 (95% CI 0.64 to 1.88) times the odds for a CBA group woman. After adjusting for covariates, the odds ratio for the PCA versus CBA group was 1.00 (95% CI 0.57 to 1.77) and this effect was not statistically significant ($p = 0.99$).

Secondary outcomes included the mean EPDS score at 6 months. The CG mean 6-month EPDS score for at-risk women was 11.3 (SD 5.8) versus 9.2 (SD 5.4) for the IG. The mean difference, –2.1 (95% CI –3.4 to –0.8) ($p = 0.002$), remained statistically significant after adjusting for 6-week variables ($p = 0.001$). There was also a significant difference in the Short-Form 12 Health Status Questionnaire (SF-12) mental component summary, SF-6D, Clinical Outcomes in Routine Evaluation (CORE-OM) total score, State–Trait Anxiety Inventory (STAI) and Parenting Stress Index (PSI), all favouring the IG.

The pre-trial sample size calculation was based on detecting an absolute difference of 15% (approximately equivalent to an odds ratio of 0.54) in the proportions of at-risk women with a 6-month EPDS score ≥ 12 [i.e. a minimum clinically important difference (MCID) of 15%]. We observed a smaller absolute difference, 11.7%, than our anticipated MCID. The 95% confidence interval suggests that the true treatment difference lies between 0.4% and 23%. So it is consistent with the data that the true treatment effect, although statistically significant, may be small and potentially not very clinically important. Therefore we are unable to confirm or exclude our a priori clinically important effect of 15%.

In total, 16.4% (150/914) of all women in the CG had a 6-month EPDS score ≥ 12 compared with 11.7% (205/1745) in the IG ($p = 0.003$). The absolute difference was 4.7% (95% CI 0.7 to 8.6). The CG mean 6-month EPDS score for all women was 6.4 (SD 5.2) compared with 5.5 (SD 4.7) for

the IG ($p < 0.001$). Most of the mean scores for the secondary outcomes for all women were statistically significant, favouring the IG.

The economic analysis results showed a consistent pattern of psychological approaches being cost-effective at funding levels used by the National Institute for Health and Clinical Excellence. This effect was produced by lower mean costs and higher mean quality-adjusted life-years gained in the IGs. Although these aggregate differences were not statistically significant in isolation, in combination they produce a high probability of the intervention being good value for money. The findings were consistent across both the at-risk women and all women cohorts at the 6-month and 12-month follow-ups. The CBA appeared to be the most cost-effective across all analyses.

Conclusions

The package of HV training was effective compared with HV usual care in reducing the proportion of at-risk women with a 6-month EPDS score ≥ 12, with a wide confidence interval for the estimated intervention effect, suggesting that the true treatment effect may be small. The effect remained for 1 year. The economic evaluation found that the HV intervention was highly likely to be cost-effective compared with the control. We found no difference between the CBA and the PCA.

Recommendations for further research

Further research should:

- explore ways to improve the accurate detection by HVs of symptoms of mental health problems experienced among postnatal women
- identify ways to improve the effectiveness of HVs' therapeutic relationships with postnatal women
- investigate the unexpected non-specific effect of the HV intervention on all women as randomised
- adopt a Bayesian approach in economic analyses and look at longer term costs within a modelling framework.

Trial registration

This trial is registered as ISRCTN92195776.

Chapter 1
Introduction

This report describes a cluster randomised controlled trial and economic evaluation of two different psychological interventions delivered by health visitors (HVs) in their usual care setting, for women with depression soon after they had given birth. The aim of the trial was to reliably estimate any differences in outcomes for mother, child or family from training HVs in systematically detecting depressive symptoms and in delivering a psychological intervention based on either cognitive behavioural principles or person-centred principles in primary care at an individual level for women at risk of postnatal depression (PND). The secondary aim was to establish the relative cost-effectiveness of both psychological interventions from an NHS perspective relative to health visitor usual care.

The original NIHR Health Technology Assessment (HTA) programme call for proposals in 1999 proceeded from a widening recognition of the gravity of the condition and an increasing awareness of the potential impact of depression on a new mother's infant and wider family.

The two experimental interventions built upon promising work on the potential for psychological interventions to help women recover from PND,[1,2] as an alternative to pharmaceutical interventions.[3] There was also further indication of the potential role for HVs in this context.[4–7] The trial therefore aimed to build upon existing evidence and to address the limitations of previous research in the area of PND and to examine, in particular, the role of HVs in this context.

Health visitors in 103 clusters in 29 primary care trusts (PCTs), mainly from the former Trent region, and 4084 women consented to take part in the 3-year study, which began formally on 1 April 2003. There was a long pre-trial preparatory phase to surmount the research governance requirements; to enlist the support of interested HVs and GPs; and to arrange a comprehensive and detailed preparation of the HV intervention, which included an 8-day equivalent group training session.

The study also examined the use of the Edinburgh Postnatal Depression Scale (EPDS),[8] which has been widely used in the UK to help detect women who are depressed after having their baby. It was designed to help indicate the top decile of women[4] most likely to be suffering from depression and able to benefit from an intervention. As such, the outcome of greatest pragmatic interest for health visiting services was the proportion of women who had moved below the threshold for concern score. Also, because of the inefficiency of administering the EPDS to all postnatal women face-to-face at home,[4] and the precedent of administering the self-reported assessment by post,[9] the trial investigated the potential clinical and economic consequences of a postal 6-week EPDS administration.

Background

Depression

Mental health is considered to be '*a state of well-being in which the individual realises his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community*'.[10]

Conversely, mental ill health covers mental health problems, strain, impaired functioning associated with distress, symptoms and diagnosable mental disorders such as schizophrenia and depression.[11] Each year, more than a quarter of European adults will experience mental ill health of one form or another,[12] most commonly depression.

Postnatal mental health

Most women feel exhausted after the birth of their baby and will be tearful and feel low because of the exhaustion. There continues to be some debate about the classification of postnatal mental health conditions and whether PND exists as a unique diagnosis or whether depression occurring postnatally is just coincidental.[13] However, both of the internationally used classification systems no longer provide a separate category of PND. In effect, the presence of depression is determined by the same set of criteria, regardless of timing or context. When mood states were measured in a sample of pregnant women and a group of matched non-childbearing women,[14] there were

no differences between the two groups in rates of major or minor depression after the babies were born, but the postnatal women had more symptoms of depression.[14] Women do experience postnatal distress and less satisfaction in their relationships at this time, especially with their partners.[14,15] It has been proposed that the depressive symptoms or distress that some women experience are an appropriate response following childbirth and so should not be confused with clinical depression.[16] Any emphasis on depression might draw attention away from the social and cultural context of parenting and the changes and losses that accompany the birth of a baby and consequently the sharing of the responsibility for the distress that the women experience.[16]

There is some evidence that women are more vulnerable to depression within the first 6 postnatal months, not just the first few postnatal weeks.[17] Because of issues of context and in particular the welfare of the infant, and other family members, health professionals need to be aware of the postnatal onset of depression, puerperal psychosis, post-traumatic stress disorder, panic disorder and relapse of other illnesses such as schizophrenia.[18]

Within the first days after the birth of a baby, 39–85% of women feel more emotional than usual, weepy, irritable and anxious and have insomnia and a low mood because of what is called postnatal 'blues' or baby 'blues'.[14] Women can be given information about symptoms and reassurance that postnatal blues resolve quickly within a few days, without treatment, and can be advised about self-help. However, there is no evidence for the effectiveness of these measures.[18]

At the other extreme, puerperal psychosis is a severe mental illness affecting one or two per thousand women soon after delivery.[19] Women with a history of a postnatal mood disorder carry a very high risk of recurrence. The dramatic symptoms are severe depression with a risk of suicide or even infanticide.[20] Mania, hallucinations or delusions require urgent psychiatric treatment, often as an inpatient. This very small but important risk of suicide and infanticide in some severely depressed mothers manifests itself in violent methods, more often than in the population generally, sometimes before and sometimes after 6 weeks postnatally.[21] Although exceptionally serious, statistically suicide is rare and most HVs will never encounter maternal suicide.

In 1992 the *International Classification of Diseases* (ICD-10)[22] first included an optional supplementary code for diseases that occur during and complicate pregnancy, childbirth or the puerperium (the O99 code can be applied to any form of mental disorder).

The American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV)[23] makes provision for a postpartum-onset specifier code that can be added to a diagnosis of manic depression, bipolar disorder or major depression among others, provided onset is within 4 weeks of childbirth. No reason for the 4-week timing is provided and the ICD does not suggest a time period for onset. The diagnosis of depression (irrespective of the gender of the sufferer or the timing of the episode) relies on the presence of at least five of the following symptoms for at least 2 continuous weeks:[23]

- depressed mood
- loss of interest or pleasure
- significant increase or decrease in appetite
- insomnia or hypersomnia
- psychomotor agitation or retardation
- fatigue or loss of energy
- feelings of worthlessness or guilt
- diminished concentration
- recurrent thoughts of suicide.

Depression is far more common than psychosis at any time as well as in the context of pregnancy and childbirth. Depression can last for up to 1 year after delivery in about 4% of all mothers[20] or a quarter of mothers who become depressed, and may last even longer.[24] But the relevance of this is not clear as not many studies have followed up women for long enough to determine the depression duration and no study has described in a standardised way the course of depression (in women) with respect to whether or not the episode occurred within the context of childbirth.

The proportion of postnatal women who might be depressed varies between 11%[20] and 22%[25,26] depending on the sample of women, the criteria used and the time of assessment postnatally.[14] Based on a meta-analysis of estimates from 59 studies internationally, the average prevalence of depression postnatally is 13%.[27] A later meta-analysis estimated that 14.5% of women may have a new episode of major or minor depression during the first 3 postnatal months, with 6.5% having a new episode of major depression.[28] The same review estimated a prevalence of 6.5–12.9% for major and minor depression at any time during the first postnatal year, and a 1–5.9% prevalence of major depression.[28]

Consequences of depression

Depression is a public health problem with financial costs to the gross domestic product associated with sickness absence,[29] mainly through lost productivity. There is a high risk of relapse.[30] The UK spends 12% of its total health expenditure on mental health,[11] and the cost for antidepressant prescriptions is around £401 million.[31] The costs of the stigma and discrimination associated with mental ill health remain intangible.

Depression can lead to more deaths from suicide each year than there are deaths from road accidents. Suicide rates and mental health states vary across European countries, reflecting their diverse traditions, cultures, situations and religious variations in reporting suicide.[11] The number of deaths from psychiatric illness is underestimated as suicidal deaths may not be classified as such, to spare family feelings.[32] The sixth report of the confidential enquiries into maternal deaths in the UK, *Why Mothers Die*,[21] reported suicide as the most common cause of maternal death for women in the first year after childbirth.

The natural history of PND varies among women, but around one-third develop a chronic problem with long-term adverse consequences. Although there is little evidence to date, there is a belief that women's depression may affect their partners,[33] who become depressed,[34–36] thereby reducing their ability to cope with supporting the mother or caring for the new infant or other children.

There has been growing concern from the literature on the evidence of the effects that depression might have on the cognitive[37] and emotional development of children[38] and the attachment of infants to their mothers, particularly for boys, possibly well beyond infancy.[39] Boys whose mothers are depressed in the first year may have particular problems with reading.[40] Infants are highly sensitive to the quality of their interpersonal contacts, which are most often provided by the mother in the first few months of life.[39] This could be because the baby has a rapidly developing brain in the first 6 months of life and is heavily dependent on external stimulation and therefore particularly vulnerable during this sensitive period.[39,40] It is also possible that the association between PND and the development of infants represents a complex two-way interaction.[41] Also, mothers with depression are more likely to report parenting stress, negative perceptions of their infant's behaviour and hostile feelings towards their infant.[42]

Aware of the link, the European Union's project on building mental health in infants, children and adolescents recognised the need to address PND.[11] Similarly, guidance from the National Institute for Health and Clinical Excellence (NICE) on treating depression in children and young people also referred to the need for parents' own depression to be treated in parallel.[43]

Causes of depression

The factors that can contribute to depression include an individual's personal experiences, biological or inherited tendencies, social support factors, and economic and environmental factors.[11] For example, people with mental health problems are more likely than the general population to live in rented housing and to say they are dissatisfied with their accommodation.[44] Because of the growing concern over mental health, policy initiatives have been developed, recognising that health-care interventions alone are not the only solution.

There is no consensus about the cause of PND, but there is an association with risk in women who have a number of psychosocial risk factors. A meta-analysis of 59 studies[27] used regression analyses to evaluate the relative contributions of several postnatal variables to the development of PND (*Table 1*). The strongest predictors are related to antenatal anxiety or depression, lack of social support and stressful life events. Weaker predictors are neuroticism, negative cognitive attributional style and obstetric variables. The suggestion that women having a traumatic delivery, by emergency Caesarean section, might be more likely to become depressed[45] may be true only for women who have a previous history of a depressive disorder.[46] For the general population of women, complications such as forceps or emergency Caesarean section are not associated with depression.[46] A link between Caesarean section and PND was not established in a meta-analysis of suitable studies.[47]

Recognising that it is a simplification, O'Hara and Swain synthesised all of the risk factors that emerged from the meta-analysis[27] to present a prototype of a pregnant women at risk of PND, as most likely to:

- occupy a lower social stratum
- have experienced stressors during pregnancy
- have had a more difficult than normal pregnancy or delivery
- be experiencing marital difficulties

TABLE 1 *Predictors of postnatal depression*

	Cohen's d[a]
Depression antenatally	0.75
Anxiety antenatally	0.68
Social support	–0.63
Stressful life events	0.60
Mother's history of psychopathology	0.57
Self-esteem	
Childcare stress	
Neuroticism	0.39
Marital relationship	–0.13
Infant temperament	
Maternity blues	
Obstetric variables	0.26
Marital status	
Negative cognitive attributional style	0.24
Socioeconomic status	
Unplanned/unwanted pregnancy	

[a]Cohen's d is the standardised effect size, in which 0.2 indicates a small effect, 0.5 indicates a moderate effect and 0.8 indicates a large effect. Reproduced from O'Hara and Swain,[27] with permission from Elsevier.

- experience her partner as providing little social support
- perceive others in her social network as not supportive
- have a history of psychopathology
- show evidence of being at least mildly depressed, anxious and worried.

A prospective study[48] of women recruited antenatally found that those who were depressed postnatally felt that the practical and emotional support provided by their partners was inadequate. The depressed women felt that they could not talk freely with their partners, they were not there for them when they needed them and they were not able to rely on them for childcare help as much as they would have liked. In general, they felt that their partners made their lives less easy.[48]

Management of postnatal depression

Assessment and detection

There is a general problem with the detection of depression in primary care.[49] For many women with PND their problem will not have been fully recognised in routine clinical practice.[24,26,50] Because the onset of PND may be gradual, it is not easy to distinguish it from the fatigue and emotional liability that most mothers feel when adjusting to the demands of a new baby and recovering from childbirth.[50] It is also not easy to detect depression, partly because some women are not willing to disclose their true feelings.[51] Some women feel that they become depressed as a result of feeling exhausted, unwell, unsupported or isolated as mothers, with no time for themselves.[52] These women may not try to access professional or other support, either because they feel that their problem is not so bad or they ought to deal with it on their own or because they do not have anyone to ask for support.[52] Some women may feel that there is a stigma attached to being depressed and they may feel embarrassed or ashamed to seek help for what they might regard as a sign of personal inadequacy or an admission of failure on their part.[53] They may not regard professional intervention as relevant or may not want to be labelled as an unfit mother.[53]

The EPDS is one of the mood assessment instruments most widely used in clinical practice.[54] It was not developed as a diagnostic test.[55] The EPDS is not adequate to confirm PND without a clinical interview to assess a mother's mood, depressive symptoms and suicidal thoughts, and explore her relationship with the baby.[56]

The National Screening Committee commissioned a review[57] to evaluate the evidence of the validity of the EPDS as a screening tool; the most effective intervention for PND; and the size of the beneficial or adverse effects for interventions. The report stated that:

> *At present, it is not recommended to the National Screening Committee that screening for postnatal depression be introduced … the introduction of isolated screening programmes which are not part of a research project will not add to the evidence base which is agreed to be insufficient to justify the introduction of screening.*
>
> *Until more research is conducted into its potential for routine use in screening for PND the NSC recommends that the EPDS should not be used as a screening tool.*
>
> *It may, however, serve as a checklist as part of a mood assessment for postnatal mothers, when it should be used alongside professional judgement and*

a clinical interview. The professional administering it should have training in its appropriate use and should not use it as a pass/fail screening tool.

The difficulties of the EPDS have been openly discussed;[58–61] many HVs do find the instrument valuable whereas others highlight the limitations. Some PCTs endorsed the systematic use of the EPDS by HVs and established a system of cascade HV training in its use.[62] Other PCTs were mindful of the criticism of the EPDS following the review commissioned by the National Screening Committee. This prompted some PCTs to restrict the use of the EPDS by HVs.

The guidance from the National Collaborating Centre for Primary Care[18] on the postnatal care of women and their babies proposes that it is good practice to ask women who have had a baby how they are feeling emotionally, but cautions that the use of the EPDS is not acceptable to some women.

Pharmacological treatment for depression in primary care

There is not enough evidence from well-controlled and reported trials about the costs and benefits of different interventions for depression. Within the UK, depression in primary care is usually treated with either tricyclic antidepressants (TCAs) or, more recently, the newer non-tricyclic drugs or selective serotonin reuptake inhibitors (SSRIs).[29] The SSRIs are believed to be as effective as TCAs but less toxic in overdose.[29] Many people are uncertain about taking drugs for depression, believing that they are addictive or that drug treatment is not appropriate for what is seen as a reasonable reaction to adverse events.[29] There are certainly concerns about the risk of adverse neonatal outcomes following exposure to antidepressants during pregnancy.[63]

Antidepressants are effective for postpartum depression.[64] However, it is not known which specific class of antidepressants or which individual antidepressant is most helpful; which is the best prevention for high-risk women; or what impact antenatal treatment or excretion of antidepressants via breast milk might have on the cognitive and emotional development of exposed infants.[64] Because there is insufficient information on the overall effectiveness of antidepressant drugs in PND, there are very little data upon which to base decisions about the safety of breastfeeding while taking these medications.[65] Women with PND prefer not to take antidepressants[66] and so compliance is not good. Physicians either prescribe a reduced, potentially non-therapeutic dose, advise women not to breastfeed or delay offering treatment until the woman has finished breastfeeding.[67]

An American expert panel[68] reached a majority consensus on the appropriateness of including antidepressants (specifically SSRIs) and non-pharmacological treatments for women with severe depressive symptoms. For milder symptoms the panel gave equal endorsement to other treatment modalities or preferred psychotherapy over antidepressant medication.[68]

Psychological interventions for mental health problems in primary care

Partly in response to concerns about antidepressants,[29] over the past 25 years there has been a move towards increasing the availability of psychological interventions.[69]

Psychological interventions include counselling and psychotherapy, and it can be difficult to distinguish between the two. Both cover a range of modalities, the most common being cognitive behavioural therapy (CBT) and psychoanalytic, psychodynamic, interpersonal and client-centred, non-directive approaches.

The British Association of Counselling (BAC)[70] presents an ethical framework for good practice in counselling and psychotherapy, including values, principles and personal moral qualities. The BAC refers to counselling as:[71]

… the skilled and principled use of relationships which develop self-knowledge, emotional acceptance and growth, and personal resources.

… concerned with addressing and resolving specific problems, making decisions, coping with crises, working through feelings and inner conflict, or improving relationships with others.

Some patients with depression actively choose counselling over antidepressants.[72] The availability of counselling will depend upon the number of effectively trained practitioners.

In primary care a range of professionals can offer psychological interventions, including counsellors,

community psychiatric nurses (CPNs), clinical psychologists, HVs and social workers.[69,73]

In primary care, generic brief counselling[74] or psychological interventions using non-directive psychotherapy are as effective as routine GP care, or perhaps more effective.[75–77] Generic counselling is as effective as antidepressants, although those taking antidepressants may recover more quickly.[72] In the short term psychological symptoms of patients who receive counselling may improve more than symptoms in those who have usual GP care.[69] Primary care patients may prefer brief psychotherapy to usual GP care[75–77] and, given the choice, patients who choose counselling over antidepressants may improve more than those who have no strong preference.[72] Interventions using CBT also appear to be cost-effective in primary care[78] and possibly helpful in preventing relapse.[30]

Health visitors' detection and treatment of postnatal depression

There is some evidence of the effectiveness of HVs in using psychological approaches to support women with PND. In a pioneering small randomised trial in Edinburgh and Livingston,[1] HVs were asked to administer the EPDS to all women at around 6 weeks postnatally. Those who had a raised EPDS score were interviewed by psychiatric interview at 13 weeks postnatally, and those identified as depressed were allocated to an intervention group (IG) ($n = 26$) or a control group (CG) ($n = 24$). The IG were offered a postnatal one-to-one non-directive type counselling intervention of eight 1-hour weekly sessions by 17 HVs, whilst the CG received routine care. Outcomes included the Goldberg Standardised Psychiatric Interview and EPDS after 13 weeks. Although the HVs providing the intervention continued to visit the CG women, the statistically significant result was that 69% of the IG women ($n = 18$) recovered compared with 38% of the CG women ($n = 9$). In the absence of stronger evidence, the findings of this trial have been widely implemented throughout the UK.

The Lewisham primary prevention programme was one of the more important, small studies, which was not a randomised controlled trial.[6,79] The study compared outcomes for women screened antenatally as 'vulnerable' (using the Leverton questionnaire) in 'Preparing for Parenthood' (for first-time mothers) or 'Surviving Parenthood' (for second-time mothers) against routine primary care. The allocation to group was not random but by the baby's date of birth and it was flawed because of the lack of concealment. HVs were asked to make contact with the women as soon as possible, in mid-pregnancy. There were five antenatal group sessions, beginning at 24 weeks, and six postnatal sessions, led by a clinical psychologist and a HV. At 3 months the women were interviewed, in part using the Present State Examination (PSE). Among the more vulnerable women, for those who had been offered the service, 19% ($n = 48$) were depressed compared with 40% of those who had not been offered the service. There was a significant reduction in EPDS for first-time mothers ($n = 21$) at 3 months compared with control subjects ($n = 24$), but no difference at 3 months for second-time mothers and no difference at 1 year for invited women. The authors concluded that some depression following childbirth can be prevented by brief psychological interventions, which can be incorporated within existing systems of antenatal classes and postnatal support groups, and pointed out that first-time mothers may be more likely to accept an invitation and attend meetings.[6]

Following the Edinburgh trial[1] Holden and Elliott wanted to give HVs the chance to take part in a training programme to adopt strategies for detecting PND and for early interventions.[4] To test whether the Edinburgh intervention, which appeared successful within a small trial, could be effective in routine HV practice they set up a three-centre study in Edinburgh, North Staffordshire and Lewisham, south-east London.

Health visitors were invited to a minimum of seven 2-hour training sessions and were asked to administer the EPDS to women, normally at the child health clinic, with a home visit for non-attenders. The preventive strategies included antenatal visits and education about PND, the realities of parenting and the potential benefit of support groups.[4] The study used an EPDS cut-off score of 12 so that each HV would counsel about three women on their caseload over the study period, using non-directive counselling (NDC). The HVs did not wish to be regarded as counsellors and preferred the term 'listening visits' to the term 'non-directive counselling'.[4] In the North Staffordshire arm, the median EPDS score changed from 7 at baseline to 5 post training.[4] There were reported improvements in counselling skills and an increase in HVs' mental health assessments, recording of symptoms and referrals to mental health services. Elliott *et al*.[7] suggested that the training and intervention should be evaluated using a rigorous research design. The study was not a randomised trial and the limited reporting suggests that it was probably subject to selection

bias. It showed the potential role for HVs in using a structured approach for delivering an intervention following a brief training in psychological counselling for PND.

Another study with postnatal women, which was not a randomised controlled trial, explored the effect of care from HVs who were trained to detect PND using the EPDS and to manage PND using counselling and cognitive behavioural techniques, such as problem-solving. In total, there were 30 women who received routine primary care before the training and who became historical control subjects and 70 women who were seen after the HV training.[5] The study, which was not rigorously controlled, or reported, found a significant reduction in EPDS scores after the training.[5]

Support for the role of health visitors in perinatal mental health

Health visitors have been working in multidisciplinary teams for some time in the area of prevention and the early identification of maternal depression and support for affected women.[80–88] A series of proposals and guidance has offered backing for the role of HVs in perinatal mental health.[79]

NICE asked the National Collaborating Centre for Mental Health (NCCMH) to develop a clinical guideline on the treatment and management of mental health problems in the antenatal and postnatal period.[89] Before this, the National Service Framework (NSF) for Mental Health[90] set priorities for the way that services were to be provided, four of which were relevant to the role of HVs. Standard one related to mental health promotion and emphasised the need to build capacity and capability in primary care by supporting staff through continuing professional development. Standards two and three referred to primary care and access to services. The NSF proposed protocols to be implemented for the management of PND, anxiety disorders and those needing referral to psychological therapies. The NSF recognised the role of HVs with training who could use routine contact with new mothers to identify PND and treat its milder forms. The NSF seventh standard[90] related to actions to reduce suicides, by ensuring that staff would be competent to assess the risk of suicide among individuals at greatest risk. This standard was relevant to HVs, as maternal suicide was cited as the largest cause of maternal death in the first postnatal year.[21] The later review of the NSF prioritised investing more in mental health promotion.[91]

The Scottish Intercollegiate Guidelines Network (SIGN) evidence-based guideline on PND and puerperal psychosis emphasised the role for HVs in the detection and management of PND.[92]

The Department of Health published guidance in September 2003, *Into the Mainstream, Implementation Plan: Mainstreaming Gender and Women's Mental Health*, for developing services for perinatal depression, which supported the role of HVs.[93]

In the UK, the Sainsbury Centre for Mental Health, the Local Government Association, the NHS Confederation and the Association of Directors of Social Services produced a joint policy paper.[94] The report presented a vision for 2015, which minimised public fear, stigma and discrimination for people with mental health problems, shifted resources to primary care, invested in the mental health workforce and extended the availability of psychological therapies to people with a range of mental health problems.

Given the absence of a national policy on PND, HVs in many PCTs developed their own local policies,[95] with differing strategies and integrated care pathways (ICPs) for the detection and management of the depression.[83] Some PCTs developed protocols for GPs for the management of PND, with information on treatment options and criteria for referral to the community mental health team. It is appropriate for HVs to refer some women to mental health services rather than offer support themselves. These circumstances include women who have obsessive compulsive disorder, eating disorders, post-traumatic stress disorder and panic disorder, as well those who have psychosis or suicidal plans, and other situations in which a HV feels very concerned.[7] This approach has been supported by Department of Health policy.[90,93]

Health visitors' professional support

Support for the role of HVs in perinatal mental health came from the HVs' professional body. In 2000 the Community Practitioners' and Health Visitors' Association (CPHVA) established a Postnatal Depression and Maternal Mental Health (PDMMH) network for HVs to enhance perinatal services for women and their families. The PDMMH network facilitated the exchange of information on the development of ICPs, conferences, resources, publications and multicultural work. The CPHVA ran workshops about the use of the EPDS as part of a full mood

assessment and advertised courses in identifying and managing perinatal depression.

An audit of the CPHVA membership was published in the network newsletter in June 2003.[96] The results suggested that 85% of PCTs had formal mechanisms for managing PND; 55% had a lead professional for perinatal mental health (72% of these being HVs); and 85% of PCTs were using the EPDS to some degree, but only 70% of these (sic) had received training in its proper use.

The generic role of health visitors

Health visiting relies on a sound interpersonal process and establishing a relationship with a client. The use of interpersonal skills and communication skills lie at the core of health visiting.[97] Whether regarded from a medical or psychosocial perspective, PND is acknowledged as an important health problem, and a key area of HVs' work given their established role and unique personal contact with postnatal women. The following explains the historical, generic role of HVs and presents the context and rationale for their role in postnatal maternal health.

Health visiting has its origins in Salford, Manchester, where the Ladies' Sanitary Reform Association first began home visiting to offer a universal service, with some focus on maternal and child welfare.[98,99] Since 1962 HVs have been qualified nurses, with special experience in child health, health promotion and health education, employed as part of the NHS community health service. They work with GPs and other primary health-care team workers (practice nurse, district nurse, midwife) and other community-based health and social care professionals, based within the GP surgery or practice premises or local health centre.

The Council for the Education and Training of Health Visitors[100] identified the four main principles of health visiting as the philosophy underpinning practice:

1. the search for health needs
2. stimulation of the awareness of health needs
3. influencing policies that affect health
4. facilitating health-enhancing activities.

As policies within the NHS and in child health surveillance services have changed over time,[101] so has the role of HVs.[99] In the 1990s HVs were encouraged to change the way that they worked, to offer a more targeted, needs-based service, rather than a universal service. The work of contemporary HVs is mainly around primary preventive activities on a broad range of health issues. However, recently there has been a strong drive for HVs to focus increasingly at the level of secondary prevention, targeting vulnerable children[102] and using more community-based public health approaches.[103]

The review of the British literature on health visiting[104] indicated that HVs' work can fall into the following categories:

- individuals and groups with special needs
- children with special needs
- elderly
- homeless families
- mothers with PND
- prevention of sudden infant death syndrome
- traveller families, vulnerable families and families in poverty
- child protection, domestic violence, childhood injury
- child health services, child health surveillance.

Health visitors are concerned with all aspects of a woman's health and the health and welfare of her child and family. HVs maintain a 'caseload' of individual clients and part of a HV's role is to visit families with new babies, in their homes, as part of routine child health surveillance. Therefore, every family with a child under 5 years has a named HV who can advise parents on everyday infant and childcare difficulties and immunisation programmes, as well as signposting families to other sources of health support, for example housing, financial benefits or specialist services. Some HVs also work in corporate teams with HVs sharing the caseload and so families have access to different HVs.

The standard HV contact times for women with a baby are around 4 weeks antenatally, at a new birth visit and in well-baby clinics. Routine contacts for assessment of infants' developmental progress are being phased out.

The effectiveness of health visiting

There has been wide discussion over the evidence of the effectiveness of the work of HVs.[97,104,105] One of the first systematic overviews of home visiting[106] indicated that there were positive outcomes in children's mental development, mental health and physical growth; reductions in mother's anxiety, depression and tobacco use; and improvements in maternal employment and nutrition, among others. There are very few reports of UK-based

research in health visiting.[107] The review of articles on the effectiveness of home visiting in relation to child and maternal outcomes[107] found evidence to suggest that home visiting programmes for parents of young children can have an effect on improvements in:

- various dimensions of parenting[108]
- some child behaviour problems
- cognitive development, especially for some groups of children
- childhood accidental injury rates[109]
- the detection and management of PND.[1]

There was no evidence that home visiting increased the uptake of immunisations or hospital admissions.[107] As is often the case, the review indicated a need to address methodological limitations of trials in this area to provide, in particular,[104] a clear theoretical framework; clear descriptions of the intervention content, intensity, timing and duration; process measures; long follow-up times; a client perspective and assessment of satisfaction.

The role of the health visitor in black and ethnic minority communities

There are specific mental health issues affecting Asian and other non-indigenous women bringing up children in the UK. For example, the suicide rate among women who are born in South Asia and live in England is higher than that in the general population. When they are providing supportive care, HVs need to consider cultural practices about childrearing.

English language is not an issue for some second-generation immigrant women who speak Punjabi and Urdu, and some HVs have used the EPDS with English-speaking women from Asian and other ethnic minority groups. Some women who have recently entered the UK from Pakistan are unable to speak English, and there are growing numbers of Arabic-speaking women as well as Kosovans, Kurdish people and asylum seekers from other mid-European countries and elsewhere. For Pakistani women, link workers are employed who speak Punjabi and can read Urdu. There are also interpreters and link workers who speak other relevant languages. Aside from any language difficulty, literacy for women from Pakistan is more likely to be an issue.

There are no effective, validated, culturally sensitive tools for many women who have English as a second language. As well as literacy and language difficulties, immigrant women may also be isolated, and so women who are vulnerable to PND may be missed. Some work is beginning to develop and validate linguistically and culturally competent tools for use in primary care, using link workers and health professionals to identify psychological distress and assist the early detection of women from South Asian communities who speak Bengali, Gujarati, Punjabi and Urdu, as well as those from other ethnic minority communities. This may be useful in instances in which it is not possible to detect PND in other ways.

A Punjabi Postnatal Depression Screening Questionnaire (PPDSQ) was developed by a consultant psychologist in Bradford City PCT and the University of Bradford.[110] Also, the CPHVA has supported the development of a pictorial method for women who have English as a second language, to detect those who may be depressed. This work is undergoing a pilot validation study.

Chapter 2

Literature review of the prevention and treatment of postnatal depression

Although the role of HVs has been promoted in perinatal mental health there is still not enough evidence upon which to base practice to prevent or treat PND. A literature search was performed in July 2005 to identify and synthesise published literature on trials of interventions to prevent or treat postnatal morbidity and the costs associated with these. This was not a systematic review.

The main method used to identify relevant articles was a search of electronic bibliographic databases from the first date that the databases would allow. The electronic databases searched to provide the best coverage of trials were:

- health databases: MEDLINE, CINAHL, EMBASE – 1966 to July 2005
- evidence-based databases: the Cochrane Library, covering the Cochrane Database of Systematic Reviews (CDSR) and the Cochrane Controlled Trials Register (CCTR)
- PsycINFO – to date.

The search strategy used the key text words depression, postpartum, postnatal, review, trial, random, blind and systematic as follows:

exp Depression, Postpartum

(postnatal or post-natal or post natal or perinatal or peri-natal or peri natal).mp. [mp = title, original title, abstract, name of substance word, subject heading word]

depress$.mp. [mp = title, original title, abstract, name of substance word, subject heading word]

exp psychological techniques/or exp psychotherapy

(post partum or postpartum or post-partum).mp. [mp = title, original title, abstract, name of substance word, subject heading word]

limit to "therapy (sensitivity)"

limit to (humans and English language and "therapy (sensitivity)")

social.mp. [mp = title, original title, abstract, name of substance word, subject heading word]

(review$or trial$or random$or blind$or systematic$).mp. [mp = title, original title, abstract, name of substance word, subject heading word)

The articles were considered relevant if they included a population of antenatal or postnatal women; psychosocial or other interventions to offer additional support; maternal reports of health status, morbidity or PND measured using validated tools; reports of use of services; and a planned comparison group using a rigorous research design.

Of the 241 published articles identified through the search, 185 potentially relevant abstracts were scrutinised and assessed for eligibility criteria and methodological quality. In total, 64 papers were selected for review and 43 were regarded as suitable for inclusion in the review. Studies were included if they were randomised controlled trials in a population of antenatal or postnatal women and they examined any association between support or interventions, to prevent or treat PND. The articles were relevant if they included maternal reports of health status.

Studies that were not written in the English language were not included. In a systematic review, two reviewers independently assign a quality rating to each trial being reviewed. Criteria that contribute to the assessment of the methodological quality of a trial are a clear and accurate description of:

1. participant selection, inclusion and exclusion criteria, and recruitment response rates
2. statistical power and sample size determination
3. random allocation, concealment, blinding, control for potential bias
4. experimental and control interventions

5. length and completeness of follow-up, compliance and attrition
6. outcome measures and statistical analysis.

Poorly controlled trials are also likely to be poorly reported, but if a well-controlled trial is not well reported it will be assessed as poor quality and the results will not be incorporated into a systematic review.

In this particular review it was difficult to grade and rank the quality of each trial as many of the quality criteria were not reported in the articles. Few authors described a pre-trial sample size calculation and the number of participants required to achieve statistical power. In reporting results many authors reported only absolute numbers, without confidence intervals, or a mean value without a standard deviation.

The quality of each study was not graded but was judged according to whether the study included a clear and accurate description of the experimental design, a sample size determination, participants' baseline characteristics and comparison of groups, randomisation, blinding, setting, intervention, control intervention, compliance and attrition.

Cochrane and other reviews[111,112] were also examined for additional relevant trials. The following reviews from the CDSR (Cochrane Depression, Anxiety and Neurosis Group and Cochrane Pregnancy and Childbirth Group) were relevant:

- Dennis CL, Creedy D. Psychosocial and psychological intervention for preventing postpartum depression.[113]
- Hodnett ED. Caregiver support for women during childbirth.[114]
- Barlow J, Coren E. Parent training programmes for improving maternal psychosocial health.[115]
- Ray KL, Hodnett ED. Caregiver support for postpartum depression.[116]

All together there were 43 relevant trials identified from the literature search and the Cochrane and other reviews. These trials are summarised under the following six headings:

- antenatal prevention of PND (9 trials)
- perinatal support or treatment to prevent PND (10 trials)
- postnatal support interventions (3 trials)
- postnatal prevention of PND (5 trials)
- postnatal treatment of PND (16 trials).

Trials of antenatal prevention of postnatal depression

Because the strongest predictors of PND are antenatal anxiety or depression, lack of social support and stressful life events, theoretically, addressing some of these features could prevent PND. The Cochrane review[113] of psychosocial and psychological interventions for preventing postpartum depression included antenatal trials, and a qualitative review[111] specifically examined antenatal group interventions to reduce PND. The antenatal trials that aimed to prevent PND are summarised in alphabetical order in *Table 2*.

The trials mainly included women variously assigned as vulnerable or high risk using a modified screening tool, or women having their first baby, or both. Among all trials several outcome measures were used, mainly at 3 months.

The trials of groups had poor attendance and were not successful in reducing PND.[117,124] In the two very small trials,[118,125] one French and one American, with limited quality, there appeared to be some effect. It is unclear whether the comparatively good attendance rate and the outcomes would be reflected in a larger trial.

There was not enough evidence from antenatal-targeted interventions provided for 'at-risk women'.[111] Overall, the women in the IG were just as likely to become depressed as those in the CG. These antenatal studies do not provide sufficient evidence upon which to base care.

Trials of perinatal support or treatment to prevent postnatal depression

The perinatal studies that aimed to prevent PND[113,114] can be summarised as midwifery, 'debriefing' or counselling studies, massage, doulas (experienced lay women providing support to women in labour) or companionship in prevention of PND, and these are summarised in alphabetical order below (*Table 3*).

The massage trial[126] was not described sufficiently well and the sample size was too small, but the reported significant difference in the mean time in labour suggests that the intervention could be worthy of further investigation and longer follow-up.

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TABLE 2 *Trials of antenatal prevention of postnatal depression*

Authors, location	Method	Subjects	Intervention	Sample	Outcomes	Results and conclusions	Comments
Chabrol *et al.*, 2002,[118] Toulouse, Narbonne, France	Controlled randomised study	'At-risk women' with EPDS scores > 8 on French version of EPDS	One antenatal session including an educational component, a supportive component and a CB component during hospitalisation	*n* = 22 IG; *n* = 38 CG	EPDS	Significant reductions in frequency of probable depression in IG: IG – 30.2%, mean EPDS = 5.0; CG – 48.2%, mean EPDS = 13.7 ($p = 0.0067$)	Poor quality. Many limitations. Not ITT. '*This programme for prevention and treatment of postpartum depression is reasonably well accepted and efficacious*'
Gorman, 2002,[119] Iowa and St Louis, USA	RCT	Pregnant women at risk of postpartum depression	Five individual antenatal sessions based on IPT by a mental health specialist, in late pregnancy, ending around 4 weeks postnatally	*n* = 24 IG; *n* = 21 CG	EPDS, SCID – at 4 and 24 weeks	Mean EPDS scores were 7.9 in the IG (*n* = 15) and 8.0 in the CG (*n* = 15) (NS)	Very small sample
Hayes *et al.*, 2001,[120] Queensland, Australia	RCT	Primiparous women	One-to-one education intervention by specially trained midwives conducted at 28–36 weeks in an interview room or in their own home, about mood changes and symptoms and help-seeking vs CG	*n* = 95 IG; *n* = 93 CG	POMS, NSSQ – at 8–12 weeks and 16–24 weeks	There was a steady reduction in POMS scale scores over all subscales in both groups, with no difference between groups at any follow-up time Women in both groups were more depressed antenatally than postnatally	Duration of IG and CG not described. Did not use a measure of PND
Logsden *et al.*, 2005,[121] Louisville, USA	Random assignment	Adolescent girls 32–36 weeks' gestation	(1) Pamphlet, (2) video and (3) pamphlet and video vs (4) CG	*n* = 128	CES-D – at 6 weeks	There were no significant differences in CES-D scores between groups at any follow-up time	The education intervention had no effect on women
Marks *et al.*, 2003,[122] London, UK	RCT with random permuted blocks of 8 and 16, stratified by 6 offices	Antenatal women with history of major depressive disorder	Continuous midwifery care vs standard maternity care	*n* = 51 IG; *n* = 47 CG	DIS DSM-III-R case of major or minor depression	No differences in rates of PND between treatment conditions	'*Continuous midwifery care had no impact on psychiatric outcomes*'

continued

TABLE 2 *Trials of antenatal prevention of postnatal depression (continued)*

Authors, location	Method	Subjects	Intervention	Sample	Outcomes	Results and conclusions	Comments
Matthey *et al.*, 2004,[123] London, UK	RCT	Antenatal women and men	Preparation for parenthood programmes: (1) 'Empathy' (experimental, focusing on psychosocial issues related to becoming first-time parents) and (2) 'Baby play' (control) vs usual service 'control'	$n = 51$ IG; $n = 47$ CG	DIS DSM-III-R case of major or minor depression	Reduction in postpartum distress in some first-time mothers at 6 weeks postpartum. Women with low self-esteem who had received the intervention were significantly better adjusted on measures of mood and sense of competence	'*This brief psychosocial intervention can be readily applied to antenatal classes and is suitable for those who attend preparation for parenthood classes*'
Stamp *et al.*, 1995,[124] Adelaide, Australia	RCT, women stratified by parity	English-speaking women with a single pregnancy identified as being more vulnerable to PND	Antenatal groups: two special classes – simple primary PND preventive intervention, focusing on access to information, practical and emotional preparation and support, and one postnatal group run by midwives vs CG	$n = 64$ IG; $n = 65$ CG	EPDS – at 6 weeks, 12 weeks and 6 months	13%, 11% and 15% of the IG women scored over 12 on the EPDS at 6 weeks, 12 weeks and 6 months, respectively, compared with 17%, 15% and 10% of the CG women, respectively	Privately insured women not able to participate. Attendance 31% overall. Return rate 92%, 92% and 87% at 6 weeks, 12 weeks and 6 months, respectively
Zlotnick *et al.*, 2001,[125] Providence, USA	Pilot RCT	Pregnant women receiving public assistance with at least one risk factor for PND	Four antenatal group sessions 'Survival skills for new moms' – four sessions (1 hour) IPT-oriented intervention vs treatment as usual	$n = 17$ IG; $n = 18$ CG	BDI, SCID – at 3 months	Significant difference in BDI score changes between IG and CG ($p = 0.001$). Women in the IG were significantly less likely to develop postnatal major depression compared with CG women ($p = 0.02$)	'*A 4-session IPT-oriented group intervention was successful in preventing major depression in the first 3 postpartum months.*' In total, 50% of eligible women declined; 77% of women were single; 88% attended three sessions. Very small sample

BDI, Beck Depression Inventory; CB, cognitive behavioural; CES-D, Center for Epidemiological Studies Scale; CG, control group; DIS, Diagnostic Interview Schedule DSM-III-R; EPDS, Edinburgh Postnatal Depression Scale; GHQ-D, General Health Questionnaire Depression; IG, intervention group; IPT, interpersonal psychotherapy; ITT, intention to treat; NS, not significant; NSSQ, Norbeck Social Support Questionnaire; POMS, Profile of Mood States; PND, postnatal depression; RCT, randomised controlled trial; SADS, Schedule of Affective Disorders and Schizophrenia; SCAN, Schedules for Clinical Assessment in Neuropsychiatry; SCID, Structured Clinical Interview for DSM-IV Disorders.

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TABLE 3 *Trials of perinatal support or treatment to prevent postnatal depression*

Authors, location	Method	Subjects	Intervention	Sample	Outcomes	Results and conclusions	Comments
Field *et al.*, 1997,[126] Miami, USA	Random assignment	Middle socioeconomic status women recruited from prenatal class	Massage by partner every hour for a total of 4 hours and partner coaching in breathing during labour vs coaching from partners	$n = 28$	CES-D, POMS	There was less depressed mood on the POMS scale in the IG: IG 6.9; CG 14.9 Also on the CES-D: 15.4 vs 19.8	'*Data suggest that the massaged mothers had shorter labours, shorter hospital stay and less postpartum depression*'
Gamble *et al.*, 2005,[127] Brisbane, Australia	RCT	Postnatal women assessed in the immediate postpartum for risk of developing psychological trauma	One midwifery-led 'debriefing' within 72 hours of birth, then another 4–6 weeks postpartum by phone vs CG standard care	$n = 50$ IG; $n = 53$ CG	EPDS – at 12 weeks	4/50 IG women EPDS score > 12 vs 15/53 of the CG women. Women in the IG reported decreased trauma and low relative risk of depression and stress	'*A brief intervention for a distressing birth experience effective in reducing trauma symptoms, depression, stress and feelings of self-blame*'
Gordon *et al.*, 1999,[128] San Fransisco Bay, USA	Randomised study	Primiparous women aged ≥ 18 years, uncomplicated deliveries	Trained doulas in hospital-based labours and deliveries vs usual care	$n = 149$ IG; $n = 165$ CG	MHI from SF-36 – at 4–6 weeks postnatally	No difference in postpartum depression or self-esteem measures	'*In general, women who had doulas were very enthusiastic about them*'
Hagan *et al.*, 2004,[129] Perth, Western Australia	Single blind randomised controlled study	English-speaking mothers of very preterm infants (< 33 weeks)	Six CBT sessions in programme by a research midwife, postnatal weeks 2–6, vs standard care	$n = 101$ IG; $n = 98$ CG	EPDS, BDI, GHQ, SADS – at 2 weeks, 2 months, 6 months and 12 months	29% of IG diagnosed with major or minor depression vs 26% CG	'*Intervention programme did not alter the prevention of depression*'
Lavender and Walkinshaw, 1998,[130] Merseyside, UK	RCT	Postnatal primigravidous women with a single birth by normal delivery	Midwife 'debriefing', 30- to 120-minute sessions, on postnatal wards, vs CG	$n = 56$ IG; $n = 58$ CG	HAD scale – at 3 weeks	Women in the IG were less likely than women in the CG to have HAD scale anxiety and depression scores of more than 10 ($p < 0.0001$)	Sample size based on HAD scores > 7; reporting by HAD scores of 10. Follow-up time of 3 weeks is too early to evaluate morbidity after childbirth
Priest *et al.*, 2003,[131] Perth, Australia	RCT	Mothers under psychological care at the time of delivery	One midwife 'debriefing' after childbirth for 15 minutes to 1 hour	$n = 875$ IG; $n = 870$ CG	EPDS – at 8 weeks, 24 weeks, 52 weeks	37/696 IG women scored > 12 on the EPDS compared with 42/705 CG women	19% attrition at 1 year

continued

TABLE 3 *Trials of perinatal support or treatment to prevent postnatal depression (continued)*

Authors, location	Method	Subjects	Intervention	Sample	Outcomes	Results and conclusions	Comments
Selkirk *et al.*, 2006,[132] Victoria, Australia	Random assignment	Women recruited in third trimester	Midwife 'debriefing' vs CG	*n* = 149	DAS, STAI, EPDS, POMS, PSI	EPDS at 3 months postpartum: IG, 6.69 low intervention and 6.13 high intervention vs CG, 5.25 low intervention and 5.57 high intervention	'*Debriefed women were no less likely to develop symptoms of postnatal depression (using EPDS) than women who did not receive debriefing*'
Small *et al.*, 2000,[133] Melbourne, Australia	RCT	Women who had given birth by Caesarean section, forceps or vacuum extraction	Midwife 'debriefing', at least 24 hours after the birth, up to 1 hour, in hospital vs standard care	*n* = 464 IG; *n* = 447 CG	EPDS, SF-36 subscales – at 6 months	17% of women in debriefing scored ≥ 13 on EPDS vs 14% CG. Also poorer health on seven out of eight SF-36 subscales	CG women received a brief visit and a leaflet. Nearly all women found the debriefing helpful
Tam *et al.*, 2003,[134] China	RCT	Chinese women who had suffered suboptimal outcomes in pregnancy and labour	One to four 'educational counselling' sessions for high-risk women by a research nurse before discharge from hospital	*n* = 280 IG; *n* = 280 CG	HADS > 4 – at 6 weeks postpartum	26/261 IG women depressed compared with 35/255 CG women. Mean depression scores 3.30 IG vs 3.50 CG	Short follow-up
Wolman *et al.*, 1993,[135] USA	RCT	189 nulliparous labouring women	Additional companionship from community volunteer vs usual care	*n* = 92 IG; *n* = 97 CG		IG women attained higher self-esteem scores and lower postpartum depression and anxiety ratings at 6 weeks	'*Companionship modifies factors that contribute to the development of postnatal depression*'

BDI, Beck Depression Inventory; CBT, cognitive behavioural therapy; CES-D, Center for Epidemiological Studies Scale; DAS, Dyadic Adjustment Scale; DIS, Diagnostic Interview Schedule DSM-III-R; EPDS, Edinburgh Postnatal Depression Scale; GHQ-D, General Health Questionnaire Depression; HADS, Hospital Anxiety and Depression Scale; MHI, Mental Health Inventory; NSSQ, Norbeck Social Support Questionnaire; POMS, Profile of Mood States; PSI, Parenting Stress Index; RCT, randomised controlled trial; SADS, Schedule of Affective Disorders and Schizophrenia; SF-36, Short-Form 36; STAI, State–Trait Anxiety Inventory.

Of the five midwifery debriefing studies, the two smaller studies, one in the UK[130] and one in Australia,[127] reported a short-term effect. The two larger trials,[131,133] however, and the most recent[132] did not report a positive outcome.

The trial of companionship[135] suggested that self-esteem might be improved. The authors of the 'doula' trial[128] indicated that participating women were very enthusiastic about the doulas and appreciated their knowledge, support and reassurance. Unlike other trials there were no differences demonstrated in perinatal outcomes.

The Cochrane review of caregiver support for women during childbirth concluded that there were a number of benefits for mothers and their babies, and there did not appear to be any harmful effects.[116]

The trial of CBT for women with very preterm infants[129] did not reduce the prevalence of major or minor depression at follow-up.

In the Chinese education sessions trial follow-up was only 6 weeks.[134]

Trials of postnatal support

Three trials of postnatal interventions to support socially disadvantaged mothers examined maternal outcomes of feeling tired, feeling miserable and negative feelings. The studies included mothers in an eastern US city,[136] 262 mothers in Dublin[137] and mothers in the eastern USA.[138] Mothers who received support were less likely to report being tired, unhappy, not wanting to go out and other negative feelings at 1 year postnatally.[137] In all three trials childhood immunisation was more likely to be complete in the IG.[138] Without valid and reliable methods of obtaining mothers' evaluations, these trials were not large or rigorous enough to examine the impact of social support on maternal and child health outcomes.

The Hackney Daycare Study[139] was a randomised controlled trial of 120 mothers with a child age from 6 months to 3½ years, allocated to receive a place at the Mapledene Early Years Centre, or not. Although not the main outcome, maternal psychological well-being was measured using the General Health Questionnaire (GHQ-12). Mothers in both groups had a mean GHQ-12 score of 10.8, indicating no apparent benefit as measured by the GHQ-12.

A Cochrane systematic review of parent-training programmes[115] for improving maternal psychosocial health among population women or clinical groups of women included data from 20 studies. The meta-analysis showed that the intervention was associated with positive outcomes for depression, anxiety or stress, self-esteem and relationship with spouse or marital adjustment. The results suggested that parenting programmes could help promote positive mental health in the short term, but there was insufficient evidence regarding the long-term effectiveness of the programmes.[115]

More recently there was a trial of two forms of postnatal social support offered to mothers living in disadvantaged inner-city areas of London.[140] Among the 367 IG women there was no evidence of an impact of either a programme of visits from HVs trained in supportive listening or the services of local community support organisations on maternal depression, child injury or maternal smoking, compared with the 364 women in the CG.

Postnatal trials to prevent postnatal depression

Because lack of social support and stressful life events have been correlated with the development of PND, many studies have aimed to ameliorate the potential impact of these by providing additional support or helping women develop coping techniques before depression develops. A Cochrane review of psychosocial and psychological interventions for preventing postpartum depression[113] identified postnatal support trials that aimed to prevent PND by offering an intervention postnatally. These trials are summarised in alphabetical order in *Table 4*.

There was some short-term benefit of the nurse home visiting programme in lower EPDS scores at 6 weeks,[141] but there was no difference in maternal mood at 4 months.[142] The only other intervention that had an impact on mean EPDS scores at 4 months was the redesigned midwifery care trial.[145] There were some implementation problems with the early GP appointment trial[144] and there were no significant differences in EPDS scores at 3 months.

In the support worker trial[146] there were no differences in any of the instruments used, even though the women said that they felt that they had benefited from the intervention. The mean cost for the support worker service was £160 per woman.

TABLE 4 *Trials of postnatal interventions to prevent postnatal depression*

Authors, location	Method	Subjects	Intervention	Sample	Outcomes	Results and conclusions	Comments
Armstrong *et al*., 1999,[141] Armstrong *et al*., 2000,[142] Fraser *et al*., 2000,[143] Queensland, Australia	RCT double-blind	Women in the immediate postpartum with self-reported vulnerability factors (Brisbane Evaluation of Needs Questionnaire)	Nurse weekly home visiting structured programme of 20–60 minutes, minimum 18 per family (weekly for 6 weeks, fortnightly to 3 months, monthly to 12 months), supported by a social worker and paediatrician, vs standard community child health services	$n = 90$ IG; $n = 91$ CG	PSI, EPDS – at 6 weeks and 12 months	Mean 6-week EPDS scores: IG 5.8 vs CG 20.7 ($p = 0.003$). Improved experience of the maternal role. No difference in breastfeeding or use of health services. Intervention was welcomed; 90 women were willing to accept the programme (one refused) No difference in mean EPDS scores at 4 months: IG 5.75 vs CG 6.64; 6.2% IG and 13.6% CG scored > 12	Targeted families in which child was at risk. Significant differences after randomisation. Focused on adjustment to parenting role 76% response to follow-up. Baseline EPDS, physical child abuse potential, PST all predicted level of PND at 12-month follow-up
Gunn *et al*., 1998,[144] Melbourne, Australia	RCT with block randomisation stratified by recruiting centre	Postnatal women who gave birth at a rural and a metropolitan hospital, recruited on second or third day postnatally	GP appointment 1 week after discharge vs GP appointment 6 weeks after discharge	$n = 232$ IG; $n = 243$ CG	EPDS, SF-36 – at 3 months and 6 months	3-month mean EPDS scores: IG 7.38 vs CG 7.48 ($p = 0.85$); 6-month mean EPDS scores: IG 5.87 vs CG 6.08 ($p = 0.67$) 3-month EPDS > 12: IG 16.6 vs CG 13.6 ($p = 0.37$); 6-month EPDS > 12: IG 11.6 vs CG 12.8 ($p = 0.69$) No difference in any SF-36 scores on any domain at 3 or 6 months 46.3% IG vs 51.4% CG breastfeeding at 6 months ($p = 0.28$)	IG women were less likely to attend their appointment ($p = 0.001$). Many commented that the 1-week appointment was too early

Authors, location	Method	Subjects	Intervention	Sample	Outcomes	Results and conclusions	Comments
MacArthur *et al.*, 2002,[145] West Midlands, UK	Cluster RCT	Postnatal women registered with 17 intervention practices and 19 control care practices. Recruitment time unclear	42 midwives offering midwifery-led care, using symptom checklists, EPDS, no routine GP contact, last visits at 28 days, discharged at 10–12 weeks, vs 38 midwives trained in postnatal care and health and trial design offering control care	$n = 101$ IG; $n = 98$ CG	SF-36 physical component summary (PCS) and mental component summary (MCS) score, EPDS at 4 months	Mean EPDS scores: IG 6.40 vs CG 8.06 ($p < 0.0001$). EPDS > 12: IG 14.39 vs CG 21.25 ($p = 0.01$) Mean PCS: IG 47.54 vs CG 50.50 ($p = 0.002$). Mean MCS: IG 46.68 vs CG 47.84 ($p = 0.089$).	IG significantly more likely than CG to rate care as better than expected. Economic evaluation reported separately
Morrell *et al.*, 2000,[146] Sheffield, UK	RCT	Postnatal women who gave birth at an urban teaching hospital	Support workers offering up to 10 home visits of up to 3 hours in the first postnatal month vs usual postnatal care	$n = 311$ IG; $n = 312$ CG	SF-36, EPDS, DUFSS, breastfeeding – at 6 months	Mean EPDS: IG 7.4 vs CG 6.7 ($p = 0.05$)	'*No evidence of any health benefit at the 6-week or 6-month follow-up*.' Cost per woman was £160
Reid *et al.*, 2002,[147] Ayrshire and Grampian, Scotland	Pragmatic RCT	Primiparous women	4 cells: (1) support pack, (2) support group, (3) support group and pack, (4) CG	(1) $n = 250$; (2) $n = 250$; (3) $n = 253$; (4) $n = 251$	EPDS, SF-36, SSQ-6 – at 3 months and 6 months	Mean EPDS scores: (1) 5.6, (2) 6.1, (3) 6.1, (4) 5.9 at 3 months Percentage scoring 12 or more on EPDS: (1) 12.0, (2) 16.8, (3) 15.2, (4) 11.7 at 3 months	Low uptake of support groups (around six attenders, with 89 groups having no attenders). Cost per group was £21.31 per attendance, packs cost £1.75

DUFSS, Duke Functional Social Support Scale; EPDS, Edinburgh Postnatal Depression Scale; PSI, Parenting Stress Index; RCT, randomised controlled trial; SF-36, Short-Form 36; SSQ-6, Social Support Questionnaire.

The trial comparing social support groups and packs[147] found that few women attended the groups, but more reported that they had read the pack at least once. The reasons given by those who did not attend were that the groups were too inconvenient or that they were too shy to attend alone. There was no difference in the mean EPDS scores between any of the groups or the percentage of women scoring 12 or more on the EPDS. The total cost for providing the packs was £439 and for running the postnatal support groups was £14,000.[147] The main outcomes indicated that intensive postpartum support showed promising results, and that identifying 'at-risk' mothers was helpful.[113] There was insufficient evidence that the diverse interventions reduced the number of postnatally depressed women.

Trials of postnatal treatment of postnatal depression

An early Cochrane review (withdrawn) to assess the effect of professional or social support interventions on postpartum depression was based on the theoretical premise that supportive relationships during the perinatal period could enhance a mother's feeling of well-being. Two trials were included in the review,[1,3] which concluded that professional and/or social support may help in the treatment of postpartum depression but that it was too early to draw conclusions for practice based on so little evidence. One of these trials[3] was also included in a Cochrane review of antidepressant treatment for PND.[67] Since this early Cochrane review, further postnatal treatment studies of psychotherapy or psychological support have been published and reviewed[13,112,148] and these are summarised below in alphabetical order (*Table 5*). The extensive range of approaches developed to treat PND reflects its broad aetiology. Among these trials are some in which the 'therapist is not professionally prepared'.[149]

Antidepressants to treat postnatal depression

The Cochrane review of antidepressant drug treatment for PND aimed to compare the effectiveness and safety of different antidepressants with other forms of treatment.[67] The Cochrane review included only one trial of fluoxetine,[3] which was rated for methodological quality as category A. This was a community-based, randomised, double-blind controlled trial of 87 depressed postnatal women in Manchester that had four treatment groups:

1. fluoxetine 20 mg with one session of cognitive behavioural counselling (CBC) by a psychologist
2. fluoxetine with six sessions of CBC
3. placebo with one session of CBC
4. placebo with six sessions of CBC.

There was improvement in all groups and fluoxetine was more effective than placebo and six sessions of CBC were more effective than one session of CBC. Fluoxetine and CBC were equally effective for non-psychotic depression in postnatal women. However, 101/188 (54%) eligible women refused to take part, mainly due to reluctance to take the drug, and there was a 30% dropout rate with 61/87 women who agreed to participate, completing.

The review concluded that women with PND can be treated equally effectively with fluoxetine or a course of CBC in the short term and that there should be more, longer-term studies comparing different antidepressants and psychosocial interventions.[67]

Psychosocial interventions

The withdrawn Cochrane review to assess the effect of caregiver support for postpartum depression included the Manchester trial[3] of fluoxetine and cognitive behavioural-type counselling and the Edinburgh trial, which was a study of a HV one-to-one NDC intervention.[1] The review indicated that it would be premature to make practice recommendations based upon only two small trials. It indicated that future research should consider lay support; home visits, phone calls or group sessions; and the prevention and treatment of PND, including outcomes of symptoms, hospital admission rates and long-term maternal and infant and family well-being. Additionally, an economic evaluation would be necessary to determine the relative efficiency of the provision of care.

The Edinburgh trial tested one-to-one NDC visits,[1] whilst the Manchester trial tested CBT[3] and the Cambridge treatment trial[2] tested CBT against person-centred therapy and psychodynamic psychotherapy. The Cambridge trial was the largest trial of psychological interventions for women with depression postnatally. Primiparous women were screened 'in the early postpartum period' to identify those who met DSM-III-R criteria for current major depressive disorder. Women were offered therapy in their homes from 8 to 18 weeks postpartum or routine care in four

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TABLE 5 *Trials of postnatal treatment of postnatal depression*

Authors, location	Method	Subjects	Intervention	Sample	Outcomes	Results and conclusions	Comments
Appleby *et al.*, 1997,[3] Manchester, UK	RCT, double-blind	Community postnatal women satisfying criteria for major depression at 6–8 weeks	(1) Fluoxetine 20 mg and one session CBC, (2) fluoxetine and six sessions CBC, (3) placebo and one session CBC, (4) placebo and six sessions CBC	$n = 87$	EPDS, HRSD – at 1, 4 and 12 weeks	Fluoxetine more effective than placebo; six sessions of CBC more effective than one session of CBC; fluoxetine and CBC equally effective	101/188 (54%) eligible women refused to participate (reluctance to take drug). Excluded breastfeeding. 61/87 completed (30% dropout)
Armstrong and Edwards, 2004,[150] Queensland, Australia	RCT	Women with an EPDS score > 11 and infant 6 weeks–18 months, and medical certificate about physical activity	12 pram-walking exercise sessions vs weekly social support meeting	$n = 12$ IG; $n = 12$ CG	EPDS and social support interview	There was a significant difference in mean (SD) EPDS scores between exercise group, 6.33 (3.67), and social support group, 13.33 (7.66) ($p < 0.05$)	Small sample. Exercise group had reduced feelings of depression and improved physical fitness; no change in perceived social support. Not ITT. Not generalisable
Chen *et al.*, 2000,[151] Kaohsiung, Taiwan	RCT	Postnatal women recruited on ward 2–3 days postnatally and scoring 9 or above on BDI at 3 weeks	Postnatal groups – four weekly meetings of 1.5–2 hours on transition to motherhood, postnatal stress, communication skills and life planning, vs CG.	$n = 30$ IG; $n = 30$ CG	BDI, PSS, ISEL, CSEI – at the end of the 4-week programme	33% IG women depressed using BDI vs 60% CG women ($p < 0.05$). Attenders had significant positive changes in BDI, PSS and ISEL scores ($p < 0.01$) but no significant changes in any measure in the CG	Poor quality. 115 met the inclusion criteria; 60 enrolled; 44% returned screening questionnaire. The postnatal time of outcome measurement is not clear. 92% average attendance.
Cooper and Murray, 1997,[152] Cooper *et al.*, 2003,[2] Cambridge, UK	RCT – the Cambridge treatment trial	Primiparous women screened to identify those who met DSM-III-R criteria for major depression	Home therapy 8–18 weeks. (1) NDC, (2) CBT, (3) dynamic psychotherapy (DPT) vs (4) routine care	(1) $n = 49$; (2) $n = 42$; (3) $n = 48$; (4) $n = 52$	EPDS, SCID – at 18 weeks, 9 months and 18 months	25–35% reduction in EPDS in three IGs vs 4% in the CG % women not depressed: (1) NDC 52%, (2) CBT 59%, (3) DPT 75%, (4) routine care 40%	By 9 and 18 months' follow-up differences between all four groups were not significant. Dropouts: (1) 14%, (2) 2%, (3) 17%
Dennis, 2003,[153] British Columbia, Canada	RCT pilot study	Women with EPDS score > 9 at 8 weeks postpartum, defined as high risk for postpartum depression	Peer telephone support mother-to-mother using trained volunteers with a personal history of PND vs standard care	$n = 34$ IG; $n = 27$ CG	EPDS – at 4 months	Significant differences in EPDS scores >12 at 4 months: 15% IG vs 52% CG. Acceptance rate 67%	'*Telephone-based peer support may effectively decrease depressive symptomatology among new mothers*'

continued

TABLE 5 *Trials of postnatal treatment of postnatal depression (continued)*

Authors, location	Method	Subjects	Intervention	Sample	Outcomes	Results and conclusions	Comments
Field *et al.*, 1996,[154] San Diego, US	Random assignment	Depressed adolescent mothers, identified using BDI	10 massage therapy sessions for 30 minutes over 5 weeks vs 10 relaxation sessions for 30 minutes over 5 weeks	$n = 32$	POMS 14-item depression scale, urinary cortisol	Massage therapy had a significant immediate effect on behavioural and stress hormone changes, including decreased anxious behaviour, pulse and salivary cortisol levels and urinary cortisol	Poor quality: small sample size, no true CG, randomisation unclear
Heh and Fu, 2003,[155] Taipei, Taiwan	Random allocation	Women scoring over 10 on the EPDS (considered to be 'at risk' of PND)	Informational support about PND during the sixth week postpartum vs routine care	$n = 35$ IG; $n = 35$ CG	EPDS – at 3 months	60% IG women scored below 10 on EPDS vs 31% CG women	'*Informational support given postnatally may contribute to psychological well-being.*' No power calculation. Small sample
Holden *et al.*, 1989,[1] Edinburgh and Livingston, Scotland, UK	Controlled random order trial	Depressed women (psychiatric interview at 13 weeks postnatally)	One-to one 'listening visits' (eight 1-hour weekly sessions) by 17 HVs vs routine care	$n = 26$ IG; $n = 24$ CG	Goldberg, EPDS – after 13 weeks	69% of IG women recovered vs 38% of CG women	The HVs providing the intervention continued to visit the CG women
Honey *et al.*, 2002,[156] Cardiff, UK	Block random allocation procedures	Women < 12 months postpartum scoring > 12 on EPDS	Eight HV 2-hour psychological–educational group (CBT and relaxation) vs routine primary care	$n = 23$ IG; $n = 22$ CG	EPDS, DUFSS, DAS	Mean EPDS: 12.55 IG vs 15.63 CG 65% IG women scored below the cut-off for major probable PND (< 13) vs 36% CG women	'*A brief psychological–educational group is an effective form of treatment for women with low postpartum mood*'
Milgrom *et al.*, 2005,[157] Melbourne, Australia	Cycled random allocation, by slips drawn from a bag. RCT	Community women with a diagnosis of depression confirmed by CIDI	12 weeks × 90 minutes: (1) CBT, (2) group counselling, (3) one-to-one counselling vs (4) routine care	(1) $n = 46$; (2) $n = 47$; (3) $n = 66$; (4) $n = 33$	BDI, Beck Anxiety Inventory, Social Provisions Scale	Proportions of post-intervention BDI scores below threshold for clinical depression were (1) 55%, (2) 64%, (3) 59% and (4) 29%	Psychological intervention per se was superior to routine care in reducing depression and anxiety
Misri *et al.*, 2000, Vancouver, Canada.[158]	RCT	Women with major postpartum-onset depression	Six psychoeducational visits weekly, four with partners, vs six psychoeducational visits	$n = 16$ IG; $n = 13$ CG	EPDS, KSQ, DAS, PBI, MINI	Mean EPDS: 8.6 IG vs 14.7 CG ($p = 0.013$). Mean KSQ: IG 2.1 vs 6.6 CG ($p = 0.021$). Lower morbidity in partners who attended vs others ($p = 0.01$)	Poor quality: randomisation not described, small sample size, group differences in baseline characteristics

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Authors, location	Method	Subjects	Intervention	Sample	Outcomes	Results and conclusions	Comments
Misri *et al.*, 2004,[159] Vancouver, Canada	RCT	Women referred to tertiary care with DSM-IV criteria for major depression	Paroxetine plus 12 sessions of CBT vs paroxetine monotherapy	$n = 16$ IG; $n = 19$ CG	HRSD, EPDS – at 12 weeks	Both groups having antidepressant therapy and CBT showed improvement ($p < 0.01$) in mood and anxiety	No treatment as usual or CG
O'Hara *et al.*, 2000,[149] Iowa, USA	RCT	120 postpartum women meeting DSM-IV criteria for major depression with modified SCID	12 × 1-hour sessions of interpersonal psychotherapy (IPT) by 10 experienced psychotherapists vs waiting list control. Women with history of major depression separately randomised	$n = 48$ IG; $n = 51$ CG	IDD, amended HRSD, BDI, SAS, DAS, PPAQ, modified SCID – at 4, 8 and 12 weeks	12-week HRSD scores: 8.3 IG vs 16.8 CG ($p < 0.001$). 12-week BDI scores: 10.6 IG vs 19.2 CG ($p < 0.001$). PPAQ and SAS scores improved in the IPT group No difference in DAS	Most women were white and well educated 132 declined participation; 20% withdrew from IPT Women in the CG were phoned every 2 weeks Non-blinded raters
Onozawa *et al.*, 2001,[160] UK	RCT	Primiparous women 4 weeks postpartum, identified using EPDS	12 × weekly 1-hour infant massage classes and 30-minute informal support group	$n = 34$	EPDS	Significant differences between groups	Poor quality: small sample size, randomisation unclear, high drop-out rate from IG, analysis not ITT
Prendergast and Austin, 2001,[161] Australia	RCT	Postnatal women with DSM-IV major or minor depression	Six modified CBC nurse-delivered home-based weekly 1-hour sessions vs standard care	$n = 17$ IG; $n = 20$ CG	EPDS, MADRS	No significant difference post treatment; 70–80% recovered (EPDS < 10) in both groups 6-month postal follow-up	'*Early childhood nurses could deliver modified CBT for PND.*' Perceived support from nurse appeared to be as effective as modified CBT
Wickberg and Hwang, 1996,[162] Goteborg, Sweden	Controlled study	Women with EPDS ≥ 12 and major depression (MADRS) at 2 months and 3 months	Six × 1-hour counselling sessions by child health nurse vs routine care	$n = 20$ IG; $n = 21$ CG	MADRS – at about 19 weeks	12/15 (80%) IG women showed no major depression after six sessions vs 4/16 (25%) CG women ($p < 0.01$)	Small sample, seriously ill excluded, randomisation not described. Nurses received 4 half-days of training

BDI, Beck Depression Inventory; CBC, cognitive behavioural counselling; CBT, cognitive behavioural therapy; CIDI, Composite International Diagnostic Interview; CG, control group; CSEI, Coopersmiths Self-Esteem Inventory; DAS, Dyadic Adjustment Scale; DUFSS, Duke Functional Social Support Scale; EPDS, Edinburgh Postnatal Depression Scale; HRSD, Hamilton Rating Scale for Depression; IDD, Inventory to Diagnose Depression; IG, intervention group; ISEL, Interpersonal Support Evaluation List Short Form; ITT, intention to treat; KSQ, Kellner's Symptom Questionnaire; MADRS, Montgomery–Åsberg Depression Rating Scale; MINI, Mini International Neuropsychiatric Instrument; NDC, non-directive counselling; PBI, Parental Bonding Index; PND, postnatal depression; POMS, Profile of Mood States; PPAQ, Postpartum Adjustment Questionnaire; PSS, Perceived Stress Scale; RCT, randomised controlled trial; SAS, Social Adjustment Scale; SCID, Structured Clinical Interview for DSM-IV Disorders.

groups, as in *Table 6*. The EPDS and Structured Clinical Interview for DSM-IV Disorders (SCID) were administered at 18 weeks. In the short term there was a 25–35% reduction in EPDS in the IG compared with about 4% in the CG.

The trial found that there was a significant improvement following NDC, CBT or psychodynamic therapy immediately after treatment compared with routine care.[2] By 9 months there had been recovery in the CG so that there was little difference between the reduction in their EPDS scores and the reduction in the scores for the women who had received counselling or psychotherapy.[2] The improvements were well maintained in the CBT group up to 18 months and, using the percentages of women who dropped out of treatment early, the CBT appeared to be the most acceptable treatment.

The trial also found a significant benefit in mothers' reports of relationship problems with their infants at 4 months postnatally.[163] Mothers' reports also indicated evidence of a benefit from NDC at 18 months for emotional and behavioural problems.

On the basis that it works for major depression, the efficacy of interpersonal psychotherapy (IPT) was tested in a randomised controlled trial[149] of 120 women in Iowa, USA, who met the DSM-IV criteria for major depression using a modified SCID. Most of the women were white and well educated. The IG women ($n = 48$) were offered 12 × 1-hour sessions of IPT, which were carried out by 10 experienced psychotherapists who were required to complete a 12-session course of IPT with a postpartum depressed woman 'at a satisfactory level of competence'. The CG was a waiting list control ($n = 51$) who were phoned every 2 weeks. In total, 20% of women withdrew from IPT. After 12 weeks all scores except the Dyadic Adjustment Scale (DAS) were significantly better in the IG than the CG, as assessed by non-blinded raters.

The Australian study comparing CBT, group counselling and one-to-one counselling against routine primary care used an allocation method of drawing slips of paper from a bag and was therefore not free from bias. This study found improvements in all three groups compared with control, and the greatest benefit appeared to be associated with individual counselling.[157]

In contrast, the very small Australian study of nurse-delivered CBC for women with depression found no significant difference immediately post treatment, but there may have been some effect at the 6-month follow-up.[161]

A very small study[156] in Cardiff, Wales, examined the effectiveness of a brief 'psychoeducational group' intervention for women who scored 12 or more on the EPDS. In total, 23 women were allocated to the intervention of eight 2-hour group meetings run by HVs. These covered education about childcare and accessing social support, cognitive behavioural techniques and relaxation techniques. Compared with the women in the CG who received routine primary care, the mean EPDS scores decreased significantly in the IG.

The very small controlled study[162] in Goteborg, Sweden, included 20 IG women and 21 CG women who scored 12 or more on the EPDS at 2 months and again at 3 months interviewed with the Montgomery-Asberg Depression Rating Scale (MADRS) and diagnosed as having major depression. The IG women were offered 6-weekly 1-hour counselling sessions in the home or clinic by the child health nurse, who had received four half-day training sessions in NDC, whereas the

TABLE 6 *Allocation to group and outcome in the Cambridge trial*

Group	Intervention	Number in group	% no longer satisfying DSM-III-R criteria
Group 1	Non-directive counselling	49	52
Group 2	Cognitive behavioural therapy	42	59
Group 3	Psychodynamic therapy	48	75
Group 4	Routine primary care	52	40

CG received routine care. In total, 80% of women (12/15) in the IG showed no major depression after six sessions compared with 25% (4/16) of CG women ($p < 0.01$). Seriously ill women were excluded and the randomisation process was not described.

Other studies

Informational support

The small Taiwanese study[155] of 70 women, offering information about PND, appeared to show some positive impact but it was not well reported.

Postnatal support groups

In the small Taiwanese study[151] 30 women who had a Beck Depression Inventory (BDI) score of 9 or more at 3 weeks attended a support group of five to six mothers with their infants. A total of 30 CG women completed two assessments. In the IG, 10 women (33.3%) remained depressed, compared with 18 women (60%) in the CG, as measured by a BDI score of less than 10, indicating a possible benefit from the intervention.

Psychoeducational visits with partners

The very small study[158] of psychoeducational clinic visits for depressed women, with partner support in four of them, found lower EPDS scores in the women whose partners attended the support group, as well as less psychological morbidity in the partners themselves, compared with those who did not attend.

Pram-walking exercise programme

In a very small Australia study women who had an EPDS score of 12 or more at baseline were allocated at random to either an exercise group ($n = 9$), who were encouraged to attend two pram-walking sessions per week, or a social support group ($n = 10$), who met once per week.[150] The women were a well-educated group (who had a pram) and the analysis was not by intention to treat. The mean EPDS scores in the pram group were significantly lower than those in the social support group after 6 weeks, but there were no significant changes in social support in either group.

Telephone support

The pilot study[153] of telephone-based peer support with 42 women found significant reduced EPDS scores in the IG at 4 months postnatally compared with the usual care group.

Massage

The two very small massage studies[154,160] were both poorly reported but appeared to demonstrate some difference between the IG and CG.

Summary of trials to treat postnatal depression

Most of these studies appeared to have positive benefits, at least in the short term. It seems that PND is amenable to treatment. However, the populations of women included were identified using different methods to assess depression, most often the EPDS, BDI or a psychiatric interview. The postnatal recruitment time varied from the first few postnatal days[151] to 18 months in the pram-walking study.[150] The outcomes were measured using more than 23 different instruments. There were problems in recruiting and retaining women in the study. Half of the studies had a sample of 60 or fewer women, and most of the studies measured outcomes at 1 and 3 months postnatally. The exception was the Cambridge trial, which followed up women to 18 months postnatally.[152]

Summary of the need for the PoNDER trial

The outcomes of health visiting studies and endorsements from official reports on the role of HVs in the context of PND indicate that HVs could have a clear role in the early detection of PND and in offering psychological interventions to women. There is not enough published evidence to determine the most effective and efficient intervention to be offered by HVs.

The PoNDER trial was commissioned, funded and initiated on the basis that there was growing demand for, and evidence of the effectiveness of, psychological interventions for the treatment of PND. Also, it was apparent that HVs were in an ideal position to detect women with depression, to establish a trusting relationship with postnatal women and to use their interpersonal skills

and communication skills, which lie at the core of health visiting. HV skills in psychological approaches may depend on the training that they receive or their natural predisposition to offering a counselling intervention.[164] The PoNDER trial built upon the potential for HVs to develop appropriate skills, to adopt an effective role in the detection of depression and to offer effective support to eligible women.

The PoNDER trial was designed to be rigorously performed and reported[165] and to address some of the methodological limitations of earlier work and, moreover, it was an economic evaluation.

Chapter 3

Rationale for the comparison of two psychological approaches

The two contrasting psychological approaches were investigated because, when the trial was commissioned, two promising trials of non-directive (person-centred) counselling and CBC for PND were included in an early Cochrane review.[1,3] In the first trial of 'listening' visits (based on Rogerian NDC), HVs in Edinburgh who had received a brief training in NDC were asked to visit depressed postnatal women for 1 hour each week for eight weeks.[1] The community-based, randomised, double-blind controlled trial of postnatal women[3] in Manchester compared 20 mg of fluoxetine or placebo with one or six sessions of CBC. Other studies also reported promising findings of a positive effect from offering sessions with a person-centred (non-directive) approach[1,2] and also from studies that had incorporated a cognitive behavioural component.[3,152,156,157,159]

Person-centred counselling and CBC rely on different assumptions about the processes underpinning psychological change. The former is based on the idea that opportunities to explore difficulties with another, who listens non-judgementally and reflects empathically, allows a person to feel validated as a person and facilitates their abilities to manage their distress and find their own solutions. CBC assumes that events, thoughts and feelings are linked in a predictable way and that, by understanding these patterns, particularly where patterns of thinking lead to distress, there is the opportunity to make active change and test out new ways of thinking and behaving. There are therefore fundamental differences underpinning these two approaches, what they require of the person in the therapeutic role and of the client. It was therefore important to consider how each different approach impacted on outcomes.

The Cochrane review indicated that future research should consider the prevention and treatment of PND, including outcomes of symptoms, hospital admission rates and long-term maternal and infant and family well-being. The review concluded that an economic evaluation would be necessary to determine the relative efficiency of provision of care. Hence the trial was planned to compare the cost-effectiveness of the two contrasting psychological approaches for postnatal women.

Aims and objectives

Primary aim

The primary aim of the trial was to reliably estimate any differences in outcomes for postnatal women attributed to special training for HVs, delivered at GP practice (cluster) level, in systematically identifying depressive symptoms and delivering experimental psychological sessions, based on either cognitive behavioural principles[166] or person-centred principles,[167] compared with HV usual care (control).

Secondary aim

The secondary aim was to establish the relative cost-effectiveness of the HV training from an NHS perspective, relative to HV usual care.

Cluster level objective

The main objective at cluster level was to provide collaborating HVs in the intervention clusters with the skills to identify women with PND and to provide effective psychological sessions. It was not clinically appropriate to train HVs to provide this without developing their skills in assessing women and identifying depressive symptoms. In this trial HVs were trained to administer the EPDS[8] and use clinical assessment skills to assess a mother's mood, including depressive symptoms and suicidal thoughts, and to explore her feelings about the baby. [65]

Individual level objectives

1. To identify women at risk of PND by the presence of depressive symptoms at 6 weeks postnatally. Eligible women were recruited to the study and the EPDS was administered postally to consented women at 6 weeks postnatally. Women who scored ≥ 12 on their 6-week postal EPDS were termed at-risk women. This pragmatically chosen threshold

score recommended for clinical practice[4] was used to identify women likely to benefit from psychological support and for whom a direct comparison would be made between the IGs and CG in the intention to treat analysis. The primary outcome was the proportion of at-risk women still scoring ≥ 12 on the EPDS at 6 months postnatally.

2. To identify IG women who were eligible for up to eight psychological sessions for 1 hour per week, based on either cognitive behavioural principles[166] or person-centred principles.[167] To achieve this the IG HVs were asked to readminister the EPDS face-to-face at 8 weeks postnatally to at-risk women in the IG to identify those who scored ≥ 12 for a second time on the EPDS. It was inevitable that not all women with a 6-week EPDS ≥ 12 would be eligible for the psychologically informed sessions, as the study was designed to filter out women with transient depressive symptoms by the readministration of the EPDS at 8 weeks postnatally. The HVs also monitored uptake and compliance with the psychological sessions.
3. To identify any differences in costs for use of services for at-risk women in the IG versus use of services for at-risk women in the HV usual care (control) group.

Secondary objectives

The main aim of the trial was the clinically important question of the effectiveness of HV psychological sessions. A further set of objectives were:

1. To monitor any change in women's health over time by following up and measuring outcomes for at-risk women at 6, 12 and 18 months postnatally.
2. To identify potential clinical or economic benefits of a postal administration of the 6-week EPDS versus face-to-face HV administration. Within the random allocation, each of the IG clusters had an equal chance of being allocated to one of four subgroups, and so there were two IGs using the face-to-face plus postal EPDS administration for comparison with two groups using postal-only EPDS administration.
3. To use the Schedule for Clinical Assessment in Neuropsychiatry (SCAN)[168] to assess the severity of depression among at-risk women. SCAN interviews were also performed in at-risk women who had a range of 6-week postnatal EPDS scores, to investigate how well the EPDS administered in a primary care setting identified depressive symptoms in women who were truly depressed (according to the SCAN classification). It was also possible to assess the proportion of IG women who were classified as depressed but whose EPDS scores were below 12.
4. To examine outcomes in women's partners to 18 months postnatally. When the women were followed up by postal questionnaire, a separate questionnaire was included for women's partners to complete to monitor their health status over time.
5. To monitor infant development to 18 months postnatally. The 18-month women and partner questionnaires also included questions on infant development.

Objectives for all women who consented to take part in the trial

It is a recognised limitation of the EPDS that not all depressed women score 12 or more. In the first EPDS validation study[8] using the threshold score of 12, the sensitivity for identifying depressed women was 86% and the specificity for detecting true negatives was 78%. A cut-off score of 10 reduced the failed detection rate to fewer than 10% but doubled the number of false positives to 10 women. Also, women may develop symptoms of depression before their baby is 6 months old, but not precisely at 6 weeks postnatally. Examining outcomes only for women who had a 6-week EPDS score ≥ 12 may have failed to identify the full effect of the cluster level intervention. Therefore, all consented women, not only the at-risk women, were followed up at 6, 12 and 18 months postnatally, to include all women who may have been depressed or who could have developed depression after 6 weeks postnatally. This allowed an examination of the broader impact of the HV training intervention beyond the at-risk women. The objectives for the cohort of all women who consented to take part in the study were the same as for the at-risk women, that is, to:

- identify the proportion of all women in the intervention and control groups scoring ≥ 12 on the EPDS at 6 months postnatally
- monitor the change in health of all women over time
- monitor the change in health of all women's partners over time
- monitor infant development for all women to 18 months postnatally
- identify any differences in costs for use of services for all women in the IGs versus women in the HV usual care group.

Design and methods

Overview of design

The study was a prospective pragmatic randomised cluster trial with clusters allocated at random to one of two experimental psychological approaches or HV usual care (control arm), stratified by number of expected births per year. It was a pragmatic trial of the effectiveness of an intervention offered under normal conditions, excluding as few women as possible and accommodating non-acceptance of the offered intervention and other co-interventions.

Pragmatic trials aim to establish the relative value of interventions, as they would be provided in routine care settings, to increase the external validity without adversely affecting the internal validity. Hence, the trial aimed to answer a real-life clinical question in a real-life clinical situation.[169] This means that the interventions reflected the clinical variation that exists in routine primary care contexts.[69] In the CG, routine care included all of the support that women would normally access, from HVs, GPs and elsewhere.

The clusters randomised in the trial were GP practices, and the HVs who worked with GPs, and held a caseload of families registered with the GP practice, were approached to take part. The intervention arm HVs were trained in delivering the psychological sessions to which their practice had been randomised.

Collaborating HVs approached pregnant eligible women aged over 17 years who were on their caseload to take part in the study. Women who consented and who had a live baby were sent a 6-week postal questionnaire. All women with a 6-week postal EPDS score ≥ 12 were regarded as at-risk women and were included in the main trial of the two psychological approaches, cognitive behavioural approach (CBA) and person-centred approach (PCA), compared with HV usual care. These two contrasting approaches were explored because earlier studies had found promising evidence of a positive effect from offering sessions with a person-centred (non-directive) approach[1,2] and also from offering sessions that incorporated a cognitive behavioural component.[3,152,156,157,159]

The IG at-risk women were invited for an interview using the SCAN.[168] Those who were found to be moderately or severely depressed were asked to state their preference for psychological sessions, an SSRI, or both. The EPDS does not provide sufficiently fine-tuned information to differentiate different levels of severity of clinical depression and does not assess depressive psychosis or mania, all of which are capable of being assessed in a standardised way using SCAN.

The IG at-risk women, all of whom had a postally administered EPDS score ≥ 12, were reassessed at 8 weeks postnatally by a face-to-face HV administration of the EPDS. Women were eligible for the psychological sessions to which their practice (cluster) had been randomised according to the HVs' management protocol if they had an 8-week EPDS score ≥ 12. The intervention therefore comprised the package of HV training to develop skills in the assessment of postnatal women and the provision of psychological sessions, plus the option of an SSRI if a woman's SCAN outcome indicated moderate or severe depression. In addition, there was a change to the original protocol so that HVs were able to provide the intervention to women irrespective of their EPDS score if the clinical assessment by the HV indicated that they might benefit from the intervention sessions.

All women were followed up at 6, 12 and 18 months postnatally, using postal questionnaires. The primary outcome was the proportion of at-risk women with a 6-month EPDS score ≥ 12. The trial is illustrated diagrammatically in *Figure 1*, and full details of the methods are explained below.

Pre-trial sample size calculation

The sample size calculation aimed to ensure that the trial had a large enough sample to identify any important effects and avoid the chance of producing a false-positive result (type I error) or of missing a clinically or practically important benefit, where one might exist (false-negative result, type II error).

The planned study population was pregnant women who were registered with participating practices and who proceeded to have a live birth during the recruitment phase. To take account of between-cluster variation when estimating the sample size (or performing the analysis) the sample size calculation has to be increased by a design effect based on the intracluster correlation coefficient (ICC).

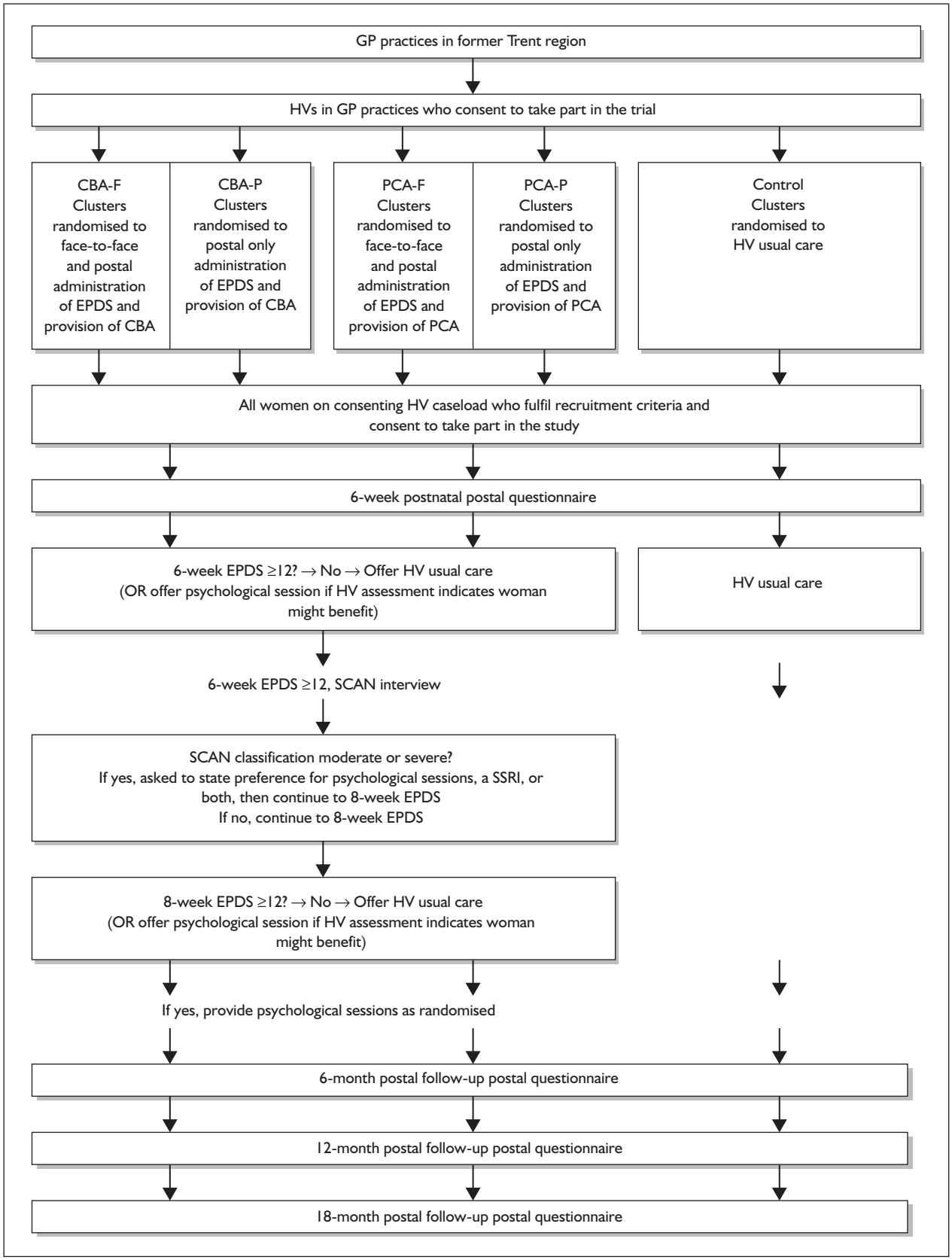

FIGURE 1 *Diagrammatic representation of overview of trial. CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; CG, control group; EPDS, Edinburgh Postnatal Depression Scale; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group; SCAN, Schedule for Clinical Assessment in Neuropsychiatry.*

Estimates of intracluster correlation coefficient

We used the ICC (ρ) estimate of 0.006 derived from 6-month EPDS scores by GP practice,[146] which indicated little clustering by practice.[170] Among the interested practices, the annual rate of births ranged from 50 to 150 per practice, with an average of 78 births. To estimate the number of clusters required and the numbers of women to be recruited per group to have 90% power at the 5% two-sided level of significance, to detect a 15% absolute difference in the proportions of intervention and control women with a 6-month EPDS score ≥ 12 (35% versus 50%) we made the following assumptions. If 12–14% of all women would be eligible for the intervention,[27] the average cluster size would be 6–8, 50% of at-risk women in the CG would have a 6-month EPDS score ≥ 12, and 50% of women would consent (*Table* 7). Within the IG there would consequently be 80% power to detect a 15% difference in the proportions of women with a 6-month EPDS score ≥ 12 (i.e. 42.5% versus 27.5%), between the two approaches (CBA versus PCA), as statistically significant at the 5% two-sided level.

We assumed an average cluster size of six women, which would require a total of 519 women recruited from 87 practices over 1 year. Assuming a 20% loss to follow-up at 6 months,[33] we required 649 women in total and a recruitment phase of 15 months. The sample size calculation was based on a two-sided statistical test and assumed an allocation ratio of one PCA group to one CBA group to one CG. This was so that, first, the outcomes for all of the intervention clusters could be compared with the outcomes for all of the CG clusters and, second, that the outcomes for the two IGs could be compared.

Random allocation

Cluster not individual allocation

In general it is preferable to randomise at the individual participant level. However, an individual woman could not be the unit of randomisation because it was not possible to ask the HVs to provide the control usual care to one woman and then to provide an intervention to another without some contamination of the CG.

Thus, although cluster randomisation is less statistically efficient than individual randomisation,[171] a cluster allocation was chosen to avoid major sources of bias and minimise contamination between groups, particularly as blinding was not possible.[170] The GP practice (cluster) was the unit of randomisation and intervention, because that is where the intervention was delivered, even though the effect was to be evaluated by measuring outcomes in individual women and analysing at the individual level, adjusting for clustering at the GP practice level.[165] To avoid any contamination between clusters, HVs for women in the control arm were not to be trained in the skills needed for the experimental intervention, which was not to be offered at any time in the control practices.

Cluster random allocation

To minimise any imbalance across the IGs, the details of practices were used to separate the clusters into three strata for random allocation. The three strata were based on the expected number of births per year, according to whether the HV caseload in the practice was small (less than 70), medium (70–100) or large (more than 100). Once stratified, the clusters were coded for allocation.

TABLE 7 *Range of values for cluster size used to estimate the number of clusters required*

Significance (%)	Power (%)	ICC	Average cluster size	Total clusters	No. of women in intervention arm	No. of women in control arm
5	90	0.006	6	87	346	173
5	90	0.006	7	75	348	174
5	90	0.006	8	66	350	175

ICC, intracluster correlation coefficient.

A computer-generated random list, using a program from the University of Southampton Medical Statistics and Computing Department, was prepared by Professor Mike Campbell, who was blind to the identity of the collaborating HVs and the GPs with whom they worked. This sequence was used to allocate clusters, stratified by the expected number of births per year, to one of the two main experimental groups, the CBA or the PCA, or to the CG. The two main experimental groups had an equal probability of face-to-face plus postal or postal-only EPDS administration, in a ratio of 1 CBA-F:1 CBA-P:1 PCA-F:1 PCA-P:2 control clusters. The random allocation took place in February and March 2003. To minimise selection bias the HVs were asked to consent to take part before allocation and were therefore blind to the allocation at the time of their consent. After the allocation some HVs expressed their strong disappointment about being in the CG but nevertheless continued to collaborate in the trial.

Participants

Inclusion and exclusion criteria

Cluster level inclusion and exclusion criteria

The setting for the trial was GP practices in the former Trent Regional Health Authority. The clusters were GP practices, and a cluster comprised the HVs and GPs working together in each GP practice. The HVs were the principal collaborators with support from the GPs. To be included in the trial the consenting HVs needed the support of their PCT, HV manager and at least one GP.

Individual level inclusion and exclusion criteria

There were few exclusion criteria to improve the external validity (generalisability) of the results by maximising the representativeness of the trial population. Women were eligible for the intervention if they were, first, at-risk women (who returned a 6-week EPDS score ≥ 12 on the postal questionnaire) and, second, had an 8-week EPDS score ≥ 12 when the EPDS was repeated face-to-face by the HV at 8 weeks postnatally. Women eligible for the intervention were therefore defined by two EPDS score ≥ 12. In addition, the HV was allowed to provide the intervention to those women whom the HV felt might benefit from the intervention, irrespective of their EPDS score.

To capture all women who might proceed to develop PND and become eligible for the HV psychological sessions, women were recruited if they were registered with participating GP practices, became 36 weeks pregnant during the recruitment phase of the trial, had a live baby and were on a collaborating HV's caseload for 4 months postnatally. Women who did not or were unable to give informed consent were not included for ethical reasons. There was no upper age limit but HVs were asked not to invite women who were below 18 years of age or who had severe and enduring mental health problems, that is, who had been taking antipsychotic medication for a bipolar disorder or schizophrenia.

Women who were unable to understand, read or write English were not included in the trial. The trial was not designed to address the postnatal needs of non-English speaking women specifically. This is partly because of the difficulties involved in providing, for some, a culturally sensitive and appropriate assessment and intervention. There were numerous different first languages other than English among the women registered in the clusters, including a range of Asian, European, Middle Eastern, Scandinavian and Russian languages. Resources were available for the use of interpreters for women who spoke Punjabi and read Urdu, who would not have been able to read the trial literature and give their informed consent without the support of an interpreter. The cost and complications involved in using an interpreting service to provide an appropriate intervention for all women who were unable to understand English was prohibitive. The trial therefore focused on English-speaking women, including some women with different first languages.

Recruitment and consent

Cluster level recruitment

To facilitate recruitment trial information was disseminated before securing funding, aiming to capitalise on existing networks of GPs, HVs and primary care research and development leads interested in research in the region. There was notable support of Trent Focus personnel in the former Trent region, the acting research and development manager in Broxtowe and Hucknall PCT and the Barnsley research fellow in primary care.

Trent Focus Collaborative Research Network and GPs

The first recruitment method was via the Trent Focus Collaborative Research Network (CRN).

To fulfil the normal requirements for this formal approach a practice briefing outlined the trial and explained the intervention and follow-up, what would be expected of participating practices, the covering of costs for involving HVs' and practice time, and what practices should do if they were considering taking part. The CRN co-ordinator sent or gave information to 56 participating practices and forwarded to the principal investigator the details of those who were interested in the trial.

Trent Focus Collaborative Research Network and HVs

In January 2003 a letter was sent via the CRN to a further 53 HVs in Nottingham whose managers had been primed in 2001 about a different HTA PND study, which was approved but subsequently not funded. The letter included information for HVs explaining the special requirements for HVs in their potential role in the IG or CG, emphasising that they should avoid contamination and not discuss their allocation, training or protocol with HVs outside their practice.

Another letter was written to GPs in May 2003, with a practice briefing to pass on to interested HVs, to ask if there were changes in people's circumstances. The Trent Focus CRN co-ordinators also provided information face-to-face when they had contact with GPs and HVs, and an article was placed in the Trent Focus newsletter in June 2003 to indicate that 15 further practices were required.

Other collaborative research networks in the region

A joint letter was sent in January 2003 to all of the GPs on the membership list for the networks BacReN (26 GPs), DocReN (8 GPs) and ShefReN (27 GPs), using the same approach as for the Trent Focus network, asking them to discuss the research with their HVs.

Academic departments of general practice

To make primary contact with other GPs a practice briefing was sent electronically within the academic departments to 19 GP practices in Nottingham and GPs in 16 practices in Sheffield. A request was made to the academic department in Leicester to ask if they would advertise the opportunity in the same way.

Community Practitioners' and Health Visitors' Association

Information about the trial was distributed at the CPHVA Harrogate conference in October 2002, where there was a special interest group meeting about PND. Also, short articles were sent to the CPHVA newsletter asking for expressions of interest in collaborating.

R&D offices in Trent

Alongside the application to PCTs for research governance approval, there was a request for information about the trial to be sent to HVs and HV managers via the internal PCT mailing system. Following this, several presentations were organised with the opportunity to give a presentation to HVs and their managers, to explain the rationale for the trial and the potential for collaborating in the trial. The greatest number of primary face-to-face contacts with HVs resulted from this direct approach to the Trent PCT research leads and the ensuing visits to PCTs. All interested HVs were asked to provide details of the number of expected births per year, the total practice population and contact details for the practice manager.

Primary care trust service managers

Directors of clinical services and managers for the health visiting services were approached directly and a series of meetings were arranged to further disseminate information about the trial. Personalised letters were sent to individual HVs who had expressed an interest in taking part.

Second approach to primary care trusts

When HVs in 72 clusters had consented, flyers were distributed via the PCT research leads, explaining that a further 18 clusters were required and highlighting confirmation from the Department of Health of NHS funds to cover the time that the HVs might spend in training, identifying or supporting women.

The letter presented the benefits for the HVs as an opportunity to:

- experience the research process first hand
- altruistically contribute to the evidence base of interventions for PND
- generate data to contribute to the debate on the use of the EPDS[8]
- take a two in three chance of being invited to attend training to develop skills in one of two different approaches to identify and support women with PND.

Presentations

There was an invitation to make a presentation to the Nottingham HVs Research Interest Group, the Lincolnshire Research Group and Nottinghamshire Healthcare, among others.

A co-applicant (EMcG), a PCT chief executive, acknowledging the major recruitment drive at the start and the possibility that saturation may have been reached at the time, suggested writing to all PCT chief executives to encourage them to support their HVs who might wish to take part in the trial.

Cluster level consent

Following approval from the Trent Multicentre Research Ethics Committee (MREC) in February 2003, at least one GP in each practice was asked to sign the consent form to indicate that they understood the HVs' research role and that the GP practice would support their collaboration. The HVs and GPs then signed a consent form stating their duties before they volunteered the women in their practice as a cluster.[172,173]

Once they had consented, the HVs were given details of the group allocation and, when relevant, the training cohorts, and a trial file with the HV protocol to guide the recruitment of women, administration of the EPDS and provision of information to the research office, according to allocation to group.

As not all of the clusters consented at the same time the randomisation process was repeated when there were sufficient clusters with enough HVs to comprise a training cohort for each psychological approach, plus the equivalent number of control HVs, to allow random allocation at one time. Because of this there were five successive training cohorts, to accommodate the training needs of the HVs who were recruited at different times.

Individual level recruitment

The protocol stated that IG women found to be at risk of PND would be offered an intervention as part of the trial. To avoid selection bias HVs were asked to invite all eligible women antenatally to consent to take part in the trial, before the development of any depression.

The HVs were asked to log the details of pregnant women and, to avoid disclosing personal details to the research office at a preconsent stage, they were asked to post the women a research information leaflet (RIL) and a consent form at 32–36 weeks antenatally. Women gave or sent their signed forms to the HVs, who were asked to send the originals and fax (or photocopy and post) the updated consented women's log each week to the research office for monitoring the consent rate and preparing the 6-week questionnaire for posting.

Individual level consent

Normally consent to take part in a trial is obtained before randomisation, to reduce the possibility of selection bias. People in a randomised controlled trial would normally be asked to consent to be part of an experiment, having been informed of their chance of being allocated to the experimental intervention. Although the clusters consented before randomisation it was impossible to obtain women's consent before the clusters were randomised.

There are ethical issues surrounding consent in cluster trials.[172,174] A balance was needed to retain women's autonomy; to provide women with enough information to avoid increasing their concern, losing the good will of disappointed CG women and, because of lack of incentives, jeopardising the recruitment rate; and to avoid non-random selection bias and differential consent affecting the validity (SJL Edwards, 2002, personal communication).[173]

It is recommended that consent should be sought at all possible levels, and for the trial these were the sponsor, the MREC, the PCTs, health-care professionals, as 'guardians', and individual women acting independently of the guardian.

The trial followed the Medical Research Council (MRC) guidance on cluster recruitment.[175] All women received explicit information about the trial and the same consent process was used for all women. The RIL explained that women were being asked to take part in a study in which one-third of HVs would continue to provide their usual care in up to 30 practices, whilst the other HVs would provide one of the two kinds of support being researched for women found to be at risk of PND. CG women were asked only to return their postal questionnaires, and they would still receive routine care.[171,173] Monitoring the rate of consent in each cluster assessed the scope for potential bias. The HVs were asked to document the women's main reasons for choosing not to participate.

Baseline measurements

Baseline measurements at cluster level

The cluster level characteristics of PCT, number of GP partners, number of full-time equivalent HVs, practice population, expected births per year and Index of Multiple Deprivation (IMD)[176] were collected and compared to establish the comparability of cluster characteristics, as well

as the representativeness among other practices within the region and nationally.

Baseline measurements at individual level

The probability of an imbalance on important prognostic variables may be greater for a cluster randomised controlled trial than an individual randomised controlled trial.[171] The measurement of baseline individual level variables also allows an assessment of how the randomisation process has worked to produce directly comparable groups. Furthermore, this comparison can be used to indicate where any baseline adjustments, if any, should be made, depending upon how great the differences might be, as well as the predictive relationship of a characteristic with the primary outcome. We therefore measured sociodemographic baseline variables. The HVs collected details of women who were ineligible or who declined to take part in each cluster – whether a woman's baby was her first, a girl or a multiple birth. They also collected information on whether a woman had had PND previously, had English as a first language, lived alone or lived in rented accommodation and on the type of housing. This information was compared with the details of consenting women and was used for describing the generalisability of the results. The MRC guidelines indicated that completely anonymised personal data could be used for such a purpose.[175]

Six-week measurements

Six-week postal questionnaire

There was a change to the original protocol, replacing the BDI with the Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM), as it was a more suitable instrument to measure the outcome of psychological therapy and because of cost considerations. The 6-week postal questionnaire included questions on demographics and feeding the baby and the following instruments:

- the EPDS
- the 36-item Short-Form Health Survey Questionnaire (SF-36v2)
- CORE-OM
- Measure of Social Relationships (MSR)
- Life Events Questionnaire (LEQ)

The Edinburgh Postnatal Depression Scale

The EPDS[8] is a self-report 10-item measure of depressive symptoms with a score ranging from 0 to 30 (the highest symptom level), which is widely used in research and clinical practice but which alone is inadequate for confirming depression without a clinical interview. The 10 questions ask women to indicate how they have been feeling over the previous 7 days, using a range of four options per question to indicate the frequency of the feeling, to provide a score of 0–4 per question. The tenth question asks about suicidal ideation.

The EPDS was originally developed as a screening tool because of the limitations in the number of available tools for screening for depression, many of which appeared to lack face validity for postnatal women. The tool was described as an acceptable, simple self-report scale, with satisfactory reliability and validity to minimise the chance of false-positive or false-negative results, as well as sensitivity to change over time. In addition, the tool was validated in a community setting. Originally, 13 items were selected from 21 as being most suitable, including seven newly constructed items and six adapted from other scales. The validity of this 13-item scale was established on 63 women and three items were removed to improve the specificity. The remaining 10 items were validated on 84 women at a mean of 12 weeks postnatally. A score of 13 identified all 21 women with a definite major depressive illness, but missed one probable major illness. There were 11 false positives at this threshold and four women with definite minor depression were missed, that is, they were false negatives. Using a threshold of 12 correctly included all people with probable and major definite depression and reduced the false negatives to three women, but increased the false positives to 14 women. At this threshold of 12, the sensitivity for identifying depressed women (true positives) was 86% and the specificity for identifying true negatives was 78%. The positive predictive value was 73%. A cut-off score of 10 reduced the failed identification rate to fewer than 10% but doubled the number of false positives to 10 women. A cut-off of 9 correctly identified all women with definite minor depression but it was judged that there would be an untenable workload for HVs if a lower threshold was used.[4]

Sensitivity to change was calculated for an undisclosed number of women who repeated the score and who were interviewed for a second time, and mean scores were found to be reduced. The authors[8] emphasised that the EPDS is not a substitute for a clinical assessment and that a score of 11 does not indicate the absence of depression. They suggested that a threshold score of 9 or 10 might be considered for use routinely in primary care. The tool has become widely used in the UK to

identify the risk of PND at 6–8 weeks postnatally, using 12 as the threshold for concern.

In a study to assess the accuracy of the EPDS in identifying psychiatric problems in a representative community group of 702 postnatal women (aged 20–40 years)[9] the return rate was 97% on a postally administered EPDS, completed when a woman's baby was 6 weeks old.[39] All women who scored 13 or more, 142 of those who scored 10–12 and 45 of those who scored less than 10 on the EPDS were interviewed using a psychiatric interview using research diagnostic criteria for depression. Using a threshold EPDS score of 10.5 identified 90% of the women with major depression and 75% of the women with minor depression. The threshold of 12.5 identified 80% of women with major depression and 50% of those with minor depression. The sensitivity for identifying true positives was found to be 67.7%, rather than 86% as reported in the Cox validation study of 84 women.[8]

A number of cautions have been raised about the EPDS. There is concern that women may not answer the questionnaire truthfully, because of fear of the stigma of depression, wanting to be a good mother and fear of having their baby taken away.[177] There is a general problem with the identification of depression in primary care,[49] including PND [24,26,50] The EPDS is one of the mood assessment instruments most widely used in clinical practice, [54] but it was not developed as a diagnostic test[55] and cannot be used to confirm PND without a clinical interview. It has advantages and disadvantages.[18,58–61] The EPDS was used in the trial to identify the women to be included because they were more likely to be at risk of PND (rather than as a screening instrument) and then as an outcome measure at 6 months.

In the trial a pragmatic threshold score of 12 was used, as recommended for clinical practice by its developers.[8,178] Women who scored ≥ 12 on their 6-week postal EPDS were termed at-risk women. The threshold score was used to identify the IG women more likely to benefit from psychological sessions and for whom a direct comparison would be made between the intervention and control groups. A cut-off score of 12 carries the risk of not including some depressed women who might score 10 or 11,[8] but was used in the trial for consistency with previous work, which predicted 'an untenable workload' if a cut-off score of 9 or 10 was used.[4] The EPDS was therefore not used as a pass or fail tool.

It was recognised that women could simply be unhappy at the time of completion and it was recommended that women with a high score should complete another EPDS after 2 weeks to identify those who needed intervention, and this was the process we followed.[56] The lack of substantive evidence of potential benefit and therefore the likely inefficiency of working with women who were not truly depressed were also important considerations.

Administration of the 6-week EPDS

In the trial the EPDS was administered at 6 weeks postnatally to coincide with an existing HV contact. To identify potential clinical or economic benefits of a 6-week postal administration over a 6-week face-to-face HV administration, half of the IG HVs administered the EPDS face-to-face. Therefore there were two IGs using the face-to-face plus postal EPDS administration for comparison with two IGs using postal-only EPDS administration. All women received the EPDS as part of the large postal questionnaire, sent from the research office. Within the random allocation schedule, each of the IG clusters had an equal chance of being allocated to the face-to-face and postal administration or postal-only administration group (*Table 8*). The four IGs for comparison were (1) CBA: face-to-face and postal, (2) CBA: postal only, (3) PCA: face-to-face and postal and (4) PCA: postal only.

Short-Form 36 (SF-36v2)

The SF-36[179] was used to measure general health status among the women in the trial at 6 weeks postnatally. The SF-36 was originally

TABLE 8 *Illustration of two-way factorial design*

	Cognitive behavioural approach	Person-centred approach
Face-to-face and postal administration of EPDS	CBA-F group	PCA-F group
Postal-only administration of EPDS	CBA-P group	PCA-P group

CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; EPDS, Edinburgh Postnatal Depression Scale; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group

developed to routinely monitor patient outcomes in medical practice, to survey health status in general population surveys and for health policy evaluations, research and clinical practice. The instrument was developed to measure a comprehensive range of health concepts and identify clinically and socially relevant differences in health status and changes over time. It can be completed individually by people aged 14 and over, by post or by a trained interviewer, either face-to-face or over the phone. The questionnaire consists of a 36-item scale covering eight health domains:

1. limitations in physical activities because of health problems: 10 items
2. limitations in social activities because of health or emotional problems: 2 items
3. limitations in usual role activities because of health problems: 4 items
4. bodily pain: 2 items
5. general mental health (psychological distress and well-being): 5 items
6. limitations in usual role activities because of emotional problems: 3 items
7. vitality (energy and fatigue): 4 items
8. general health perceptions: 5 items.

For the 10 questions on physical functioning, for example, the respondents indicate whether they are limited a lot, limited a little or not limited at all. Responses are scored and coded on a scale having from 3 to 5 points and are then summed and transformed for each domain onto a scale ranging from 0 (worst possible health) to 100 (best possible health).

The SF-36 was used in the trial as an appropriate measure of general health as it has been shown to be acceptable and easy to use, with good postal response rates, and to have good psychometric performance in terms of internal consistency using Cronbach's alpha statistic, retest reliability and construct validity.

Clinical Outcomes in Routine Evaluation Outcome Measure

This instrument was developed to audit and measure the outcome of psychological therapy across a wide range of service types by measuring global distress, making it suitable for use as a self-report assessment tool as well as a self-report outcome, to distinguish clinical and general populations.[180] It is licensed for use without royalty charges, provided others do not change it or make financial profit from it.[181]

There are 34 items, scored on a 5-point scale from 0 (not at all) to 4 (all or most of the time), with a higher score indicating worse health. Four of the items measure subjective well-being; 12 items measure problems or symptoms (anxiety, depression, physical or traumatic symptoms); 12 measure life functioning (general; with close and social relationships); and six measure risk of self-harm. Eight of the items are positively phrased. The tool is acceptable (overall omission rate 1.7%) with appropriate internal reliability (0.75–0.95 for all domains). Some questions are used to compare the intensity of a problem. The total mean score is calculated using the number of completed items as the denominator, to take into account missing data. The mean score for each of the four separate dimensions can be calculated separately, also using the number of completed items as the denominator.

Recently the scoring procedure for the CORE-OM has been changed and the new cut-off score is 1.0 and a clinical score is used, which is more consistent with other scoring systems.[182]

Measure of Social Relationships

Lack of social support is one of the predictors of PND. The MSR questions were used to estimate the number of people to whom the woman felt close, including relatives, friends and acquaintances, distinguishing adults that the women lived with from others with whom the woman did not live. Inter-rater reliability is good and stability over time is moderate and statistically significant.[183] Adults with a total primary group size of three or fewer people have been shown to be at greatest risk of psychiatric morbidity.

Life Events Questionnaire

Brown and Harris[184] indicated that a severe life event might act as a provoking agent and increase the risk of depression. One of the predictors of PND is stressful life events.[27] The LEQ was therefore used to investigate any relationship between brief depression and any recent stressful life event. The questionnaire consists of 12 questions, derived from the Life Events and Difficulties Scales interview by Brown and Harris on common life events that are likely to be threatening, such as bereavement, serious illness or financial crisis. Originally it was used as in a semistructured interview schedule. With only a yes or no response required it is regarded as being brief, convenient and acceptable to subjects.[185] Three or more threatening life events

in the previous 6 months might predict a negative outcome.

Processing the 6-week questionnaires

Returned questionnaires for the IGs were opened and date stamped. The 6-week EPDS was manually scored and for consistency these EPDS scores (rather than the HV face-to-face scores) were used according to the research protocol to determine which women should have a repeat EPDS. For all IGs the HV was informed if the EPDS score on the postal questionnaire was 12 or more or the woman had replied positively to item 10 (the thought of self-harm). For the postal groups (CBA-P, PCA-P) the HV was informed of the complete EPDS score on the postal questionnaire. If the HV was unavailable the GP was informed about a positive score on item 10. The return date, the EPDS score and the date that the HV was informed of the score were recorded on the research office Excel spreadsheet.

The CG questionnaires were not opened, to avoid knowing what a woman's EPDS score was in case, ethically, the research office was obliged to inform the HV of a raised score (or a positive response on item 10, indicating the thought of self-harm), which, in turn, may have affected the CG usual care. The questionnaires were therefore date stamped on the outside of the envelope and filed for 6 months before being opened. The return date was recorded on the research office Excel spreadsheet. Reminder telephone calls, reminder letters and duplicate questionnaires were used to gather missing responses.

The intervention

Cluster level intervention

The cluster level intervention comprised the package of HV training in assessing women and identifying depressive symptoms (using the EPDS and clinical assessment) and the delivery of either CBA[166] or PCA[167] psychological sessions to at-risk women.

The manualised HV training addressed therapy allegiance and prepared the HVs to provide an appropriate, pragmatic, distinctive, derivative approach, delivering critical elements from CBT or person-centred therapy, not psychotherapy.

The common areas for both training approaches were to enable HVs to acquire further generic skills in developing helpful relationships, such as positive regard and empathy. The cognitive behavioural training emphasised a normalising rationale and the identification of unhelpful patterns of behaviours, perceptions or thoughts in the woman's life, in order to help the woman to change these herself.[166] The person-centred training used the three principles of the actualising tendency, a non-directive attitude and the necessary and sufficient conditions of change.[167] Further details of the HV training are provided in the section on training of the intervention group HVs.

Individual level intervention

The proportion of women with a 6-week EPDS score ≥ 12 was very important, as this was the group of at-risk women whose outcomes were compared across all IGs and the CG at 6 months postnatally. It was not possible to use the group of women eligible for the intervention with an EPDS score ≥ 12 on two occasions in the comparison as the HV 8-week EPDS scores were not available for the CG women.

At-risk women were interviewed at 7 weeks postnatally using the SCAN, which incorporates algorithms using ICD-10 criteria for depression to determine depression severity (none, mild, moderate or severe).[168] Those with an ICD-10 SCAN classification of moderate or severe depression were asked to state their preference for psychological sessions, an SSRI, or both.

The HV readministered the EPDS to at-risk women face-to-face at 8 weeks postnatally. Women with an 8-week EPDS score ≥ 12 were offered the psychological sessions as cluster randomised. These consisted of a 1-hour CBA or PCA session, focusing on the needs of the mother, once per week for up to 8 weeks, commencing around 8 weeks postnatally. Because of the limitations of the EPDS some HVs also offered the sessions to women, irrespective of their 6-week or 8-week EPDS scores, if their assessment indicated that they were likely to benefit.

Health visitor usual care

The system of health visiting in the UK provides unique routine contact with postnatal women, at a new birth visit and in well-baby clinics. HVs completed preallocation questionnaires to establish their usual care. This indicated that 67% of HVs had attended brief training in the previous 5 years on identifying or supporting women at risk of PND, and that they were more confident in identifying women with PND than supporting

them. Practice varied with 47% of HVs using EPDS assessment at 6 weeks postnatally, according to PCT policy.

In both the control and intervention groups, HVs were typically not experienced in offering psychological sessions but would refer to a GP. After randomisation the control HVs continued to represent this variability, and women in the CG continued to receive the range of postnatal care as usually provided by these HVs. All HVs continued to fulfil other aspects of their role.

Outcome measurements

Primary outcome: at-risk women

The primary outcome was the difference between the proportion of at-risk women scoring ≥ 12 on the 6-week EPDS administered by postal questionnaire and the proportion scoring ≥ 12 at 6 months postnatally, to assess persisting risk of PND.

Four-month follow-up: at-risk women

A 4-month follow-up was proposed for IG women who received an intervention to compare outcomes immediately at the conclusion of the intervention sessions. However, the 4-month follow-up was not possible to achieve, mainly because it was impractical to send a further questionnaire, which may have imposed a further burden on already unwell women and may have served as a deterrent to returning the 6-month postal questionnaire (the primary outcome) 8 weeks later. For some women whose intervention did not begin exactly at 8 weeks postnatally, the outcome would have been assessed before the end of the intervention. It may also have led to a further degree of incomparability when only the women who had received an intervention were asked to complete a questionnaire at 4 months.

Secondary outcomes

A range of other outcomes was measured to capture the potential benefit from the intervention in different dimensions of health and use of services. The secondary outcomes were measured in at-risk women at 6, 12 and 18 months postnatally by postal questionnaires. Standard instruments were used as the main and secondary outcomes, with supplementary questions.

Six-month secondary outcomes: at-risk women

At-risk women's 6-month follow-up questionnaire

A follow-up questionnaire was posted to the at-risk women just before their baby was 6 months old. Apart from the EPDS the other instruments were:

- SF-12 Health Survey
- CORE-OM
- State–Trait Anxiety Inventory (STAI)
- Parenting Stress Index (PSI) (Short Form)
- Dyadic Adjustment Scale (DAS) (Short Form).

The SF-12 is a shorter instrument than the SF-36.[186] It contains the items that best represent the physical and mental health summary scores from the SF-36.[187] The SF-12 has two main dimensions, the physical component summary (PCS) and the mental component summary (MCS), with scores standardised to have a mean of 50 and a SD of 10, the same as for the reference population. As our trial had a large sample size and we monitored change in health over time, the SF-12 had advantages over the SF-36 in reducing some of the burden for the participants who were asked to complete several other measures in the follow-up questionnaires.

State–Trait Anxiety Inventory

Anxiety states are transitory, provoked by stimuli peculiar to certain individuals, with features of apprehension, feelings of tension, nervousness and worry, and arousal of the autonomic nervous system. Rather than a transitory state, trait anxiety refers to a relatively stable acquired predisposition to both perceive cues of certain situations as stressful and be activated to respond to the cues in a particular way, through past experience. The stronger the trait anxiety, the more likely that an individual will have a more elevated state anxiety in a particular stressful situation. It was important to assess women and their partners for anxiety disorders postnatally, to more accurately reflect adjustment to new parenthood.[188]

The STAI[189] is a self-administered questionnaire recommended for studying anxiety in research and clinical settings, to measure the level of intensity of an emotional state at a given point in time. It has been used in clinical practice and research to measure state and trait anxiety. Some items ask about the presence of anxiety symptoms and others ask about their absence. The 20 questions in the 'State' questionnaire ask respondents to report how they feel 'right now, that is, at this moment' and the

'Trait' questionnaire asks how they 'generally (that is, how you usually) feel'. Each item is scored from 1 to 4 (with 4 indicating high anxiety), with a range from 20 to 80. A missing score for one or two items can be incorporated by calculating the mean score (1–4) for completed items and multiplying by 20. The normative state anxiety scores for 451 adult women were 35.2 (SD 10.4) and the trait anxiety scores were 34.8 (SD 9.19), with a trend for lower scores in older women.

Parenting Stress Index Short Form

The PSI Short Form[190] is designed to measure any perceived stressful impact of having a young child. Respondents were asked to circle their responses on a 5-point scale to indicate their level of agreement with each statement, and were given a score of 1 for each 'strongly agree' response and a score of 5 for each 'strongly disagree' response. The first 12 items relate to the parenting distress subscale, which asks about feelings of parental competence, stresses associated with restrictions on lifestyle, conflicts with the child's other parent, lack of social support and depression. The following 12 items relate to the parent–child dysfunctional interaction (PCDI) subscale, which asks about the parent's perception that the child does not measure up to expectations and whether the interactions with the child are reinforcing. The final 12 questions relate to the difficult child subscale, which asks about the child's behavioural characteristics that affect their management. The sum of the three subscales gives the total stress score. A separate defensive scoring total is derived from the responses to questions 1–3, 7–9 and 11. The mean total stress score is 224 (SD 38), the mean child domain is 98 (SD 20) and the mean parent domain is 127 (SD 26) for the parent of a 1-year old child.

Dyadic Adjustment Scale

This 32-item instrument[191] was designed to measure components of the primary relationship between unrelated adult couples living together (whether married or not), as a snapshot at the time of data collection. The DAS is one of the tools most widely used to assess the severity of problems between couples.[192] The main components or subscales measured were dyadic consensus, satisfaction, cohesion and affectional expression. The 32-item scale can be incorporated into a self-completed questionnaire or used in an interview. Each of the subscales can also be used independently. Respondents indicate the extent of agreement between them and their partners on a Likert-type scale (always agree, almost always), and disagreement (occasionally disagree, frequently, almost always or always) with each of the items on the list of questions. The other items ask the respondent to indicate how often situations occur (all of the time, most of the time, more often than not, occasionally, rarely or never). The replies were all scored on a 6-point scale, where 0 is worst and the highest theoretical score 51 is best.

Twelve-month secondary outcomes: at-risk women

At-risk women's 12-month follow-up questionnaire

The trial ended before the 12-month follow-up point was reached for many at-risk women. Therefore, a smaller number of postal questionnaires was administered at the 12-month postal follow-up. A 12-month follow-up questionnaire was posted to the at-risk women just before their babies were 1 year old. The questionnaire included the following instruments:

- EPDS
- SF-12
- CORE-OM
- STAI
- PSI (Short Form)
- DAS (Short Form).

Eighteen-month secondary outcomes: at-risk women.

At-risk women's 18-month follow-up questionnaire

The trial ended before the 18-month follow-up point was reached for many at-risk women, therefore a smaller number of postal questionnaires was administered at this follow-up time. A follow-up questionnaire was posted to the women just before their babies were 18 months old. The questionnaire included the following instruments:

- SF-12
- CORE-OM
- STAI
- PSI (Short Form)
- DAS (Short Form).

18-month SCAN interviews and monitoring remission and relapse

The 18-month follow-up assessed both the level of depression remaining at 18 months and the proportion of the time that women had felt well since their baby was born. During the 18-month follow-up visits, remission and relapse were assessed among women from all three groups, including the CG. The women were provided with an indication of their depression immediately after the SCAN

interview, as a benchmark. The women were asked to remember how they felt over the previous 18 months using memorable dates, such as the baby's and their own birthdays, Christmas, Easter and the summer holidays. They were asked to indicate on a user-friendly chart whether their health had previously been better or worse in comparison with the way that they felt over the most recent month. This kind of life charting is important in conditions that endure over time and where there might be great fluctuation over that time interval.[193]

Six-, 12- and 18-month secondary outcomes: all women

All consented women, not only at-risk women, were followed-up at 6, 12 and 18 months postnatally, as some women with a postal 6-week EPDS score < 12 may have been depressed or may have developed depression after 6 weeks postnatally. At all time points postnatally the same postal questionnaire was sent to all consented women, including the same outcome measures as for the at-risk women.

Six-, 12- and 18-month secondary outcomes: partners

The self-perceived health status of the partners was measured by postal questionnaire at 6, 12 and 18 months after the baby was born.

A questionnaire for the women's partners to complete was included in the same envelope as the questionnaire sent to the women, at the same three follow-up time points as the women. At 6 months this included demographic questions and the MSR, the LEQ, the SF-12, the PSI and the DAS. At 12 and 18 months it included the SF-12, the PSI and the DAS. At 18 months the partners' postal follow-up questionnaire also included the CORE-OM.

Infant outcomes

To examine infant development outcomes from the perspective of both parents, on the 18-month questionnaire women and their partners completed questions on their toddler's growth and development and on concerns about toddler development, the modified Behaviour Screening Questionnaire (BSQ) and the Checklist for Autism in Toddlers (CHAT). The scores on the infant outcomes were rescaled onto a 1–100 scale. The HVs extracted infant immunisation data from the GP records.

Behaviour Screening Questionnaire

The BSQ was developed to assess behavioural difficulties in 3-year-old children. It was modified for 18-month-old infants in a study to investigate the cognitive, social and emotional development of infants of mothers with PND, compared with infants of non-depressed mothers.[39] This modified questionnaire was administered at 18 months postnatally as part of the mother's and partner's questionnaires. It covers feeding and sleeping problems, temper tantrums, excessive dependency, miserable mood, relationships with peers and problems in management. All questions had a 3-point response rating to indicate no problem, a mild problem or a marked problem.

Checklist for Autism in Toddlers

The CHAT is a short questionnaire of nine items,[194] which is completed by a parent to identify children aged 18 months who are at risk for a social–communication disorder. It looks at joint attention, pretend play, protodeclarative pointing and producing a point. It is quick and easy to complete with nine questions requiring a yes or no response. A negative response on five items indicates whether a child has a high or medium risk of developing autism.

Statistical analysis

All analyses were by intention to treat with a p-value of < 0.05 regarded as being statistically significant. The intention to treat primary statistical analysis included all women with both a 6-week and a 6-month EPDS score and there was no imputation of missing data. The trial was reported according to the CONSORT statement extension to cluster randomised trials.[195]

Primary outcome

The primary outcome was the proportion of at-risk women with a 6-week EPDS score ≥ 12. The primary comparison was between those at-risk women in the combined clusters randomised to intervention and those women in practices randomised to provide HV usual care (control). The secondary comparison was to determine any differences between the proportions of women with a 6-week EPDS score ≥ 12 for the two main IGs.

A marginal generalised linear model, with coefficients estimated using generalised estimating equations,[196] with robust standard errors and an exchangeable autocorrelation matrix in STATA v8[197] was used to analyse the outcomes and allow for the clustered nature of the data. For binary outcomes, such as EPDS score < 12 or ≥ 12, a logit

link with a binomial distribution for the outcome was used.

Secondary outcomes

For continuous outcomes, such as mean EPDS score, an identity link with a normal distribution for the outcome was used. Estimates for the group coefficients from these regression models were reported along with their associated 95% confidence intervals. In all of the analyses both a simple unadjusted model and a model to adjust the outcome comparisons for individual level covariates, for example lives alone, history of PND, life events and baseline (6-week) EPDS score, were fitted.

The exchangeable correlation structure corresponds to an equal correlation model, meaning that the correlations of outcomes with a cluster (GP practice) were constant.

For the other secondary maternal outcomes, that is, the CORE-OM, STAI, SF-12, PSI and DAS, the mean values were compared between the intervention and control groups at 6, 12 and 18 months using similar models.

The family outcomes collected from women's partners at 6, 12 and 18 months were compared between the intervention and control groups. For the infants, outcomes at 18 months were compared between the intervention and control groups.

The primary analysis was for the at-risk women with an EPDS score ≥ 12 who had completed a 6-month EPDS score ($n = 418$). The analysis was also reported for the cohort of all women who consented and who completed a 6-week and a 6-month EPDS ($n = 2659$).

There is no general consensus on what procedure to adopt to allow for multiple comparisons[198,199] Following this we have reported unadjusted p-values and confidence limits. However, because of multiple hypotheses testing, some caution should be applied in the interpretation of the p-values we have reported, particularly for the various secondary outcomes and end points.

Training the intervention group health visitors

Training Reference Group

The implementation of the psychotherapeutic HV training programmes and intervention was informed by the documented methodological prerequisites for comparative psychotherapy research.[200,201] The major requirement was to minimise any biasing effect of any of the researchers' allegiances to either of the therapeutic approaches. To enhance the rigour and effectiveness of training for both psychotherapeutic approaches, to maximise the comparability of the programmes and to ensure that the trial would be considered by advocates of each method to have been a credible and fair test of that method, a Training Reference Group (TRG) was established before the trial, at the end of 2002. This comprised experienced academically based psychotherapy trainers from England and Scotland, including representatives of both the cognitive behavioural and person-centred approaches.

The TRG considered the potential for bias and distortion of results of comparative studies attributed to researchers' loyalties to their preferred therapeutic method.[202] Two of the practical recommendations to try to minimise any potential impact of a researcher's therapy allegiance unfairly influencing the effect size of the therapy compared were to include a mix of researchers who represent different therapy allegiances and to arrange for the people providing the therapy to be supervised by those representing the same intervention mode.

Training manuals

The two main psychotherapist trainers (TR and KT) were specialists with experience in practice as trainers and supervisors. They prepared a manual for each HV to keep throughout the trial, and a separate trainer's manual. The manuals were to include the theoretical basis for the relevant psychological approach and the training plan so that, if necessary, the training could be replicated elsewhere. The manuals were drafted in January 2003 and final changes were made in February 2003.

Principles and standards for training for the intervention

The TRG held two verification meetings at the University of Sheffield in November 2002, chaired by Professor David Shapiro. The following summarises the main principles and standards for the HV training and manuals.

Recognising the training employed in previous trials in Edinburgh – '*a brief training in the principles of person-centred counselling*'[1] – and in Manchester,

using CBT,[3] the training in the planned trial was to prepare HVs to provide a brief, derivative intervention, not psychotherapy, mainly for pragmatic reasons. That is, the outcomes to be compared between the IG and CG would be associated with a brief training in delivering critical elements derived from one of the two therapies (cognitive behavioural therapy and person-centred therapy). The training had to be delivered at an appropriately pragmatic level to enthuse HVs and develop their skills, rather than to develop their theoretical knowledge, recognising the preference of HVs to support women with psychological difficulties rather than to become mental health workers. It was not intended that the HVs should regard themselves (or be regarded) as therapists, whose training takes much longer than 8 days. Therefore, the terms 'person-centred approach' and 'cognitive behavioural approach' were to be used consistently, to avoid the use of the term 'therapy', 'counselling' or 'counsellors'.

Comparable training

The TRG was asked to verify that the training manuals for both intervention arms were comparable, with an appreciation of the differing ethos and styles of the two psychological approaches.

For the CBA the purpose of the training was to prepare HVs to provide a simple, easily communicated intervention related to the phenomenology of PND. The basis of the training was the worksheet approach, in which HVs learned to carry out a problem-focused assessment in five key areas of a woman's experience and then select and use appropriate PND-specific worksheets for each woman.

For the PCA the purpose of the training was to prepare HVs using key principles and issues in such a way that they would be able to help the women to accept and ameliorate their depressive process.

The training preparations aimed to make the training experience equal, as far as possible, for all IG HVs. To enhance comparability it was agreed that all training cohorts should ideally be no larger than 12 (to allow for four small groups of three HVs working together during the training day) and no fewer than eight HVs. The training used the term 'client' or 'woman' rather than 'patient'. Key qualities of the training environment were that they should be uninterrupted and secure and congruent with what would normally be expected of a training environment, with a pragmatic consideration of reproducibility and deliverability in the NHS.

Appropriate training

The TRG emphasised the avoidance of unfamiliar language and jargon, for example the term 'negative automatic thoughts', to avoid putting off HVs and to provide accessible, distinguishable, theoretically congruent and reproducible models with key skills. As well as being appropriate for the HVs, the intervention was planned to be appropriate for the women, with little time or energy to do too much homework.

Clinical supervision

The HVs also needed access to clinical supervision and support, for example when dealing with distressing information from a client, such as negative thoughts towards the baby. Regular formally structured reflective practice sessions using role-play were offered for HVs who may not have had the opportunity to work with affected women. HVs also attended peer-supervisory sessions.

Prior beliefs of health visitors

Because of the random allocation of clusters to the groups (control, CBA or PCA), the HVs would not be able to choose any preferred option. Therefore, there was the potential for incongruence between HVs' personal predispositions or beliefs and one of the approaches. To be able to check the balance of the randomisation in terms of HVs' prior beliefs, there was a prerandomisation measurement before random allocation of all of the HVs' attitudes and levels of interest and motivation in counselling, using the Opinions on Psychological Problems (OPP)[203] within a pre-trial questionnaire. The OPP is a self-report, two-part questionnaire developed to measure how people view the causes of and treatments for psychological problems. The first part measures how people view the causes of psychological problems. The second part, the treatment section, includes 47 questions about people's views on what may help psychological problems. The questions are grouped under the following headings:

- psychodynamic
- humanistic/interpersonal
- behavioural
- cognitive
- organic

- social/economic
- naïve.

Each question has six responses and is scored on a 6-point scale from –3 to +3, where +3 means agree strongly and –3 means disagree strongly. The HVs were asked to indicate their level of agreement with each of 37 statements. The OPP in the HV questionnaire included only 37 questions as the naïve questions were not included. The second part of the OPP was included in a post-trial questionnaire for intervention and control group HVs, when the intervention was complete, to assess any post-trial differences between the three main groups.

Pre-trial health visitor questionnaire

To gather personal views and experience within the pre-trial questionnaire, to establish baseline practice, HVs were asked to answer truthfully, without discussing any of their answers. Codes were used so that all answers could be treated completely confidentially. The questionnaire included questions about:

1. Skills – details, the title, length, year and location of training, qualifications achieved for training on identifying or supporting women at risk of postnatal depression.
2. Assessing and identifying women – at baseline, how much confidence they had in identifying and supporting women who may be at risk of postnatal depression and how, over the previous 6 months, they had assessed and identified women who might have been at risk of PND.
3. Use of the EPDS – personal use of the EPDS over the previous 6 months and whether used universally with every postnatal woman; at how many weeks, when administered; and whether used selectively and how they had decided to use it.
4. General experience – the number of years since they qualified and how many years they had worked as a HV.
5. Experience with PND – how they had supported women whom they felt were suffering from PND in the previous 6 months.

Introductory training day

The IG HVs were invited to attend an introductory day during the week before contact with the psychotherapist trainers, to introduce the features and problems that women report and the different ways of understanding PND and covering risk issues (*Table 9*). These were run by Jane Morrell (principal investigator, trained as a HV, with group work and presentation skills) and Jan Cubison (Sheffield Community Health Maternal and Mental Health Services). Before the introductory day was finalised, in January 2003, JM attended the 1-day training in London on Perinatal Depression: Detection in Primary Care, which was organised by the CPHVA to train HVs in the use of the EPDS.

Each HV was provided with their own, named introductory training day manual, which they were asked not to share with anyone else, or copy, as one measure to reduce contamination when HVs may have come into contact with other HVs or their clients from another arm of the trial. They were also each given a copy of a scored EPDS, several copies of blank EPDS forms, laminated cards and sheets with questions to assist the clinical interview, and their own copy of the PowerPoint slides.

The day covered the use and meaning of the term 'postnatal depression', prevalence, factors associated with PND, consequences and a summary of the research about treatments for PND, including the pioneering work in Edinburgh on HV

TABLE 9 *Introductory day health visitor training dates and locations*

Introductory training day	Date	Location
1	7 March 2003, 30 health visitors	East Retford, Lincolnshire
2	24 March 2003, 19 health visitors	Nottingham
3	29 April 2003, 16 health visitors	North Nottingham
4	3 September 2003, 11 health visitors	Sheffield
5	14 January 2004, 6 health visitors	Sheffield
6	9 February 2004, 6 health visitors	Sheffield
7	1 November 2004, 3 health visitors	Sheffield

listening visits.[1] It also covered the limitations of research into PND and the need for the trial. The service perspective was presented, covering *Why Mothers Die*[21] (confidential enquiry into maternal deaths) and the relevant standards within the NSF for mental health.[90]

The clinical perspective covered core features of depression and core features of PND, distinguished from puerperal psychosis. The training on the clinical interview covered risk management and assessing risk to mothers, infants and children.

The practical skills development focused on how to recognise PND, describing the review commissioned by the National Screening Committee,[57] the SIGN publication on PND.[92] The development and appropriate use of the EPDS were reviewed, covering its strength, limitations and recommended practice. The HVs were all asked to interview another HV, to gain experience in the practical use of the tool.

The HV protocol for the administration of the EPDS at 6 weeks postnatally within the trial was explained in detail, with a copy for each HV included within the introductory day manual. This indicated four main actions: first, when there was urgent concern about a woman (suicide risk, risk to the baby, risk to others and severe impairment); second, when there was a positive response to question 10 on the EPDS (indicating the risk of self-harm); third, the need to repeat the administration of the EPDS at 8 weeks postnatally if the score reached or exceeded the threshold of 12 when first administered at 6 weeks postnatally; and, finally, what to do if the EPDS score was below the threshold score of 12.

Five-day training

There were four CBA training cohorts and five PCA training cohorts (*Table 10*).

Evaluation of the health visitor training

Introductory day evaluation

The HVs were asked how they felt that the content of the day was pitched and about the background presentation, the presentations on the EPDS, the clinical interview, risk management, skills development and the time allocated to discussion. The final questions asked about their confidence in identifying and supporting women at risk of PND.

Five-day training evaluation

When each training cohort was completed, the HVs in both the CBA and PCA clusters were asked to complete a questionnaire to provide feedback on how the training was delivered and how helpful it was. They were asked to circle one answer on each line for each question, without discussing their answers with their colleagues. All of the questionnaires were coded so that answers could be treated completely confidentially. The HVs were told that the trainers would only receive a summary of the replies for the cohort of HVs, not individual replies. There were questions on the course content and methods (clarity of the course objectives, theoretical content, how the course was pitched, course structure, appropriateness of the educational methods) and the teaching (how motivating were the course leaders, effectiveness in relating to the group, competence, theoretical congruence of the course leaders' teaching styles). The general questions asked about the relevance, appropriateness and acceptability of the course for HVs supporting women with PND, and how interesting it was. The skills questions asked about whether the course had improved the HVs' understanding and skills in supporting women with PND, and how confident they felt in applying any skills that they had developed using the approach. The HVs were asked about how well the course had met their expectations, whether they would recommend this course to other HVs and, taking everything into account, how satisfied

TABLE 10 *Five-day health visitor training dates*

Training cohort	Cognitive behavioural approach	Person-centred approach
1	13 March 2003, 8 health visitors	18 March 2003, 10 health visitors
2	3 April 2003, 14 health visitors	26 March 2003, 9 health visitors
3	8 May 2003, 12 health visitors	30 April 2003, 7 health visitors
4	10 September 2003, 8 health visitors	16 September 2003, 6 health visitors
5		22 January 2004, 8 health visitors

or dissatisfied they were with the five core training days they received as part of the research. They were asked to list the most important things that they had learned on the course and how, if at all, the content and delivery of the training could be different. They were then asked to list the three best and three worst things about their overall experience of the course, and to write any additional comments.

Intervention monitoring

When participants do not accept an intervention, the estimated treatment effects are diluted in an intention to treat analysis. The HVs in the IG were asked to complete a monthly intervention monitoring form to provide an update on which women had been offered and accepted intervention sessions, how many sessions had been audiotaped, and whether Agnew Relationship Measures (ARMs) had been completed.

Intervention process evaluation

Reviews of psychotherapy studies indicate that there is little evidence for the differential efficacy of therapies, partly because of the quality of the research evidence.[204] This is referred to within psychotherapy research as the equivalence paradox. It is assumed that, although different models may have specific effects, for example cognitive behavioural therapy operates by identifying and changing negative cognitions, all therapy models contain common factors or non-specific effects, such as warmth, reassurance, instillation of hope and feelings of support. To help understand how a therapy works, several process evaluation methods can be used, for example to look at a client's change in mood, such as the Session Evaluation Questionnaire or the Session Impact Rating Scale.[205]

Therapeutic alliance and Agnew Relationship Measure

One of the most frequently measured characteristics of the intervention in psychotherapy research is the quality of the therapeutic alliance between a client and therapist. This is characterised by, for example, the client–therapist bond and agreement about treatment goals and ways of achieving these. The quality of the therapeutic alliance or partnership has a significant positive contribution to the outcome. Among the tools considered for measuring the therapeutic alliance, some were firmly based in the context of therapeutic work with a client. In contrast, the ARM focuses on the relationship between the client and worker and is more easily transferable to the context of a HV and mother working together. An original validated 28-item ARM was shortened to a 12-item ARM, which has very high correlation with the longer version.[206,207] The short-form ARM was chosen as the least time-consuming, most easily completed and most comprehensive measure of alliance components with useful UK comparative data. These features were important in minimising the demands on the women in the PoNDER trial, as the HVs were asked to use the 12-item version of the ARM after each intervention session. This involved the woman completing one version and the HV completing a corresponding version of the brief questionnaire. The two forms both consist of 12 items and the instructions state, '*Thinking about today's meeting, please indicate how strongly you agree or disagree with each statement*', with responses given on a 7-point scale from strongly disagree to strongly agree. Four domains are covered:

- bond, which concerns the friendliness, acceptance, understanding and support
- partnership, concerning working jointly towards therapeutic goals
- confidence, optimism and respect for the therapist's professional competence
- openness, the client's feel freedom to disclose, without fear of embarrassment.

The responses were analysed at the dyad level, that is, the correlation of means across HV–client pairs, and at the session level. A total mean score was calculated, within a range from 1 to 7, with a higher score indicating a stronger alliance.

The PoNDER Adherence Rating Scale

To assess the level of adherence of HVs to the interventions that they had been trained to deliver, HVs were asked to tape record intervention sessions, so that sessions from both IGs could be rated.

Developing the PoNDER Adherence Rating Scale rating manual

A 26-item rating sheet and accompanying rating manual was designed and called the Ponder Adherence Rating Scale (PARS). The PARS was written by an experienced psychotherapy researcher blind to all details about the submitted tapes. Following discussion between the researcher and the HV trainers, the PARS was designed to rate the presence of three factors:

1. General facilitative conditions (GFC), which were assumed from the start to be equally present in both interventions. Seven of the 26 PARS items were intended to rate the presence of GFC, for example '*Warmth: did the HV convey a sense of warmth towards the mother?*'
1. CBA-specific factors (13 PARS items), for example '*Problem solving: did the HV encourage the use of a problem-solving approach with the mother?*'
1. PCA-specific factors (6 PARS items), for example '*Self-concept: did the HV focus on valuing aspects of the mother's self-concept?*'

The women were given an RIL about the ARM and the audio recording of the sessions to explain that the purpose was to examine the effectiveness of the HV training, but that they could choose for the session not to be recorded or not to complete the ARM. The IG HVs were given a separate information sheet and checklist on completing the ARM and taping the intervention sessions.

Local co-ordinators and SCAN interviewers

The local co-ordinators (LCs) commenced in July 2003 and their main role was to liaise with, support and offer feedback to collaborating HVs. The LCs had weekly contact with the HVs, face-to-face or by telephone. Once the HV training modules were under way, support visits began at the end of July 2003 to prepare HVs for their varying collaborative roles in recruitment, follow-up and data collection. The research team acknowledged the HVs' additional workload, particularly administrative, and possible stress as a result of taking part in the trial. The main elements of the LCs role were to ensure that the HVs were organised to follow the HV research protocol, to motivate them and to offer them practical support. The LCs' face-to-face visits with the HVs allowed discussion to reinforce the protocol in relation to the women on their caseloads. The LCs had a list of things to discuss during a visit. Once recruitment was under way, in September 2003, the LCs began to collect information on the numbers of women invited to take part and the numbers consented or declined, to monitor the consent rate of eligible women in each practice. They discussed local tailored techniques that the HVs could use to maximise the consent rate per practice, for example using labels on records and computer prompts and putting up a display of the trial in the waiting area. The LCs offered feedback to HVs on progress individually, as well as collectively by way of a newsletter prepared and edited by one of the LCs (KR).

Preparation of local co-ordinators

To enhance their research role the LCs were able to attend training to develop their research skills and appreciation in critical appraisal, health economics, literature searching, qualitative research, research governance, statistics, use of NUD*Ist and NVivo qualitative software and use of the Statistical Package for Social Scientists (SPSS). The LCs also attended the Society for Reproductive and Infant Psychology conference in Sheffield in 2004. The LCs' main training was in preparing them to undertake the SCAN interviews.

SCAN interview

The purpose of the SCAN[168] interview was to establish the baseline severity of depression among those women with a 6-week EPDS score ≥ 12. A secondary aim of the SCAN interview was to examine the identification of depressive symptoms by the EPDS.

SCAN interviewers' roles

In 1992 the ICD-10 first included a category for puerperal disorders, to be used when the other criteria for psychiatric diagnosis were not fulfilled.[22] The American Psychiatric Association DSM-IV classifies PND as major depression with postpartum onset, beginning within 4 weeks postpartum.[23]

The SCAN was developed as a semistructured diagnostic interview, composed around the PSE, to be administered by a specially trained interviewer. Interviewers use suggested wording but can probe until they are satisfied with the information that they obtain. The respondents' replies to the SCAN interview were recorded directly onto a laptop computer, to measure and classify psychiatric symptoms and behaviour. The SCAN is to be used by clinicians who know about psychopathology and who have taken a course at a training centre designated by the World Health Organization (WHO) and who are familiar with the glossary of differential definitions. The first part of the interview covers anxiety, depressive and bipolar disorders, physical functional health and use of alcohol and other substances. The second part covers abnormalities in speech, affect and behaviour and psychotic and cognitive disorders. For the trial, ICD-10 criteria were used to determine the severity of any depression (none, mild, moderate or severe), but data can be

presented in different outputs according to both ICD-10 and DSM-IV definitions.

The first part of the interview is used to gain an overview of all possible physical and mental health problems, which are precisely rated later in the interview. The questions are categorised into unexplained physical symptoms, worrying, anxiety, obsessional symptoms, depressed mood, concentration, bodily functions, eating disorders, expansive mood, use of alcohol and use of other psychoactive substances.

Clinical severity is rated by taking account of the duration, frequency and intensity (interference with mental function) of symptoms. A zero rating indicates complete absence of a symptom. For an item to be rated, the symptom must be distressing, difficult to control and excessive – 1 indicates minor, not clinically significant; 2 indicates moderately severe for some of the time; and 3 indicates moderately severe for most of the time. Only ratings of 2 or 3 contribute to diagnostic categories; the mild rating is not regarded as being sufficiently clinically significant to meet specific diagnostic criteria.

SCAN training

The formal 2-week SCAN training for the SCAN interviewers (SIs) began in August 2003 in Leicester. The SIs had regular monthly meetings with Professor Pauline Slade for debriefing and to maintain quality control.

SCAN quality control

The SCAN trainer (Jane Smith) accompanied each of the SIs separately to SCAN interviews in women's homes, to ensure that all of the SIs were working to the same standard and to prevent drift from the SCAN training protocol.

Identification of women for SCAN interview

The 6-week postal EPDS score determined which women were invited for a SCAN interview. All women with a 6-week EPDS score ≥ 12 were invited for interview, to determine the presence and severity of any depression (none, mild, moderate or severe). Further women who had borderline EPDS scores of 9–11, plus a random sample of those who scored between 0 and 8, were also invited for a SCAN interview, as part of the assessment of the performance of the EPDS (*Figure 2*).

Each day, after all of the questionnaires of the IG women were scored manually in the research office, all women who scored 9 or more on the EPDS were identified for an interview, plus a selection of those who scored less than 9. The SIs were given each woman's name (separately from her PCT, practice and id code to protect privacy), address and her baby's date of birth. The SI contacted each woman to arrange the interview time, unless the woman's HV stated a preference for contacting the woman first. For women for whom the SI could not get a reply on the phone, or for those who did not have a phone, the SI wrote invitation letters asking them to contact her. The replies from the women were grouped as consented, declined, missed or assumed declined, if the SI had unsuccessfully tried to make contact many times.

Before her SCAN interview, each woman was asked to sign a consent form. If the outcome was moderate or severe the woman was given an information sheet after the SCAN interview, which explained that the interview indicated that she might be feeling depressed. The sheet gave brief details about psychological therapies and antidepressants and indicated that the woman should discuss her planned care with the HV or an antidepressant could be prescribed by her GP.

Safety for SCAN interviewers and women

To prepare them for their role in visiting women's homes unaccompanied, the LCs were made aware of the potential minimal risks of being invited into the home of a woman with a new baby. They were carefully prepared in personal safety by watching a video on lone working and by holding their own copy of a safety booklet, following lone working guidelines and reading about techniques in dealing with violence and aggression and defusion and de-escalation. The SIs also had a detailed plan about the sequence of contact when an SI did not inform her buddy that an interview was complete.[208] The HVs were asked to inform the research office of any circumstances in which there might be a safety risk in an SI going to visit a particular woman's home alone. In cases in which a risk was anticipated, two SIs went to carry out the interview together. Conversely, the HVs had photographs of the SIs in their trial file, to show to the women who were invited for a SCAN interview.

Health visitor feedback and reward programme

To maintain the HVs' enthusiasm, as well as the regular LC support visits, the principal investigator made a visit to the HV clusters, with some additional feedback presentations to the whole practice team. A HV reward system of vouchers was established in the autumn of 2004, based on the proportion of eligible women in a HV caseload

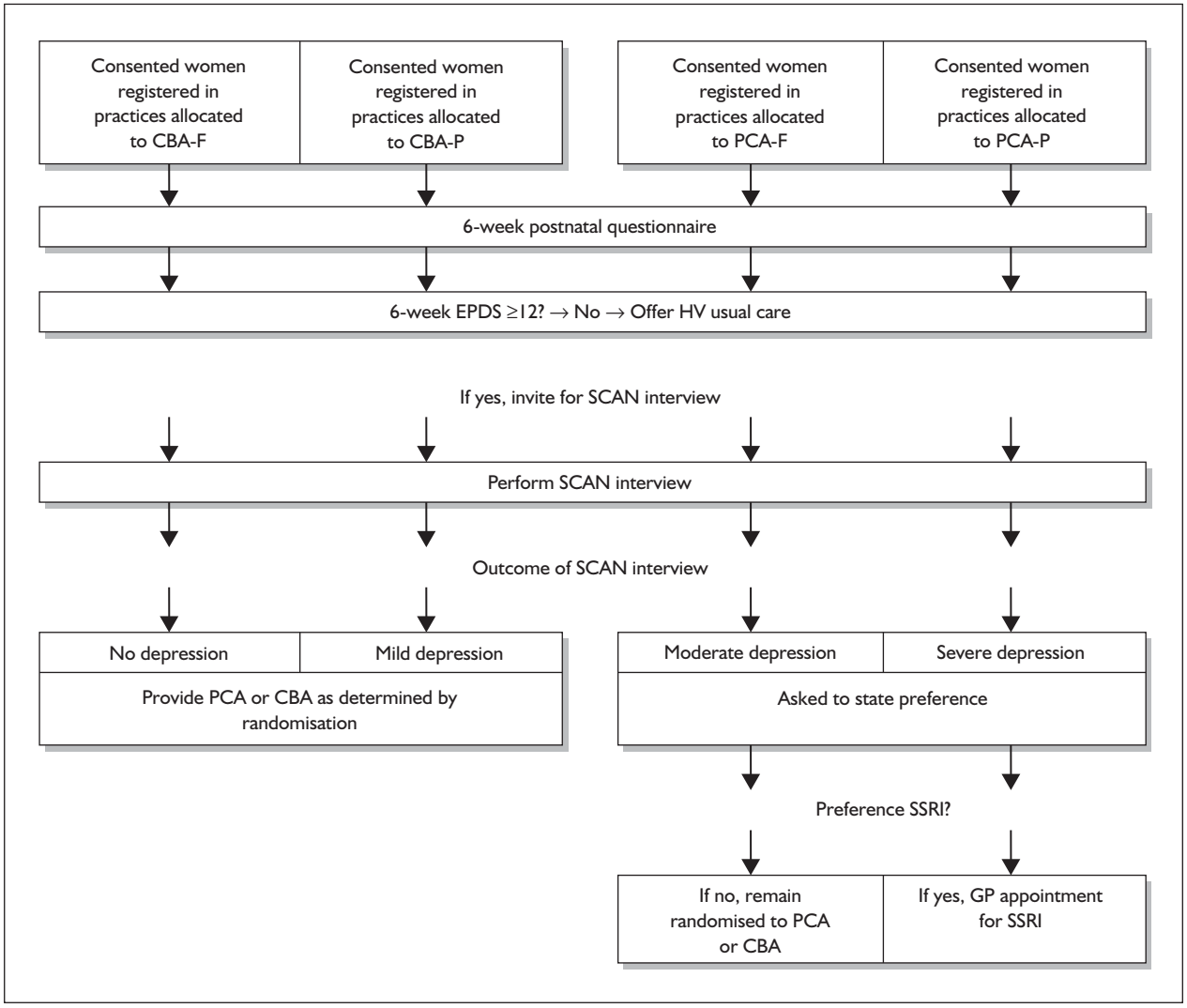

FIGURE 2 *Procedure for SCAN interviews. CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; EPDS, Edinburgh Postnatal Depression Scale; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group; SCAN, Schedule for Clinical Assessment in Neuropsychiatry; SSRI, selective serotonin reuptake inhibitor.*

who consented to take part and the proportion of women who were offered an intervention.

Approval for the trial

Application to the Multicentre Research Ethics Committee

In December 2002 the MREC application included a draft RIL, consent forms and questionnaires for the committee to consider. These drafts were to be further developed once the trial began, having been reviewed by the service users (consumer involvement) and the wording amended.

In January 2003 the MREC requested clarity on:

- the CG HV continuing to provide care currently given
- the use of the EPDS as part of the initial assessment and as an outcome
- the recruitment of women
- the protocol for women with severe depression
- the recruitment of subjects for interview
- infant outcomes
- visits to women who scored ≥ 12 at 6 weeks postnatally
- the Punjabi Postnatal Depression Screening Questionnaire (PPDSQ)[110]
- safeguards, to avoid approaching women who had a stillbirth or perinatal death.

Adverse events

Around 6 months after recruitment began, a letter was sent to the GPs in the practices where the HVs worked to update them on recruitment and to reinforce the request about compliance with the practice flowchart. The letter also asked the GPs to

inform the research office about all women in the trial who had attempted suicide, or who had died, or about other adverse events that had occurred.

Consumer involvement

In December 2002 a group of Asian women was invited to a focus group with a HV to talk about PND and to ask their views on the research proposal before the research began. Consultation with service users began in January 2003. HVs provided the names of women who had recently had a baby and had agreed to be interviewed, either individually or in a group situation, and a focus group was held on 13 August 2003. The women were asked to sign a consent form before any audiotaping of the discussion. The women were offered travelling expenses and were given tokens to recognise the value of their time. In light of the feedback from these women, the RIL was further developed to make the information easier to understand.

Administration

Application for indemnity

A non-clinical trial insurance certificate was issued by the University of Sheffield Department of Finance.

Application for research governance approval within primary care trusts

Whilst the trial was in progress, the research governance arrangements for health and social care, first published in 2001, were changed.[209] The second edition framework set out the principles, requirements and standards (including ethics) with an implementation plan for improving research and safeguarding the public.

Rather than complete a separate, local application form for each of the 39 PCTs in the region, a generic application form was sent to the research leads in the relevant PCTs and research alliances covering groups of PCTs. Because of the inconsistent approaches of the PCT research offices, on request, in different combinations, some PCTs were sent copies of, for example, the MREC application form, Annexe D, copies of the protocol and researchers' CVs.

The communication below from one of the local research leads indicates some variation in the interpretation of the new rules:

> *I'll let you know about how we can assist and on how the approval processes work locally. With the MREC approval, studies then have to pass to the LREC for local consideration. I'll let you know how we fit in at this stage and how PCT support is indicated. The Alliance approval process (on behalf of PCTs) will start to operate when you need to apply for LREC consideration of your study after it has been to MREC. I'll need a copy of all the MREC paperwork and correspondence. We'll check PCT support as part of this process and forward on to our LREC. If ** is going to be the Local Investigator this submission would have to be in his name . . . . My main concern for you is the timescale as I noticed you wanted to randomise by early January. I note that you were going for MREC approval on 5 December . . . . LREC submission won't be possible until MREC approval has been granted. I won't get into detail here but the LREC deadline for January (and this affects the Alliance one) is quite early because of Christmas. There were sometimes special sub-groups of the LREC for consideration of MREC studies, although the schedule of these is normally set in months.*

Financial costs of the collaboration of health visitors

In the past, health-care professionals' time has been used in research usually without reward. The time of health-care professionals should be costed with reimbursement to ensure that participation in research is not at the expense of their normal roles. The document *Attributing revenue costs of externally-funded non-commercial research in the NHS*[210] indicated which costs should be allocated as NHS service support and which should be allocated as NHS excess treatment costs. In the application for this funding, assumptions were made about the amount of time that it might take a HV to carry out each element of the research, and a cost was attributed to this. Key assumptions were that there would be, on average, 78 women per practice taking part in the study and that around 14% of these women (about 11 per practice) would be at risk of PND and eligible for the intervention. The cost per HV time was calculated as £17.50 per hour.

The CG HVs were asked to label and post prepared letters to eligible antenatal women (10 minutes) and then gain written consent from these women (10 minutes). HVs were asked to count the number of GP and HV contacts for 78 women, every 6 months, in the 18-month follow-up phase (30 minutes), amounting to 65 hours of time per practice or £14.50 per woman.

In the CBA and PCA postal-only groups, in addition to the role of HVs in the CG, HVs

were asked to administer the EPDS at 8 weeks postnatally for women with a 6-week EPDS score ≥ 12 (30 minutes). For women eligible for the intervention, the HVs were asked to make a maximum of eight visits of 1 hour per week, amounting to a further 93.5 hours of HV time per practice or £20.98 per woman.

In the CBA and PCA face-to-face and postal administration groups, HVs were asked to administer the EPDS face-to-face to all consenting women at 6 weeks postnatally. This amounted to a further 39 hours of HV time per practice at £8.75 per woman.

In all intervention practices the HVs were also asked to attend the equivalent of 8 full days of training to prepare them to provide the intervention to at-risk women. Assuming two part-time HVs working per practice, the training was to involve 120 HVs, amounting to 64 hours (£1120) per HV, £2240 per practice and £134,400 for 120 HVs. The total request for service support costs and excess treatment costs in all 90 practices was £355,425 (£102,375 + £253,050).

The application for service support costs and excess treatment costs was tedious because, again, the rules were in the process of change. Funds for the reimbursement were all paid to Broxtowe and Hucknall PCT, which then sent the payments to individual PCTs.

This protracted process served as a disincentive to some PCTs, whose research leads wished the funding arrangements to be confirmed before allowing their HVs to participate in the trial.

Local Research Ethics Committees

Individual Local Research Ethics Committees (LRECs) also issued approval letters with differing requests to audit the research, and for annual reports, a final report and copies of materials sent for publication. An audit required an inspection of the final approved protocol, information sheets, consent forms, data collection tools, data storage arrangements, correspondence with the Research Ethics Committee, evidence of indemnity arrangements, sponsorship agreement, research governance approval letters, contractual agreements, research team CVs, consent documents, participant records, membership of the project advisory group and honorary contracts.

Application for honorary contracts

To ensure compliance with the changing requirements of the research governance framework for health and social care, towards the end of the recruitment phase, an honorary contract request form was completed for PCT R&D offices for the whole trial team, researchers and administrative staff. It was necessary for an individual who might have contact with 'patients/staff or identifiable or sensitive data', and such individuals had to attach a copy of their CV and give their home address and details of any Criminal Records Bureau Disclosures. Again, each PCT or cluster of PCT research offices stipulated differing requirements. The complexity of administrative arrangements created a further significant administrative burden for the trial.

Trial Advisory Group

The Trial Advisory Group (TAG), chaired by Professor Michael Barkham, met every 3 months throughout the duration of the trial. The purpose of the group was:

- To provide overall supervision for the trial on behalf of the trial sponsor (the Department of Health by way of the HTA programme)
- To ensure that the trial was conducted to the rigorous standards set out in the MRC guidelines for good clinical practice.
- To concentrate on the progress of the trial against the project plan, adherence to the protocol, participant safety and the consideration of new information of relevance to the research question.
- To provide advice, through its chair, to the principal investigator, the HTA programme and the host institution on all aspects of the trial.

In addition:

- Membership should include an independent chair, at least two other independent members, one or two principal investigators and, when possible, a consumer representative. Involvement of independent members provides protection for both trial participants and the chief investigator.
- Observers from the HTA programme and the host institution should be invited to all TSC meetings.
- Responsibility for calling and organising TSC meetings lies with the principal investigator.

- There may be occasions when the trial sponsor will wish to organise and administer these meetings for particular trials. In the HTA programme's case this is unlikely, but they reserved the right to convene a meeting of the TSC in exceptional circumstances.

Chapter 4
Results and outcomes

Results

Cluster level recruitment and consent

Health visitors and GPs from 241 clusters expressed an interest in the trial, of whom 141 did not consent and participate in the study. There were 30 clusters allocated to CBA, 32 to PCA and 38 to control. Within the intervention clusters there were 13 allocated to CBA-F, 17 to CBA-P, 15 to PCA-F and 17 to PCA-P. *Figure 3* illustrates the recruitment and allocation of clusters to each of the five groups, and the flow of the clusters up to 18 months' follow-up, that is, the clusters in which women returned a questionnaire and contributed to overall data.

Baseline measurements at cluster level

The IMD 2004[176] was used to compare the characteristics of the recruited GP clusters with those of the GP practices in the former Trent region and also with those of GP practices in England. The IMD measures deprivation for special census geographies called super output areas (SOAs). It combines indicators across seven domains into a single deprivation score and rank. The domains are income deprivation; employment deprivation; health deprivation and disability; education, skills and training deprivation; barriers to housing and services; living environment deprivation; and crime. Graphs were created using the functionality of geographical information systems (GIS) by coding IMD 2004 data to SOAs. These areas allow socially similar areas to be grouped together, allowing for more realistic patterns to emerge in the spatial data; it also allowed a GP practice to be tied to this measure. It is assumed that a practice placed in a SOA has the characteristics of that spatial unit rather than those of neighbouring ones. The source of the GP locations was an NHS website.[211] An automated extraction tool lifted and restructured the address and other information from the website before formatting and importing into a GIS.

IMD scores for GP practices in England, the former Trent Region and the PoNDER study

Across England, IMD scores vary considerably. A lower score signifies greater deprivation, indicating practices located in areas with multiple problems. The values for all GP practices in England, the former Trent Region and the PoNDER study are presented in *Table 11*.

Description of the PoNDER study

The mean IMD for the 97 PoNDER study practices (23.8, SD 15.3) for which data were available was similar to the means for the 823 former Trent region practices (24.0, SD 15.6) and the 32,533 GP practices in England as a whole (21.7, SD 15.7). That is, the PoNDER study practices had similar levels of deprivation to GP practices in Trent and England.

Description of participating clusters

The clusters in which women contributed to the study are described below. The mean practice population was 7664 and the mean number of expected births per year was 79 (based on the actual number of births in the previous 2 years). The number of women in each cluster ranged from 1 to 140 (*Table 12*). *Figures 4* and *5* indicate the distribution of registered practice populations and the total number of expected births per year in recruited clusters respectively. *Figure 6* indicates the distribution of the number of women recruited per cluster.

Individual level recruitment and consent to the trial

Baseline measurements at individual level: all recruited women

Among all of the 8716 women who were pregnant in the participating clusters during the recruitment phase for whom details were available, most of them spoke English as their first language and most were white British and living in a house with a husband or partner. Comparing the characteristics of the five groups there was some variation; however, all of the five groups were broadly similar (*Table 13*).

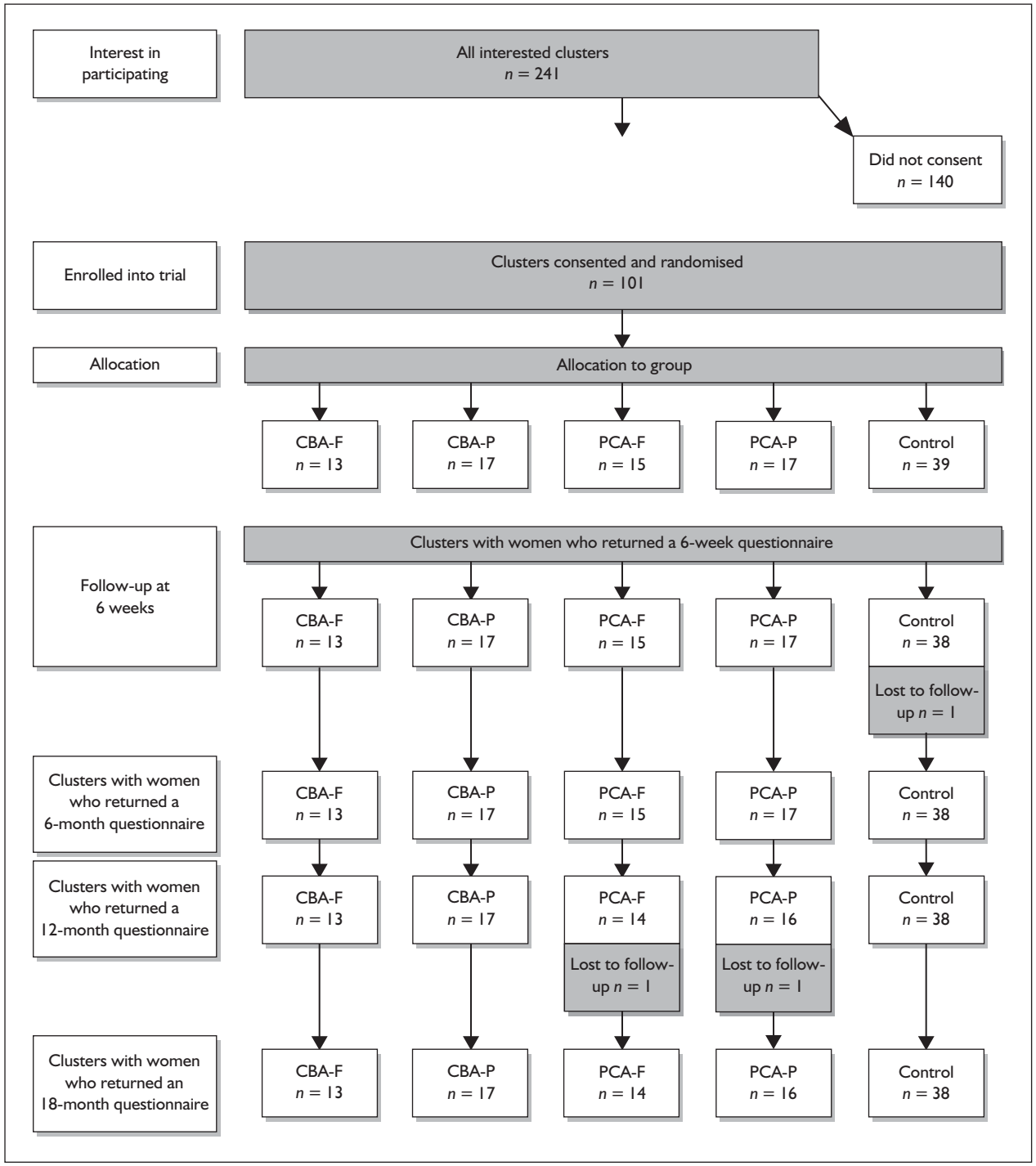

FIGURE 3 *Diagrammatic representation of cluster participation. CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group.*

TABLE 11 *Index of Multiple Deprivation 2004 scores for all GP practices in England, the former Trent region and the PoNDER study*

Number of GP practices	Minimum	Maximum	Mean	SD
England, *n* = 32,533	0.72	86.36	21.7	15.7
Former Trent region, *n* = 823	2.49	77.43	24.0	15.6
PoNDER study GP clusters, *n* = 97	2.80	63.02	23.8	15.3

TABLE 12 *Characteristics of GP practices in the PoNDER study*

Descriptor	Minimum	Maximum	Mean	SD
Total registered practice population	2300	19,000	7664	3662
Expected births per practice per year[a]	21	157	79	34
Total number of women recruited to the study	1	140	42	29
IMD 2004 score for sample cases	3	63	24	15

IMD, Index of Multiple Deprivation.
[a]Expected births per year were based on the actual number of births in each practice in the previous 2 years.

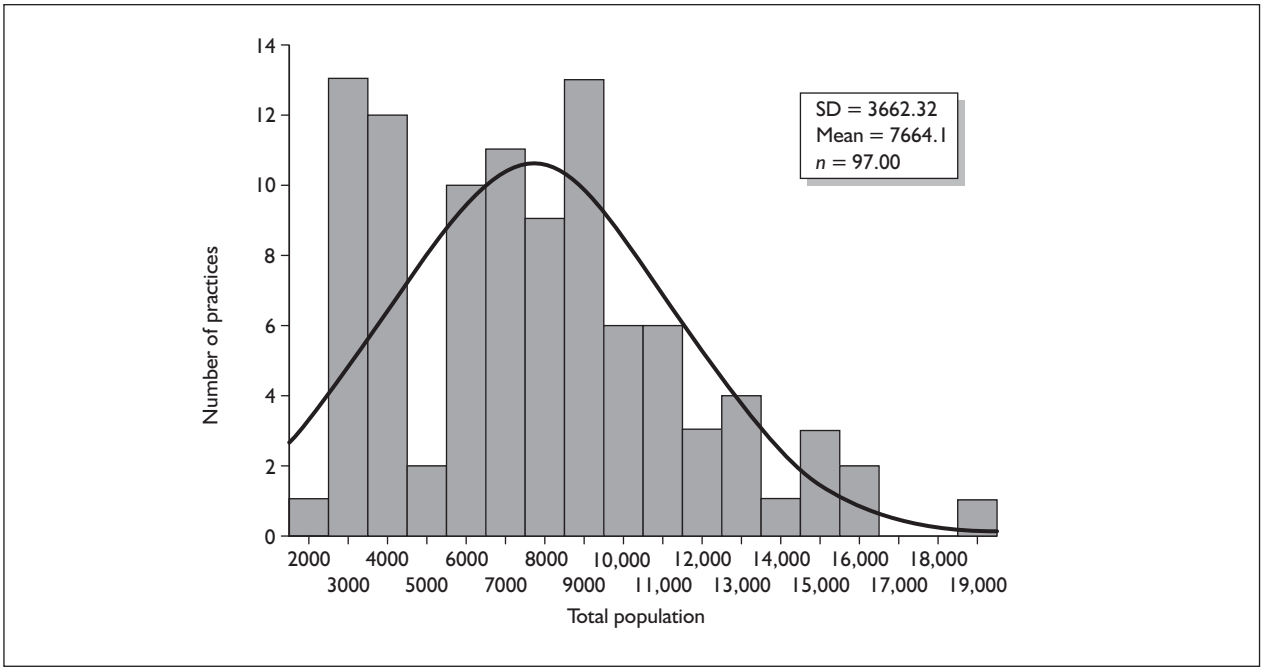

FIGURE 4 *Distribution of registered populations for GP practices in the study.*

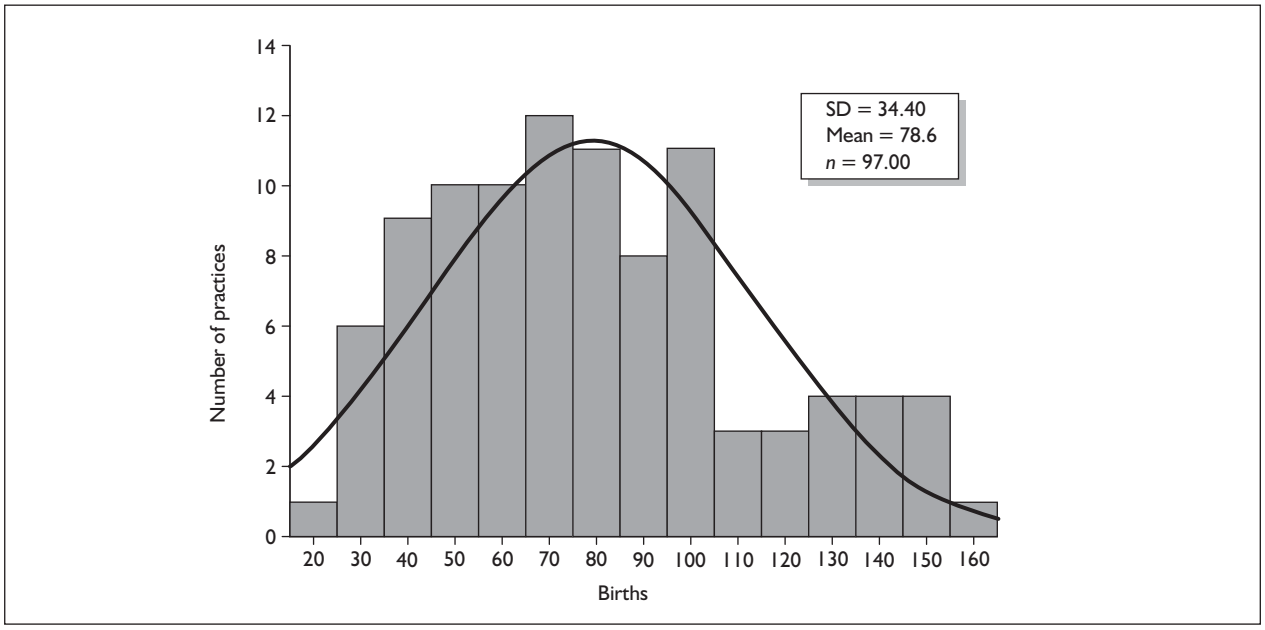

FIGURE 5 *Distribution of total expected births in GP practices in the study.*

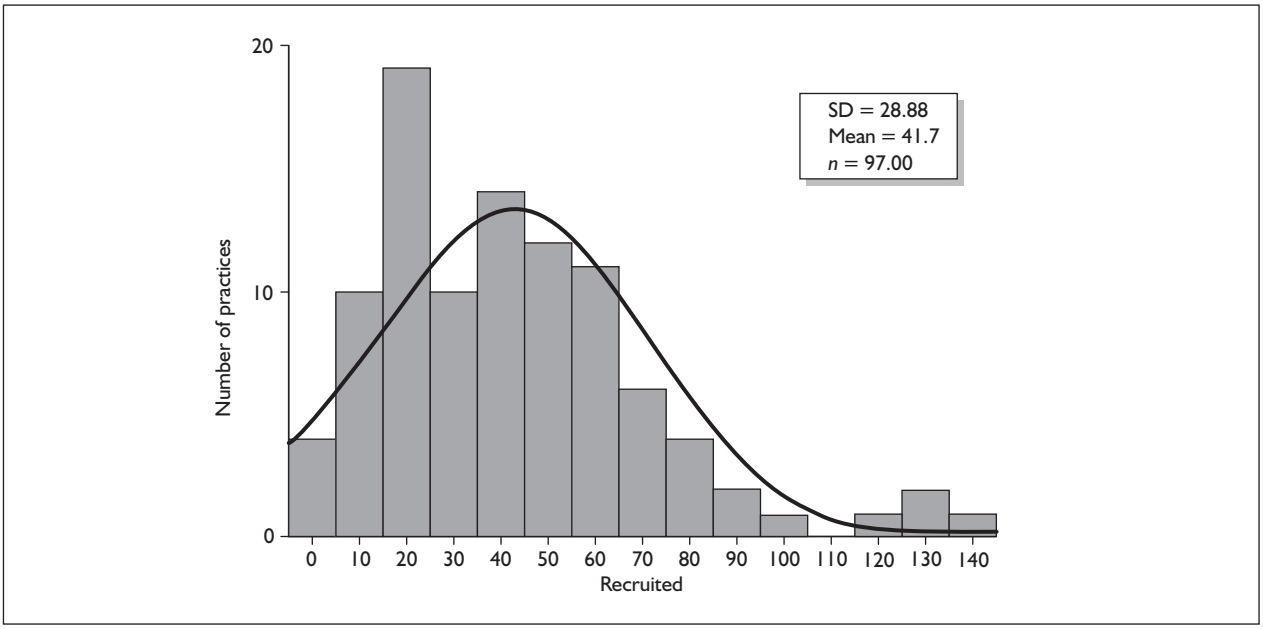

FIGURE 6 *Distribution of number of women consented per practice in the study.*

In the 2001 national census data for England and Wales,[212] 91% of the population are recorded as white British, 69% lived in owner-occupied accommodation, 21% lived in council or housing association rented accommodation, and 7% rented privately. Therefore, the characteristics of all 8716 antenatal women in all consenting practices are broadly similar to those for the whole population.

TABLE 13 *Individual level baseline measurements of all (consenting and non-consenting) antenatal women (n = 8716) by group*

	Control (%)	CBA-F (%)	CBA-P (%)	PCA-F (%)	PCA-P (%)	Int (%)	All (%)
Eligible	92.0	90.9	84.1	87.5	90.0	87.8	89.3
Consented	51.4	64.1	52.2	59.1	47.0	56.2	53.3
First baby	45.4	31.9	43.0	42.8	37.0	39.0	41.3
PND among all women	8.5	7.0	7.8	7.2	9.8	8.1	8.3
PND among women with a previous pregnancy	15.7	10.3	13.7	12.6	15.6	15.3	14.1
English first language	99.7	99.4	94.6	99.6	99.0	97.8	98.5
White British	93.4	97.4	86.7	94.9	94.6	92.7	93.0
Living with partner	93.7	93.7	89.6	91.7	91.7	91.5	92.2
Living alone	3.2	2.5	5.6	3.8	3.2	3.9	3.7
Living with others	3.2	3.8	4.8	4.5	5.0	4.6	4.1
Living in a house	96.4	96.6	93.4	95.4	96.5	95.4	95.7
Living in flat	2.8	2.6	5.3	2.7	2.7	3.4	3.2
Owner occupied	76.4	74.6	57.9	74.4	74.9	69.6	71.8
Rent council/HA	13.6	17.1	29.3	15.4	17.0	20.4	18.2
Rent privately	7.0	5.4	8.5	5.3	4.3	6.0	6.3
Twins/triplets	1.1	1.9	0.9	1.4	1.8	1.6	1.4

CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; HA, housing association; Int, intervention group; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group; PND, postnatal depression.

Exclusion criteria applied

In total, 89.3% of all antenatal women were eligible to take part and 10.7% were ineligible. The main reasons that women were not eligible were that they were changing GP practice or address (4.8%), they were aged less than 18 years (1.4%) or they had mental health issues (1.1%), which meant severe and enduring mental health problems such as bipolar disorder or schizophrenia (*Table 14*).

Baseline measurements of consented women at individual level

Of all of the eligible pregnant women, 53.3% consented. Among those for whom details were available, the greatest proportion of women who did not consent said that they were not interested (76%), with others saying that they were too busy (7%) or not replying (11%). *Table 15* presents the characteristics of the women who consented.

In total, 15.1% of women who consented to take part had had PND previously versus 14.1% of all antenatal women. *Table 16* presents the characteristics of women who both consented and returned a 6-week questionnaire.

Individual level follow-up

The overall participant flow chart (Appendix 1, *Figures 27* and *28*) illustrate the number of women in the study at baseline and follow-up.

Of the 7649 eligible women in all clusters, 4084 (53.4%) consented and 3449 returned a 6-week questionnaire (88% return rate). A total of 2875 women (72%) returned a 6-month questionnaire; 2029 women (61%) returned a 12-month questionnaire; and 1097 women (56%) returned an 18-month questionnaire (Appendix 1, *Figure 27*).

A total of 595 women returned a 6-week questionnaire and scored ≥ 12 on the EPDS to become the at-risk women. The follow-up of the at-risk women is illustrated in *Figure 7* and Appendix 1, *Figure 29*.

Individual level baseline measurements for at-risk women: intervention versus control

At 6 months 70.3% (418/595) of the at-risk women (those who had scored ≥ 12 on the 6-week EPDS) had a 6-month EPDS score available for the analysis. The characteristics of the at-risk women for whom a 6-month EPDS score was available ($n = 418$) are presented in *Table 17*. A slightly greater percentage of women in the IG had had PND before, lived alone and had experienced stressful life events in the previous 6 months.

Individual level baseline measurements for women who returned a 6-month questionnaire

The characteristics of all of the women for whom a 6-week EPDS score was available and who returned a 6-month EPDS score ($n = 2659$) are presented in *Table 18*.

TABLE 14 *Reasons why women were ineligible to take part by group*

	Control group		CBA-F		CBA-P		PCA-F		PCA-P		Int		All	
	n	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Age < 18 years	26	0.9	10	0.9	39	2.2	15	1.3	27	1.7	91	1.8	117	1.4
Baby died	4	0.1	2	0.2	2	0.1	1	0.1	2	0.1	7	0.1	11	0.1
Miscarriage/ termination	19	0.6	5	0.5	8	0.4	6	0.5	7	0.4	26	0.5	45	0.5
Stillbirth	6	0.2	1	0.1	4	0.2	5	0.4	2	0.1	12	0.2	18	0.2
Moved away/ temporary resident	98	3.3	46	4.2	79	4.4	60	5.3	71	4.5	256	4.6	354	4.6
Moved practice	23	0.8	5	0.5	19	1.3	11	1.1	5	0.4	40	0.7	63	0.8
Baby ill/premature	9	0.3	6	0.5	7	0.4	7	0.6	5	0.3	25	0.4	34	0.4
Child protection/social issues	3	0.1	1	0.1	4	0.2	2	0.2	2	0.1	9	0.1	12	0.2
Mental health issues	16	0.6	8	0.8	19	1.3	16	1.6	8	0.6	51	0.9	67	0.9

CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; Int, intervention group; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group.

TABLE 15 *Baseline measurements of consented women by group (n = 4084)*

	Control (%)	CBA-F (%)	CBA-P (%)	PCA-F (%)	PCA-P (%)	Int (%)	All (%)
First baby	41.7	34.3	36.4	36.8	39.4	36.8	38.9
PND among all women	7.5	6.4	6.9	6.6	9.5	11.1	9.9
PND among women with a previous pregnancy	16.5	10.9	15.4	14.1	17.5	14.5	15.1
English first language	99.7	100.0	97.4	99.6	99.6	99.1	99.3
White British	94.5	98.6	91.6	97.7	96.2	95.7	95.3
Living with partner	94.5	95.1	90.8	94.4	94.3	93.5	93.8
Living alone	3.2	2.2	5.7	3.4	1.9	3.4	3.3
Living with others	2.3	2.7	3.5	2.2	3.8	3.1	2.8
Living in a house	97.1	97.5	94.8	96.8	97.3	96.5	96.7
Living in flat	2.4	2.2	4.3	1.6	2.0	2.6	2.5
Owner occupied	81.8	81.1	65.3	81.7	81.7	77.0	78.6
Rent council/HA	11.1	11.9	23.9	10.0	10.4	14.5	13.4
Rent privately	5.1	5.1	7.6	4.6	4.5	5.5	5.4
Twins/triplets	0.6	1.0	0.3	2.0	2.2	1.3	1.1

CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; HA, housing association; Int, intervention group; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group; PND, postnatal depression.

TABLE 16 *Baseline measurements at individual level of women who returned a 6-week questionnaire (maximum n = 3436) by group*

	Control	CBA-F	CBA-P	PCA-F	PCA-P	Int	All
Maximum *n*	1101	521	601	507	549	2116	3217
First baby (%)	46.4	37.4	40.6	39.4	43.5	40.3	42.4
PND among all women (%)	7.9	7.3	8.2	7.2	11.2	8.6	8.3
PND among women with a previous pregnancy (%)	14.8	10.8	14.0	12.9	17.7	13.9	14.2
English first language (%)	99.6	100	98.6	99.8	99.6	99.5	99.5
White British (%)	94.9	98.4	93.1	97.8	96.2	96.3	94.2
Living with partner (%)	95.2	96.1	91.2	95.2	94.8	94.4	94.6
Living alone (%)	2.7	1.8	5.0	2.5	1.2	2.7	2.7
Living with others (%)	2.1	2.1	3.4	2.3	4.0	3.0	2.7
Living in a house (%)	97.2	98.6	95.7	97.6	97.5	97.4	97.5
Living in flat (%)	2.3	1.2	3.1	1.6	1.8	1.9	2.0
Owner occupied (%)	85.8	83.9	70.2	85.1	82.8	80.4	82.2
Rent council/HA (%)	8.1	9.6	20.2	9.0	8.8	12.0	10.7
Rent privately (%)	4.5	4.9	6.8	3.3	4.9	5.0	4.9
Twins/triplets (%)	0.6	1.2	0.2	1.7	1.8	1.3	1.0

CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; HA, housing association; Int, intervention group; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group; PND, postnatal depression.

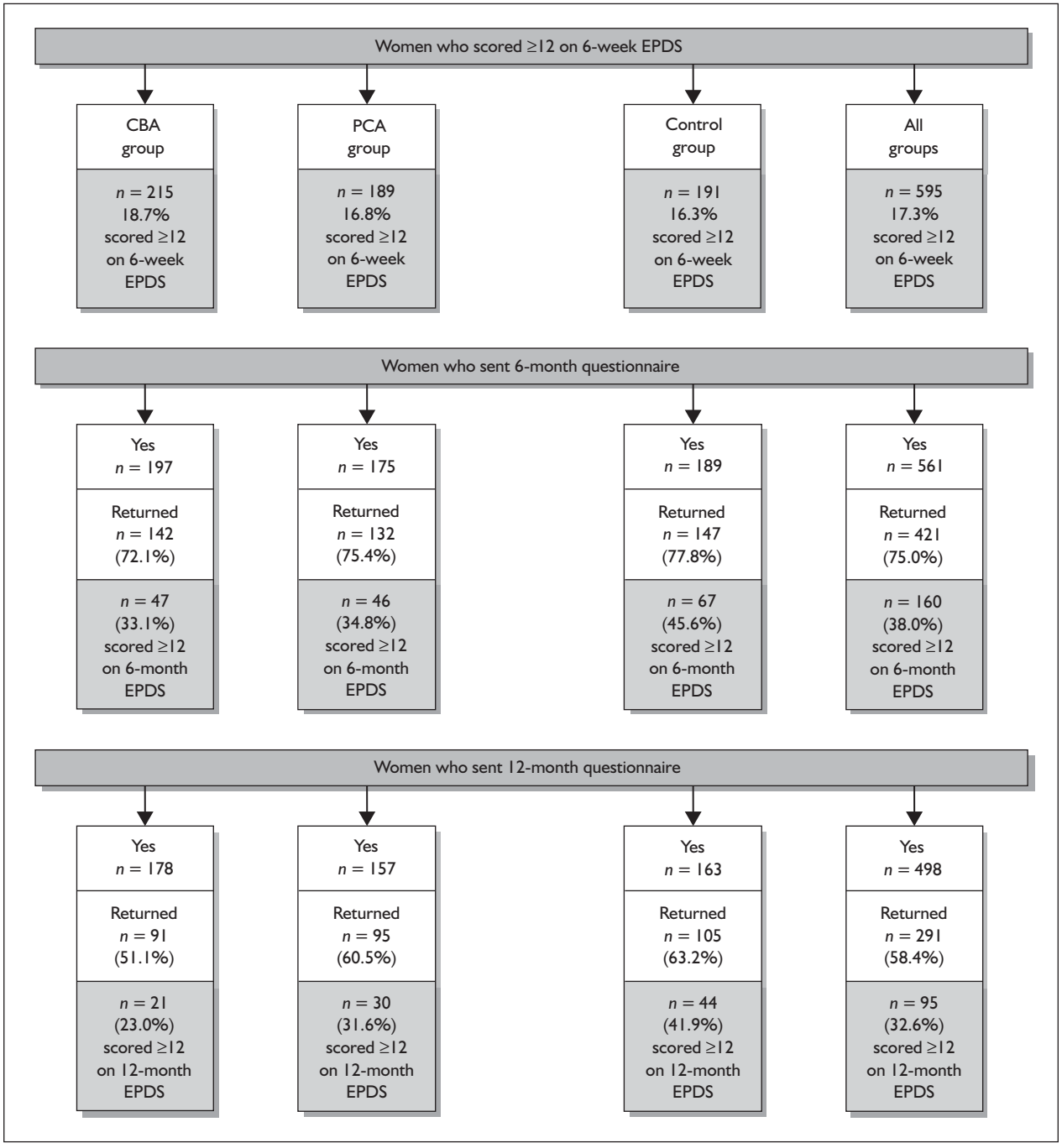

FIGURE 7 *Flow chart for at-risk women by group (n = 595). CBA, cognitive behavioural approach; EPDS, Edinburgh Postnatal Depression Scale; PCA, person-centred approach.*

TABLE 17 *Individual level baseline characteristics for at-risk women (n = 418): intervention vs control*

	Control group			Intervention group			All		
	n	%		*n*	%		*n*	%	
First baby	73	49.7		124	45.8		197	47.1	
PND among all women	13	9.4		44	17.5		57	14.6	
PND among women with a previous pregnancy	13	18.1		44	30.6		57	26.4	
English first language	136	92.5		266	98.2		402	96.2	
White British	133	90.5		257	94.8		390	93.3	
Living alone	7	4.8		19	7.1		26	6.3	
Living with others	139	95.2		250	92.9		389	93.7	
Twins/triplets	2	1.5		3	1.2		5	1.2	
Single girl	60	43.8		140	52.4		200	49.5	
Single boy	75	54.7		124	46.4		199	49.3	
Life events	73	50.3		152	56.5		225	54.3	
	n	Mean	SD	*n*	Mean	SD	*n*	Mean	SD
Woman's age when baby born (years)	147	30.6	5.5	271	31.0	5.4	418	30.9	5.4
Woman's age when first child born (years)	145	27.5	6.0	265	27.4	5.8	410	27.4	5.8
No. of other children	147	0.7	1.0	271	0.8	0.9	418	0.8	0.9
EPDS 6 weeks	147	15.4	3.2	271	15.1	2.9	418	15.2	3.0
SF-12 PCS 6 weeks	143	48.5	10.9	265	50.1	9.4	408	49.6	10.0
SF-12 MCS 6 weeks	143	29.4	9.2	265	29.1	8.0	408	29.2	8.4
SF-6D 6 weeks	142	0.59	0.08	268	0.60	0.07	410	0.60	0.07
CORE-OM total score 6 weeks	146	1.40	0.50	269	1.35	0.49	415	1.37	0.49

CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; EPDS, Edinburgh Postnatal Depression Scale; MCS, mental component summary; PCS, physical component summary; PND, postnatal depression.
Better health represented by a lower score in CORE-OM and EPDS and a higher score in the SF-12 and SF-6D.

Outcomes

Primary outcome for at-risk women

Primary outcome: intervention group versus control group

Of the 418 at-risk women, 45.6% (67/147) in the CG versus 33.9% (93/271) in the IG scored ≥ 12 on the EPDS (*Table 19*). The absolute difference of 11.7% (95% CI 0.4 to 22.9%) was statistically significant ($p = 0.028$ adjusted for covariates). The adjusted odds ratio (0.6, 95% CI 0.38 to 0.995, $p = 0.036$) indicated that the at-risk women were 40% less likely then the CG women to have a 6-month EPDS score ≥ 12.

The primary analysis was based on a complete case analysis with no substitution for missing data. The intention to treat analysis included all women with a 6-week EPDS score ≥ 12 and a valid 6-month EPDS score. After adjusting for covariates such as 6-week EPDS score, living alone, previous history of PND and any life events experienced, the point estimate of the odds ratio for the IG effect was relatively unchanged (at around 0.60) and this effect remained statistically significant or marginally significant.

Sensitivity analysis: imputation of missing 6-month EPDS data for at-risk women

In total, 595 at-risk women had a 6-week EPDS score ≥ 12 and 418 of these women also had

TABLE 18 *Individual level baseline characteristics of all women who returned a 6-month questionnaire (n = 2659), by intervention and control group*

	Control group			Intervention group			All		
	n	%		*n*	%		*n*	%	
First baby	443	48.5		785	45.0		1228	46.2	
English first language	877	96.0		1699	97.4		2576	96.9	
White British	871	95.3		1686	96.6		2557	96.2	
Living alone	31	3.4		58	3.3		89	3.4	
Living with others	874	96.6		1680	96.7		2554	96.6	
Twins/triplets	5	0.6		19	1.1		24	1.0	
Single girl	406	48.0		819	48.3		1225	48.2	
Single boy	434	51.4		859	50.6		1293	50.9	
Life events	368	40.6		715	41.2		1083	41.0	
	n	Mean	SD	*n*	Mean	SD	*n*	Mean	SD
Woman's age when baby born (years)	913	32.0	5.1	1745	31.3	5.0	2658	31.5	5.1
Age when first child born (years)	889	29.0	5.3	1714	28.0	5.3	2603	28.4	5.3
No. of other children	914	0.7	0.8	1745	0.7	0.9	2659	0.7	0.9
EPDS score 6 weeks	914	6.8	5.0	1745	6.6	4.8	2659	6.7	4.8
SF-12 PCS 6 weeks	888	50.5	8.7	1719	51.4	8.0	2607	51.1	8.3
SF-12 MCS 6 weeks	888	42.7	9.5	1719	42.9	9.3	2607	42.9	9.4
SF-6D 6 weeks	885	0.66	0.09	1716	0.67	0.09	2601	0.67	0.09
CORE-OM total score 6 weeks	906	0.55	0.51	1735	0.51	0.49	2641	0.52	0.50

CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; EPDS, Edinburgh Postnatal Depression Scale; MCS, mental component summary; PCS, physical component summary; PND, postnatal depression.
Better health represented by a lower score in CORE-OM and EPDS and a higher score in the SF-12 and SF-6D.

6-month follow-up EPDS scores. The results for these 418 women were therefore available for the primary statistical analysis. A sensitivity analysis was performed to impute the missing 6-month EPDS scores for the 177/595 (29.7%) at-risk women who were lost to follow-up. Two types of missing data imputation were performed:

- last observation carried forward (LOCF)
- regression imputation.

For most postnatal women symptoms of depression will naturally reduce over time, as seen in the CG at-risk women, among whom 54.4% (87/147) no longer had an EPDS score ≥ 12 at the 6-month follow-up. LOCF imputation represents the worst-case scenario, in which, for example, a 6-week EPDS score of 12 would be carried forward to be used as a woman's missing 6-month EPDS score. This woman would therefore still be regarded as being in the above-threshold group of at-risk women.

Regression imputation is more logical for this group of postnatal women, as it better reflects the natural reduction in symptoms of depression over time. A regression imputation, based on 2659 women who returned both a 6-week and a 6-month EPDS, produced the following model (*Figure 8*):

$$\text{EPDS}_{6\text{ months}} = 2.287\ (\text{SE}\ 0.135) + 0.526\ (\text{SE}\ 0.17) \times \text{EPDS}_{6\text{ weeks}}\ (R^2 = 26.9)$$

Using regression imputation, a woman with a 6-week EPDS score of 12 and a missing 6-month EPDS score would have a regression-imputed 6-month EPDS score of 8.6 [i.e. 2.287 + (12×0.526)]. Only women with a 6-week

TABLE 19 *Primary outcome: at-risk women by intervention or control group at 6 months* (n = *418)*

6-month EPDS	Int group	Control group	All	Absolute difference%	95% CI	Odds ratio, int to control	95% CI	*p*-value
Score < 12								
n	179	80	259					
%	66.1	54.4	62.0					
Score ≥ 12								
n	92	67	159					
%	33.9	45.6	38.0	11.7	0.4 to 22.9	0.62	0.40 to 0.97	0.036
						0.64[a]	0.40 to 1.01[a]	0.058[a]
						0.60[b]	0.38 to 0.95[b]	0.028[b]
						0.57[c]	0.36 to 0.90[c]	0.017[c]
Total *n*	271	147	418					

EPDS, Edinburgh Postnatal Depression Scale; Int, intervention.
[a]*n* = 409, adjusted for 6-week EPDS score.
[b]*n* = 409, adjusted for 6-week EPDS score, lives alone, history of postnatal depression, any life events (y/n)
[c]*n* = 409, adjusted for lives alone, history of postnatal depression, any life events.

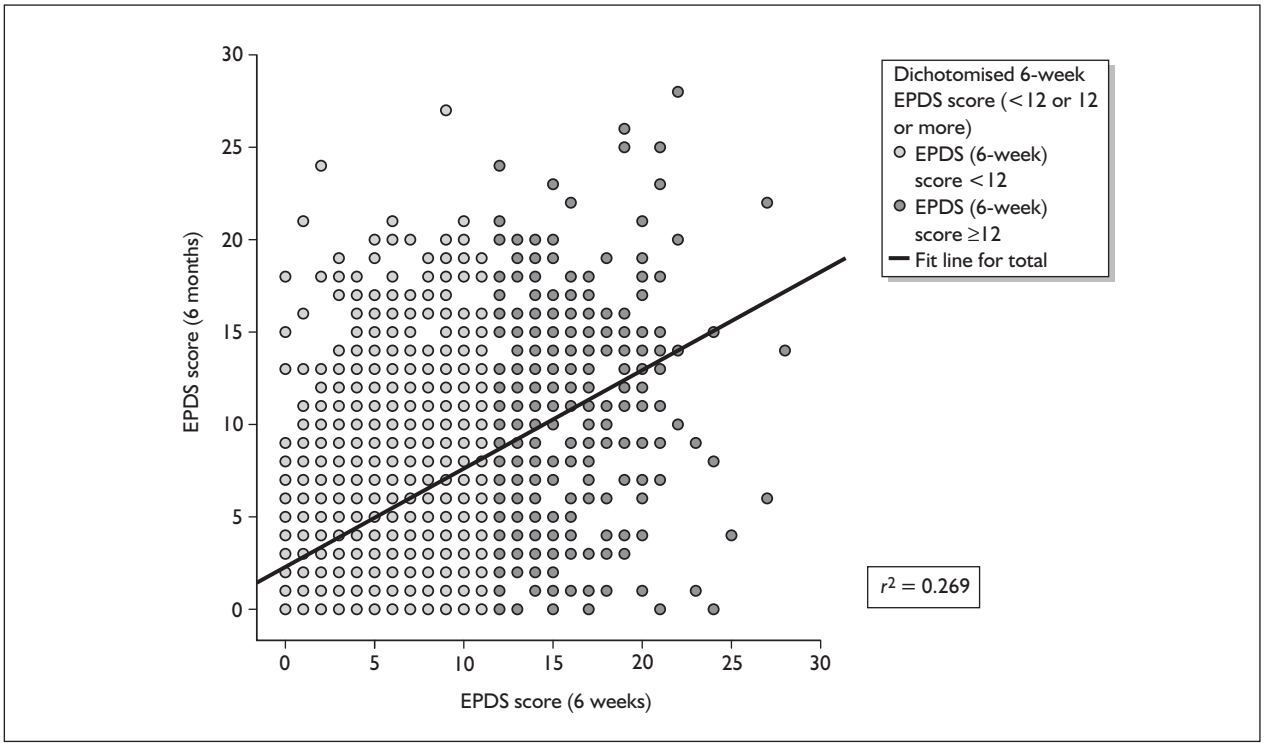

FIGURE 8 *Scatter plot of the relationship between the 6-month and 6-week EPDS scores* (n = *2659) with the regression imputation line of best fit.*

EPDS score ≥ 19 would have a 6-month EPDS score ≥ 12.

Table 20 shows the results of the sensitivity analysis for the imputation of missing data by LOCF and regression imputation compared with the primary statistical analysis. Using LOCF the results changed markedly and the observed treatment effect was smaller and not statistically significant. Using regression imputation the results were similar to those of the primary analysis although the treatment effect was smaller (odds ratio of 0.72 versus 0.62) and not statistically significant, with a *p*-value of 0.089 (compared with $p = 0.036$ for the observed data). The results for the regression-imputed model adjusted for covariates were statistically significant and very similar to the observed data (odds ratio of 0.62 versus 0.60).

Primary outcome: comparison of the CBA and PCA groups versus the control group

In total, 32.9% (46/140) of women in the CBA group versus 35.1% (46/131) in the PCA group had a 6-month EPDS score ≥ 12 (difference 2.2%, 95% CI –14.2% to 10.1%, $p = 0.74$) (*Table 21*). This suggests that the odds of having a 6-month EPDS score ≥ 12 in the PCA group is 1.09 (95% CI 0.64 to 1.88) times that of the odds in the CBA group. After adjusting for covariates (6-week EPDS score, living alone, history of PND, life events) the odds ratio for the PCA versus the CBA was 1.00 (95% CI 0.57 to 1.77, $p = 0.99$) and this effect was not statistically significant.

Intracluster correlation coefficient for at-risk women

As recommended by the cluster CONSORT guidelines,[197] *Table 22* reports the observed ICC for the primary outcome.

TABLE 20 *Primary outcome: proportions of at-risk women with a 6-month EPDS score ≥ 12, control vs intervention, after LOCF and regression imputation of missing scores*

	6-month EPDS score ≥ 12							
	Control group	Int group	Valid *n*	Difference (%)	95% CI	Odds ratio, int to control	95% CI	*p*-value
Primary analysis								
n	67	92						
%	45.6	33.9		11.7	0.4 to 22.9	0.62	0.40 to 0.97	0.036
						0.60[a]	0.38 to 0.95[a]	0.028 ($n = 409$)[a]
Total *n*	147	271	418					
LOCF								
n	111	225						
%	58.1	55.7		2.4	–6.6 to 12.7	0.90	0.62 to 1.31	0.58
						0.87[a]	0.59 to 1.27[a]	0.47 ($n = 582$)[a]
Total *n*	191	404	595					
Regression								
n	74	126						
%	38.7	31.2		7.5	–1.3 to 16.4	0.72	0.49 to 1.05	0.089
						0.62[a]	0.41 to 0.96[a]	0.032 ($n = 582$)[a]
Total *n*	191	404	595					

EPDS, Edinburgh Postnatal Depression Scale; Int, intervention; LOCF, last observation carried forward imputation.
[a]Adjusted for 6-week EPDS score, lives alone, history of postnatal depression, any life events.
Regression imputation based on the following model from 2659 women who completed both a 6-week and a 6-month EPDS: $EPDS_{6\ months} = 2.287$ (SE 0.135) + 0.526 (SE 0.17) × $EPDS_{6\ weeks}$ ($R^2 = 26.9$).

TABLE 21 *Primary outcome: proportions of at-risk women with a 6-month EPDS score ≥ 12 by CBA, PCA or control group (n = 418)*

6-month EPDS	CBA group	PCA group	Control group	Odds ratio, CBA to control	95% CI	*p*-value	Odds ratio, PCA to control	95% CI	*p*-value
Score < 12, *n* (%)	94 (67.1)	85 (64.9)	80 (54.4)						
Score ≥ 12, *n* (%)	46 (32.9)	46 (35.1)	67 (45.6)	0.59	0.35 to 0.99	0.046	0.65	0.38 to 1.10	0.108
				0.62[a]	0.36 to 1.06[a]	0.080[a]	0.66[a]	0.39 to 1.14[a]	0.137[a]
				0.59[b]	0.34 to 1.02[b]	0.061[b]	0.61[b]	0.36 to 1.03[b]	0.064[b]
Total *n*	140	131	147						

CBA, cognitive behavioural approach; EPDS, Edinburgh Postnatal Depression Scale; PCA, person-centred approach.
[a]*n* = 409, adjusted for 6-week EPDS score.
[b]*n* = 409, adjusted for 6-week EPDS score, lives alone, history of postnatal depression, any life events.

Six-month secondary outcomes for at-risk women

Six-month secondary outcomes: intervention group versus control group

The mean EPDS was a secondary outcome. At 6 months, among the at-risk women who also had an EPDS score on their returned 6-month questionnaires, the mean EPDS score was 11.3 (SD 5.8) for women in the CG and 9.2 (SD 5.4) for women in the IG (*Table 23*). The mean difference was –2.1 (95% CI –3.4 to –0.8). This difference was statistically significant ($p = 0.002$) and remained statistically significant after adjusting for 6-week variables ($p = 0.001$).

In addition, there were also significant differences between the groups in the SF-12 MCS, the SF-6D, the CORE-OM total score, the STAI and the PSI, all in favour of the IG. The mean 6-month secondary outcome scores are presented in *Table 23*.

Six-month secondary outcomes: CBA-F, CBA-P, PCA-F and PCA-P versus control group

The mean 6-month EPDS score was 9.2 (SD 5.3) for the at-risk women in the CBA group and 9.2 (SD 5.5) in the PCA group ($p = 0.99$). There were no differences in the mean scores for any of the other secondary outcomes (*Table 24*). The mean 6-month EPDS score was 9.2 for each of the four IGs.

Twelve-month secondary outcomes for at-risk women

Of the 741 questionnaires not sent at 12 months, 597 (81%) were not sent because the women had not reached the 12-month postnatal follow-up time. Twelve-month outcomes were therefore available for 94 CG and 167 IG at-risk women.

Twelve-month EPDS scores for at-risk women: intervention versus control group

At 12 months, among the at-risk women who had an EPDS score on their returned 6-month questionnaires, the mean EPDS score was 10.6

TABLE 22 *Estimated intracluster correlation coefficients (ICC) for primary outcome, the number scoring ≥ 12 on the EPDS at 6 months*

	n	No. of clusters	Average cluster size	Min. to max. cluster size	ICC	95% CI lower	95% CI upper
At-risk women	418	86	4.9	1–15	0.037	0.000	0.114

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TABLE 23 *Six-month secondary outcomes for at-risk women (n = 418): control vs intervention, unadjusted and adjusted*

	Control			Intervention			Unadjusted			Adjusted[a]		
6-month outcome	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	**Difference**	**95% CI**	***p*-value**	**Difference**	**95% CI**	***p*-value**
EPDS	147	11.3	5.8	271	9.2	5.4	–2.1	–3.4 to –0.8	0.002	–2.1	–3.3 to –0.9	0.001
SF-12 PCS	142	54.3	9.0	263	53.0	7.6	–1.4	–3.5 to 0.7	0.204	–1.7	–3.6 to 0.1	0.069
SF-12 MCS	142	37.8	11.8	263	42.3	10.8	4.7	1.8 to 7.6	0.001	5.2	2.5 to 7.8	0.001
SF-6D	144	0.70	0.12	266	0.73	0.1	0.03	0.004–0.06	0.025	0.03	0.00 to 0.06	0.025
CORE-OM well-being	146	1.6	0.95	269	1.19	0.9	–0.4	–0.6 to –0.1	0.001	–0.3	–0.5 to –0.2	0.001
CORE-OM risk	145	0.2	0.37	269	0.10	0.2	–0.1	–0.1 to 0.0	0.135	–0.0	–0.1 to 0.0	0.149
CORE-OM symptoms	146	1.1	0.8	269	0.9	0.7	–0.2	–0.4 to –0.1	0.014	–0.2	–0.4 to –0.1	0.005
CORE-OM functioning	146	1.2	0.8	269	1.0	0.8	–0.3	–0.5 to –0.1	0.006	–0.3	–0.4 to –0.1	0.001
CORE-OM total score	146	1.1	0.7	269	0.8	0.6	–0.2	–0.4 to –0.1	0.006	–0.2	–0.4 to –0.1	0.001
State anxiety (STAI)	136	45.5	12.5	254	41.7	11.8	–3.8	–6.6 to 1.0	0.008	–3.9	–6.6 to –1.3	0.003
Trait anxiety (STAI)	130	45.0	10.9	257	41.6	10.4	–3.4	–5.9 to –0.9	0.008	–3.7	–6.1 to –1.4	0.002
PSI parenting distress	114	38.1	9.5	229	41.3	8.8	3.2	0.9 to 5.4	0.006	3.5	1.3 to 5.8	0.002
PSI PCDI	118	53.6	6.9	231	55.7	5.8	2.2	0.7 to 3.6	0.003	2.1	0.7 to 3.5	0.003
PSI difficult child	113	48.1	7.7	217	51.5	6.9	3.4	1.8 to 5.0	0.001	2.9	1.7 to 4.2	0.001
PSI total stress	106	139.6	20.4	211	148.9	17.0	9.2	4.8 to 13.7	0.001	9.3	137.3 to 13.4	0.001

CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; EPDS, Edinburgh Postnatal Depression Scale; MCS, mental component summary; PCDI, parent–child dysfunctional interaction; PCS, physical component summary; PSI, Parenting Stress Index.
[a]EPDS, SF-12, SF-6D, CORE-OM all adjusted for 6-week score, lives alone, history of postnatal depression, any life events.
Better health represented by a lower score in CORE-OM, EPDS and STAI. Better health represented by a higher score in PSI, SF-12 and SF-6D.

TABLE 24 *Six-month secondary outcomes for at-risk women (n = 418): CBA and PCA vs control, unadjusted and adjusted*

	Control		CBA				PCA				CBA		PCA	
6-month outcome	***n***	**Mean (SD)**	***n***	**Mean (SD)**	**Difference (95% CI)**	***p*-value**	***n***	**Mean (S.D)**	**Difference (95% CI)**	***p*-value**	**Adjusted[a] difference (95% CI)**	***p*-value**	**Adjusted[a] difference (95% CI)**	***p*-value**
EPDS	147	11.3 (5.8)	140	9.2 (5.3)	–2.1 (–3.6 to –0.6)	0.006	131	9.2 (5.5)	–2.1 (–3.5 to –0.6)	0.005	–2.1 (–3.5 to 0.6)	0.004	–2.1 (–3.4 to –0.8)	0.002
SF-12 PCS	142	54.3 (9.0)	134	53.8 (7.5)	–0.6 (–2.8 to 1.56)	0.596	129	52.2 (7.7)	–2.1 (–4.4 to 0.3)	0.081	–0.9 (–2.9 to 1.2)	0.354	–2.5 (–4.6 to –0.4)	0.018
SF-12 MCS	142	37.8 (11.8)	134	42.0 (10.5)	4.3 (1.0 to 7.6)	0.010	129	42.7 (11.3)	5.1 (1.9 to 8.3)	0.002	4.6 (1.5 to 7.7)	0.003	5.8 (2.8 to 8.7)	0.001
SF-6D	144	0.70 (0.12)	137	0.73 (0.13)	0.03 (–0.0 to 0.63)	0.051	129	0.73 (0.14)	0.32 (–0.00 to 0.67)	0.068	0.03 (0.00 to 0.06)	0.025	0.32 (0.00 to 0.06)	0.043
CORE-OM well-being	146	1.6 (1.0)	138	1.2 (0.9)	–0.4 (–0.6 to –0.1)	0.003	131	1.2 (0.9)	–0.3 (–0.6 to –0.1)	0.006	–0.4 (–0.6 to –0.1)	0.001	–0.3 (–0.5 to –0.1)	0.003
CORE-OM risk	145	0.2 (0.4)	138	0.1 (0.2)	–0.0 (–0.1 to –0.0)	0.248	131	0.1 (0.2)	–0.1 (–0.1 to 0.0)	0.101	–0.0 (–0.1 to 0.0)	0.206	–0.0 (–0.1 to 0.0)	0.155
CORE-OM symptoms	146	1.1 (0.8)	138	0.9 (0.7)	–0.2 (–0.4 to –0.0)	0.030	131	0.9 (0.7)	–0.2 (–0.4 to–0.0)	0.023	–0.2 (–0.4 to –0.0)	0.014	–0.2 (–0.4 to –0.1)	0.012
CORE-OM functioning	146	1.3 (0.8)	138	1.0 (0.7)	–0.3 (–0.5 to –0.1)	0.008	131	1.0 (0.8)	–0.2 (–0.4 to –0.0)	0.026	–0.3 (–0.5 to –0.8)	0.002	–0.2 (–0.4 to –0.1)	0.005
CORE-OM total score	146	1.1 (0.7)	138	0.8 (0.6)	–0.2 (–0.4 to –0.1)	0.011	131	0.8 (0.6)	–0.2 (–0.4 to –0.0)	0.015	–0.2 (–0.9 to –0.1)	0.004	–0.2 (–0.4 to –0.1)	0.006
State anxiety (STAI)	136	45.5 (12.5)	130	41.0 (11.7)	–4.4 (–7.7 to –1.1)	0.009	124	42.0 (11.9)	–3.2 (–6.2 to –0.1)	0.043	–4.6 (–7.7 to –1.5)	0.003	–3.2 (–6.0 to 0.3)	0.029
Trait anxiety (STAI)	130	45.0 (10.9)	133	41.1 (9.6)	–3.9 (–6.8 to –1.1)	0.007	124	42.1 (11.1)	–2.9 (–5.7 to –0.1)	0.044	–4.2 (–7.0 to –1.5)	0.003	–3.2 (–5.9 to –0.6)	0.016
PSI parenting distress	114	38.1 (9.5)	114	41.9 (8.6)	3.8 (1.3 to 6.4)	0.003	115	40.7 (9.0)	2.6 (0.1 to 5.0)	0.039	1.0 (0.0 to 2.0)	0.039	1.2 (0.3 to 2.2)	0.012
PSI PCDI	118	53.6 (6.9)	116	55.3 (6.4)	1.8 (–0.1 to 3.6)	0.061	115	56.2 (5.1)	2.6 (1.1 to 4.0)	0.001	1.6 (–0.2 to 3.4)	0.084	2.6 (1.2 to 4.0)	0.001
PSI difficult child	113	48.1 (7.7)	109	51.7 (7.1)	3.5 (1.8 to 5.3)	0.001	108	51.3 (6.6)	3.3 (1.5 to 5.1)	0.001	3.0 (1.5 to 4.5)	0.001	2.9 (1.4 to 4.4)	0.001
PSI total stress	106	139.6 (20.4)	106	149.9 (18.1)	10.3 (5.0 to 15.6)	0.001	105	147.8 (15.7)	8.2 (3.6 to 12.7)	0.001	10.1 (5.1 to 15.1)	0.001	8.4 (4.3 to 12.5)	0.001

CBA, cognitive behavioural approach; CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; EPDS, Edinburgh Postnatal Depression Scale; MCS, mental component summary; PCDI, parent–child dysfunctional interaction; PCA, person-centred approach; PCS, physical component summary; PSI, Parenting Stress Index.
[a]EPDS, SF-12, SF-6D and CORE-OM all adjusted for 6-week score, lives alone, history of postnatal depression and any life events.
Better health represented by a lower score in CORE-OM, EPDS and STAI. Better health represented by a higher score in PSI, SF-12 and SF-6D.

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TABLE 25 *Twelve-month secondary outcomes for at-risk women: control vs intervention, unadjusted and adjusted*

	Control			Intervention			Unadjusted			Adjusted[a]		
12-month outcome	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	**Difference**	**95% CI**	***p*-value**	**Difference**	**95% CI**	***p*-value**
EPDS	94	10.6	6.2	167	8.1	5.6	–2.6	–4.3 to –0.9	0.003	–2.4	–4.1 to –0.7	0.005
SF-12 PCS	92	54.1	7.5	161	53.9	7.0	–0.2	–2.0 to 1.7	0.857	–0.4	–2.0 to 1.3	0.650
SF-12 MCS	92	40.8	10.9	161	44.9	10.9	4.1	1.3 to 6.9	0.004	3.8	1.0 to 6.6	0.008
SF-6D	93	0.7	0.1	165	0.8	0.1	0.0	0.0 to 0.1	0.007	0.0	0.0 to 0.1	0.013
CORE-OM well-being	94	1.4	0.9	167	1.1	0.9	–0.3	–0.5 to –0.1	0.013	–0.3	–0.5 to –0.1	0.013
CORE-OM risk	94	0.1	0.4	167	0.1	0.2	–0.1	–0.1 to 0.0	0.191	–0.0	–0.1 to 0.0	0.353
CORE-OM symptoms	94	1.1	0.8	167	0.8	0.7	–0.2	–0.5 to –0.1	0.010	–0.2	–0.4 to –0.0	0.021
CORE-OM functioning	94	1.2	0.8	167	0.9	0.8	–0.3	–0.5 to –0.1	0.005	–0.3	–0.5 to –0.1	0.011
CORE-OM total score	94	1.1	0.7	167	0.7	0.6	–0.3	–0.4 to –0.1	0.005	–0.2	–0.4 to –0.0	0.015
State anxiety (STAI)	93	45.0	13.2	162	40.7	12.6	–0.4	–8.1 to –0.7	0.019	–4.2	–7.8 to –0.5	0.025
Trait anxiety (STAI)	89	43.2	11.4	162	39.3	10.8	–4.0	–7.3 to –0.6	0.019	–3.9	–7.2 to –0.5	0.023
DAS Likert	89	3.3	1.4	158	3.8	1.4	0.5	0.1 to 0.8	0.011	–0.2	–0.6 to 0.1	0.217
DAS	89	19.2	3.2	154	18.2	3.0	–0.9	–1.8 to –0.1	0.027	0.0	–0.7 to 0.8	0.965
PSI parenting distress	93	38.6	9.5	158	42.5	10.0	3.9	1.4 to 6.4	0.002	3.9	1.5 to 6.3	0.002
PSI PCDI	94	54.3	7.1	163	55.9	6.1	1.6	–0.3 to 3.1	0.055	1.6	0.0 to 3.2	0.047
PSI difficult child	91	47.6	8.4	164	50.5	7.4	3.0	1.0 to 5.0	0.003	2.9	1.2 to 4.7	0.001
PSI total stress	90	140.7	21.4	156	148.7	19.2	8.1	3.1 to 13.0	0.001	8.1	3.6 to 12.6	0.000

CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; DAS, Dyadic Adjustment Scale; EPDS, Edinburgh Postnatal Depression Scale; MCS, mental component summary; PCDI, parent–child dysfunctional interaction; PCS, physical component summary; PSI, Parenting Stress Index.
[a]EPDS, SF-12, SF-6D, CORE-OM all adjusted for 6-week score, lives alone, history of postnatal depression, any life events.
Better health represented by a lower score in CORE-OM, EPDS, STAI. Better health represented by a higher score in DAS, PSI, SF-12 and SF-6D.

(SD 6.2) for women in the CG and 8.1 (SD 5.6) for women in the IG (*Table 25*). This difference was statistically significant ($p < 0.001$). After adjusting for 6-week variables, the difference remained statistically significant ($p = 0.005$). *Figure 9* shows the reduction in mean EPDS score over time in the intervention and control groups from 6 weeks to 12 months. Most of the benefit is gained at 6 months and is then maintained up to 12 months postnatally.

Twelve-month secondary outcomes for at-risk women: intervention versus control group

As well as a difference between the groups in mean EPDS score at 12 months there were also differences in the SF-12 MCS, the SF-6D, the CORE-OM total score, the STAI score and some of the PSI domains, all in favour of the IG (*Table 25*).

Twelve-month secondary outcomes for at-risk women: CBA and PCA versus control

Examining the two main IGs separately, the mean EPDS score was 8.0 (SD 5.4) for women in the CBA group and 8.3 (SD 5.9) for women in the PCA group.

Twelve-month secondary outcomes for at-risk women: CBA-F, CBA-P, PCA-F and PCA-P versus control

Examining all four IGs separately there were some differences between the 12-month mean EPDS scores for the women who returned a 12-month questionnaire, ranging from 7.4 (SD 5.0) for the CBA-P group to 9.0 (SD5.5) for the PCA-F group.

Eighteen-month secondary outcomes for at-risk women

Eighteen-month outcomes for at-risk women: intervention versus control

Of the 2113 questionnaires not sent at 18 months, 1879 (88.9%) were not sent because the women had not reached the 18-month postnatal follow-up time. The EPDS was not administered at 18 months as it is not validated for use beyond 12 months. There were some statistically significant differences between the CG and the IG at 18 months for some of the PSI subscales. These are presented in *Table 26*. *Figures 10–13* illustrate the changes in mean scores for at-risk women from 6 weeks to 18 months for the secondary outcomes SF-12 MCS, SF-12 PCS, SF-6D and CORE-OM respectively.

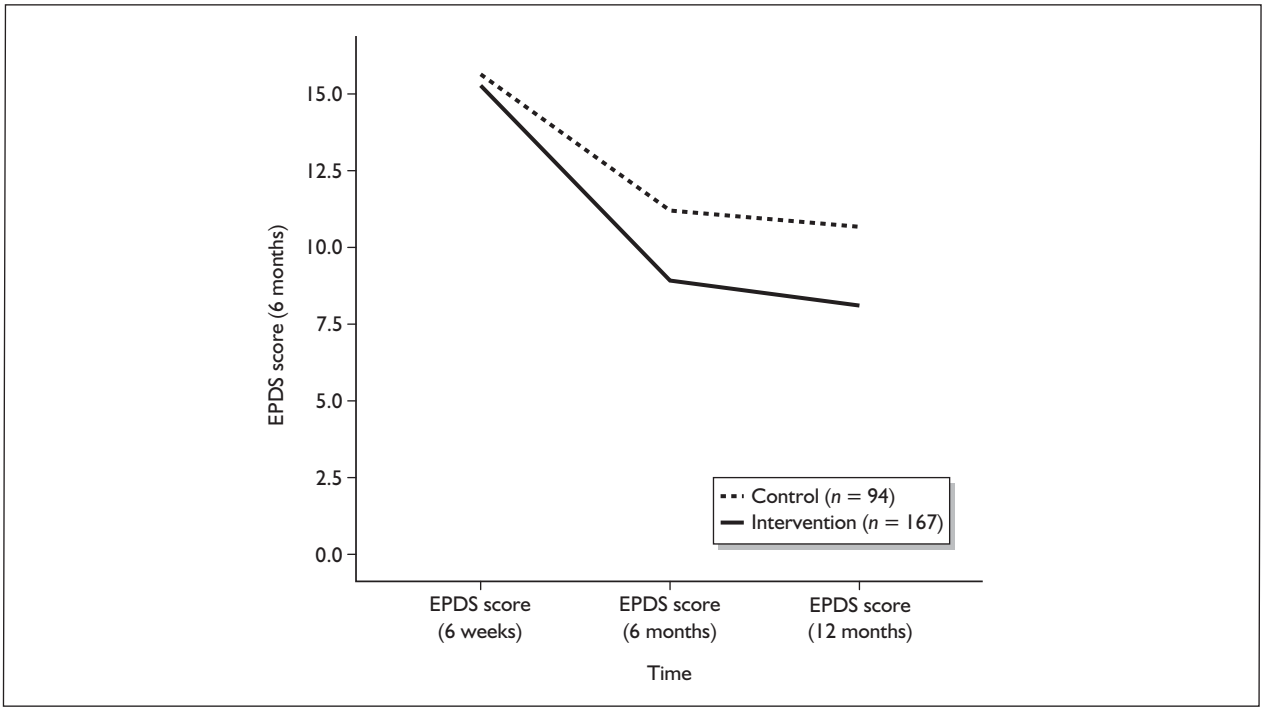

FIGURE 9 *Mean EPDS scores for at-risk women at 6 weeks, 6 months and 12 months by intervention and control group.*

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TABLE 26 *Eighteen-month secondary outcomes for at-risk women: control vs intervention, unadjusted and adjusted*

	Control			Intervention			Unadjusted			Adjusted[a]			
Outcome	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	**Difference**	**95% CI**	***p***	***n***	**Difference**	**95% CI**	***p***
SF-36 PCS 6W	143	48.5	10.9	265	50.1	9.4							
SF-12 PCS 18M	46	52.1	12.9	86	56.0	8.6	4.1	1.1 to 7.1	0.007	86	2.9	–0.1 to 6.0	0.062
SF–36 MCS 6W	143	29.4	9.2	265	29.1	8.0							
SF-12 MCS 18M	46	40.2	7.1	86	39.5	5.4	–0.8	–2.9 to 1.3	0.463	86	–0.7	–2.7 to 1.3	0.509
SF-6D 6W	142	0.59	0.08	268	0.60	0.1							
SF-6D 18M	47	0.73	0.15	87	0.78	0.15	0.04	–0.00 to 0.09	0.063	87	0.03	–0.01 to 0.07	0.122
CORE-OM well-being 6W	146	2.1	0.74	269	2.0	0.7							
CORE-OM well-being 18M	47	1.4	1.0	88	1.2	1.0	–0.2	–0.6 to 0.2	0.309	88	–0.1	–0.4 to 0.2	0.523
CORE-OM risk 6W	145	0.2	0.33	269	0.14	0.3							
CORE-OM risk 18M	47	0.2	0.4	88	0.1	0.3	–0.1	–0.2 to 0.1	0.328	88	–0.0	–0.1 to.01	0.670
CORE-OM symptoms 6W	146	1.6	0.6	269	1.6	0.6							
CORE-OM symptoms 18M	47	1.0	0.9	88	0.8	0.8	–0.2	–0.5 to 0.1	0.192	88	–0.1	–0.4 to 0.1	0.212
CORE-OM functioning 6W	146	1.6	0.6	269	1.5	0.6							
CORE-OM functioning 18M	47	1.1	0.9	88	0.9	0.8	–0.2	–0.5 to 0.2	0.290	88	–0.1	–0.3 to 0.1	0.497
CORE-OM total score 6W	146	1.4	0.5	269	1.4	0.5							
CORE-OM total score 18M	47	1.0	0.8	88	0.8	0.7	–0.2	–0.4 to 0.1	0.228	88	–0.1	–0.3 to 0.1	0.374
State anxiety (STAI) 18M	46	42.7	14.5	85	40.8	14.5	–1.7	–6.9 to 3.5	0.521	85	–1.3	–5.8 to 3.2	0.578
PSI parenting distress 18M	47	38.8	9.9	84	43.3	10.1	4.6	0.8 to 8.4	0.017	84	4.6	1.3 to 8.0	0.006
PSI PCDI 18M	46	53.5	7.6	87	55.2	6.3	1.4	–1.0 to 3.8	0.243	87	1.2	–0.9 to 3.4	0.263
PSI difficult child 18M	47	46.0	8.6	85	49.1	8.0	3.3	0.4 to 6.2	0.027	85	3.2	0.3 to 6.0	0.028
PSI total stress 18M	46	138.1	23.2	82	147.2	21.2	9.3	1.1 to 17.4	0.026	82	9.0	1.6 to 16.4	0.017

6W, 6 weeks; 18M, 18 months; CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; MCS, mental component summary; PCDI, parent–child dysfunctional interaction; PCS, physical component summary; PSI, Parenting Stress Index.
[a]EPDS, SF-12, SF-6D, CORE-OM all adjusted for 6-week score, lives alone, history of postnatal depression, any life events.
Better health represented by a lower score in CORE-OM, EPDS and STAI. Better health represented by a higher score in PSI, SF-12 and SF-6D and SF-36.

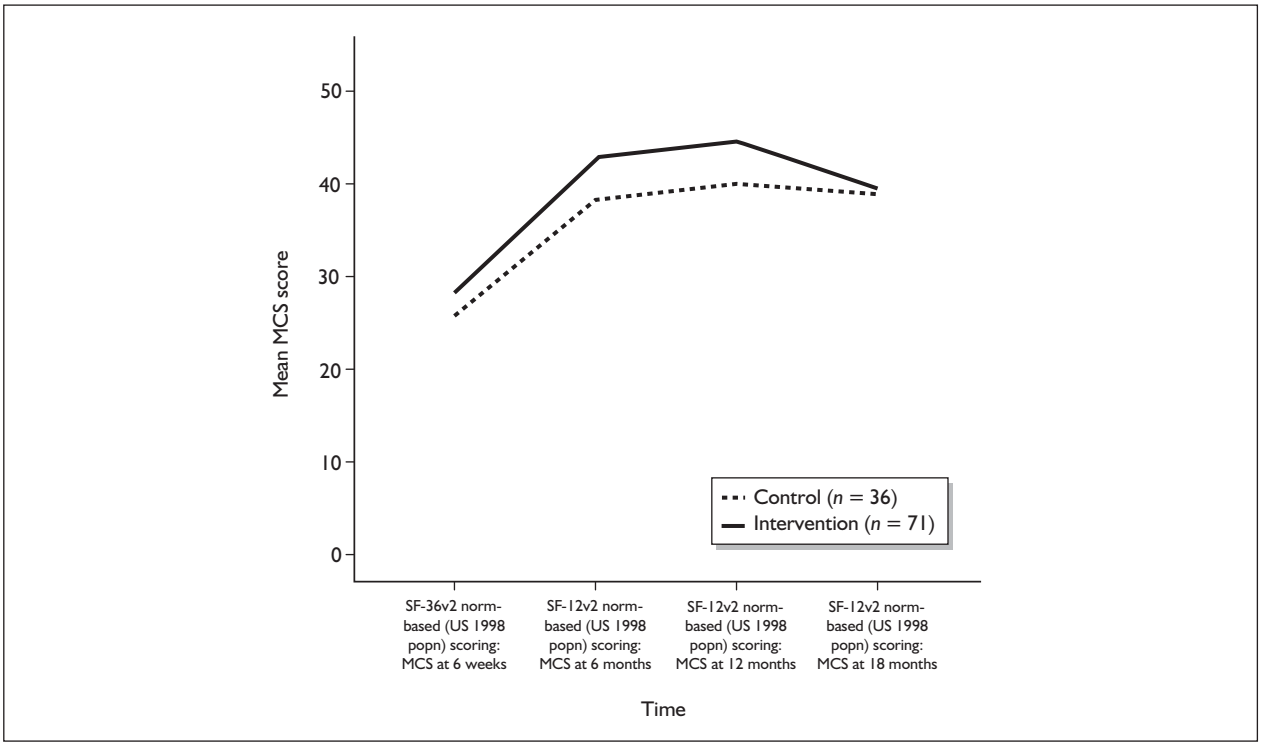

FIGURE 10 *Mean SF mental component summary (MCS) score for at-risk women from 6 weeks to 18 months, by intervention and control.*

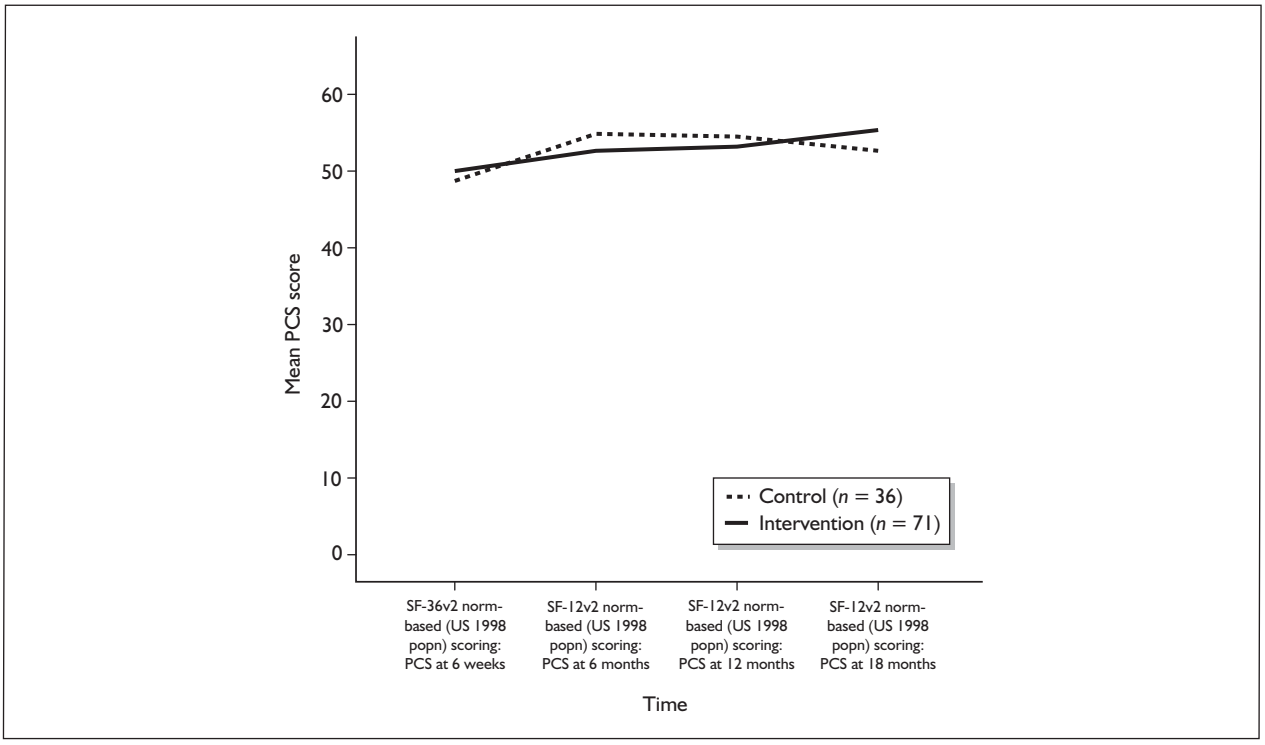

FIGURE 11 *Mean SF physical component summary (PCS) score for at-risk women from 6 weeks to 18 months, by intervention and control.*

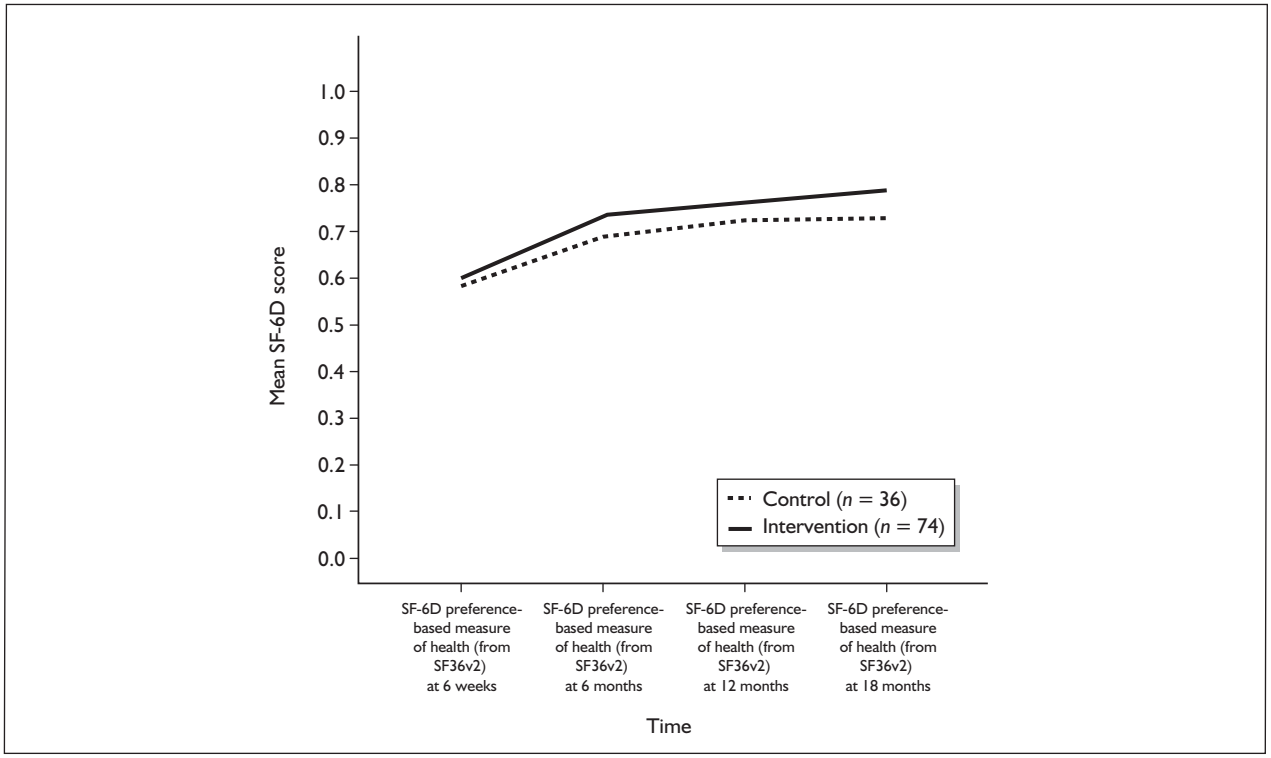

FIGURE 12 *Mean SF-6D scores for at-risk women from 6 weeks to 18 months, by intervention and control.*

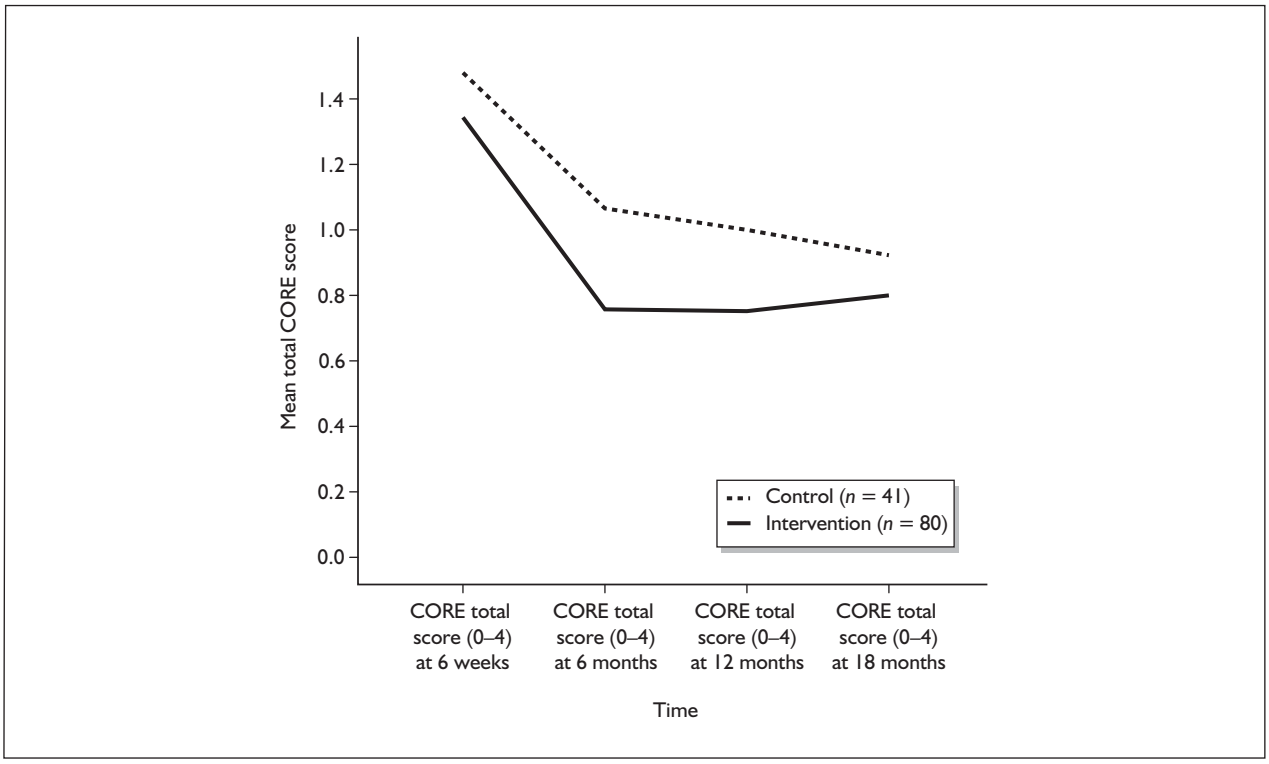

FIGURE 13 *Mean CORE-OM total score for at-risk women from 6 weeks to 18 months, by intervention and control.*

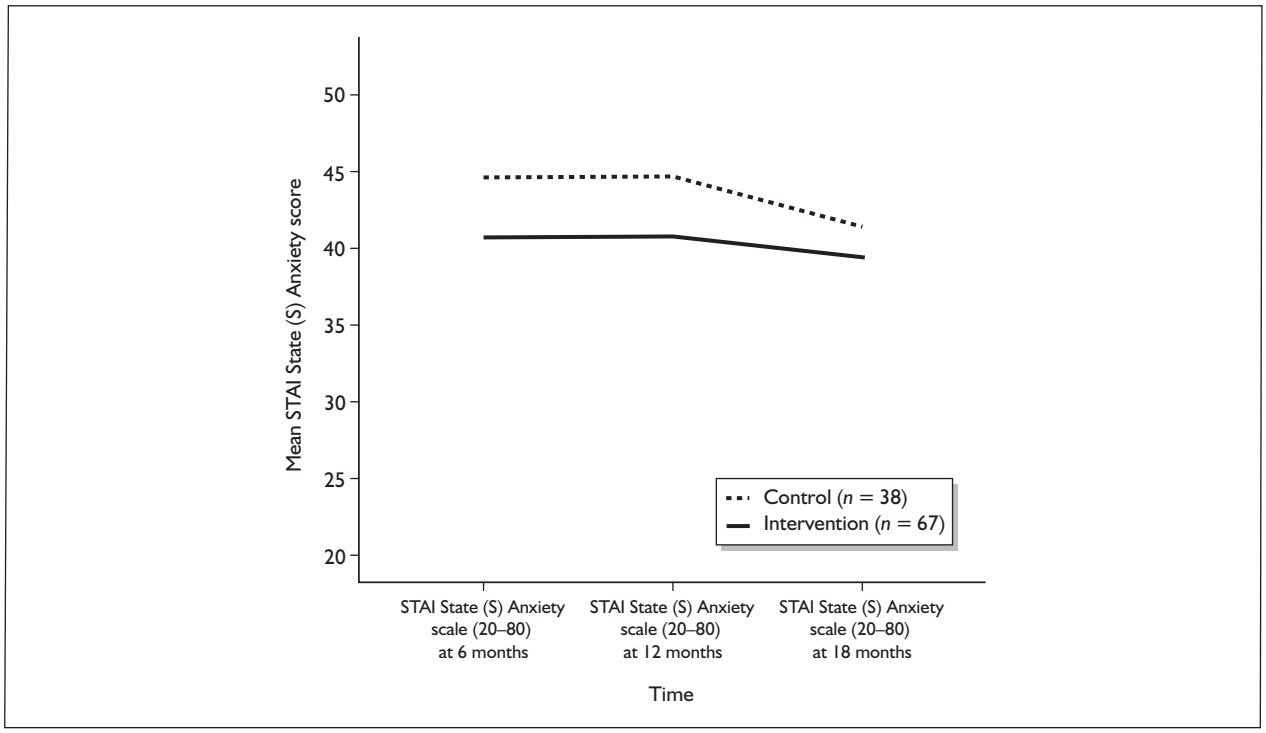

FIGURE 14 *Mean state anxiety scores for at-risk women from 6 months to 18 months, by intervention and control.*

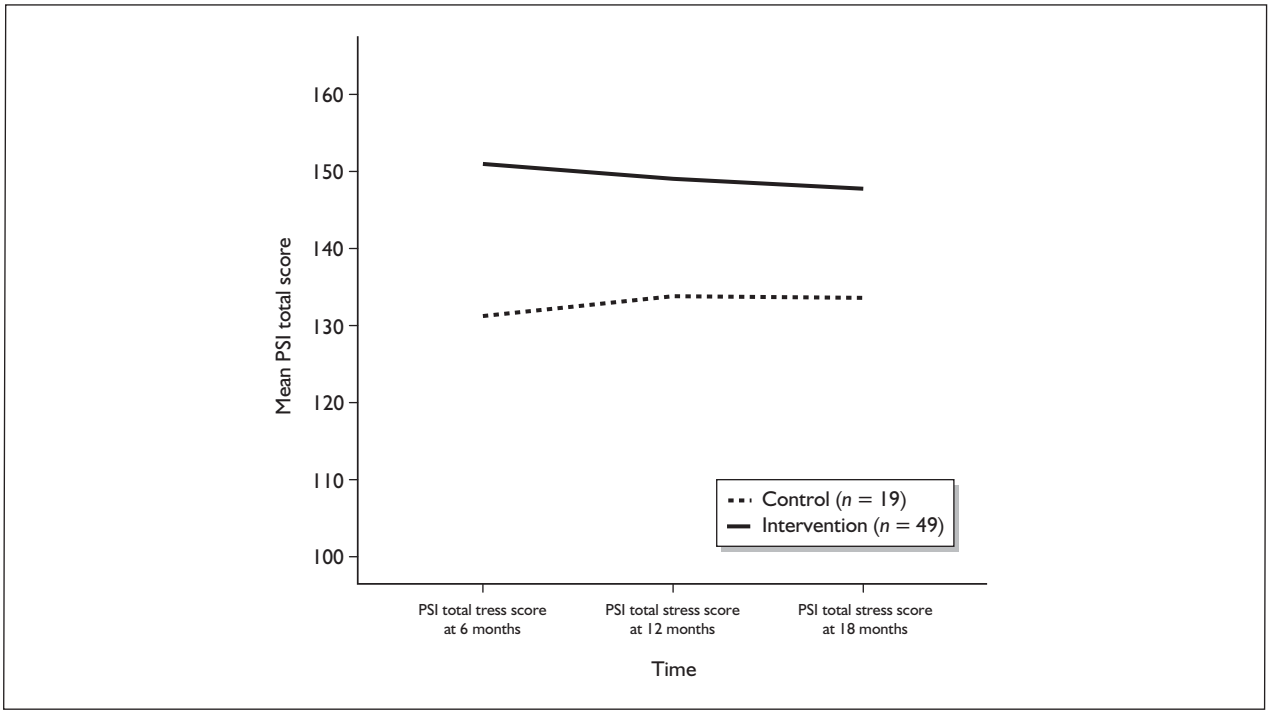

FIGURE 15 *Mean Parenting Stress Index total scores for at-risk women from 6 months to 18 months, by intervention and control.*

Figures 14 and *15* illustrate the changes in mean state anxiety and PSI scores for at-risk women from 6 months to 18 months.

Remission and relapse to 18 months

The results from the unvalidated measure of at-risk women's self-reported health for women who scored ≥ 18 on the 6-week EPDS are shown in *Figure 16*. This illustrates changes in symptoms of depression from the time of a baby's birth to 18 months postnatally on a scale from 0 to 4, where 0 indicates no symptoms and 4 indicates severe symptoms of depression.

SCAN outcomes

Threshold score of 12

There were 860 SCAN interviews performed for the study, 355 with at-risk women. Of these 355 at-risk women the outcome for 18.6% (66/355) was mild depression and for 14.1% (50/355) was moderate or severe depression. That is, among all the at-risk women who had a SCAN interview, 32.7% (116/355) had an outcome of depression (*Tables 27* and *28*). Apart from depression, the SCAN indicated depersonalisation syndrome, generalised anxiety disorder, nightmares, non-organic insomnia or panic disorder in some women, some of these in conjunction with depression. In total, 38.3% (136/355) of at-risk women and 19.8% (170/860) of all women who were interviewed had some outcome on the SCAN (*Table 29*). The SCAN outcome was no depression for 219 women with a range of EPDS scores from 12 to 22. A total of 80 women with an outcome of mild depression had EPDS scores ranging from 5 to 25. Similarly, 52 women who had a SCAN outcome of moderate depression (either alone or with another outcome) had EPDS scores ranging from 7 to 27. Of the five women who had an outcome of severe depression, EPDS scores ranged from 7 to 25.

Using a threshold of 12 (score ≥12), the sensitivity of the EPDS (the proportion of depressed women who scored ≥12 on the EPDS) was 0.866 (CI 0.808 to 0.923) and the specificity (the proportion of non-depressed women who scored ≤11 on the EPDS) was 0.671 (CI 0.637 to 0.705) (*Table 30*). The sensitivity for detecting moderate or severe depression using the threshold of 12 was 0.926 (CI 0.856 to 0.996), whereas the specificity was 0.622. The positive predictive value [proportion of women above the threshold of 12 on the EPDS ($n = 355$) who had an outcome of depression ($n = 116$)] was 32.7%.

Threshold score of 13

Using a threshold of 13 (score ≥13) (*Tables 31–34*) the sensitivity of the EPDS was 0.791 and the specificity was 0.755 (*Table 33*). The sensitivity for detecting moderate or severe depression using the threshold of 13 was 0.852, whereas the specificity was 0.705 and the positive predictive value was 37.3% (106/284).

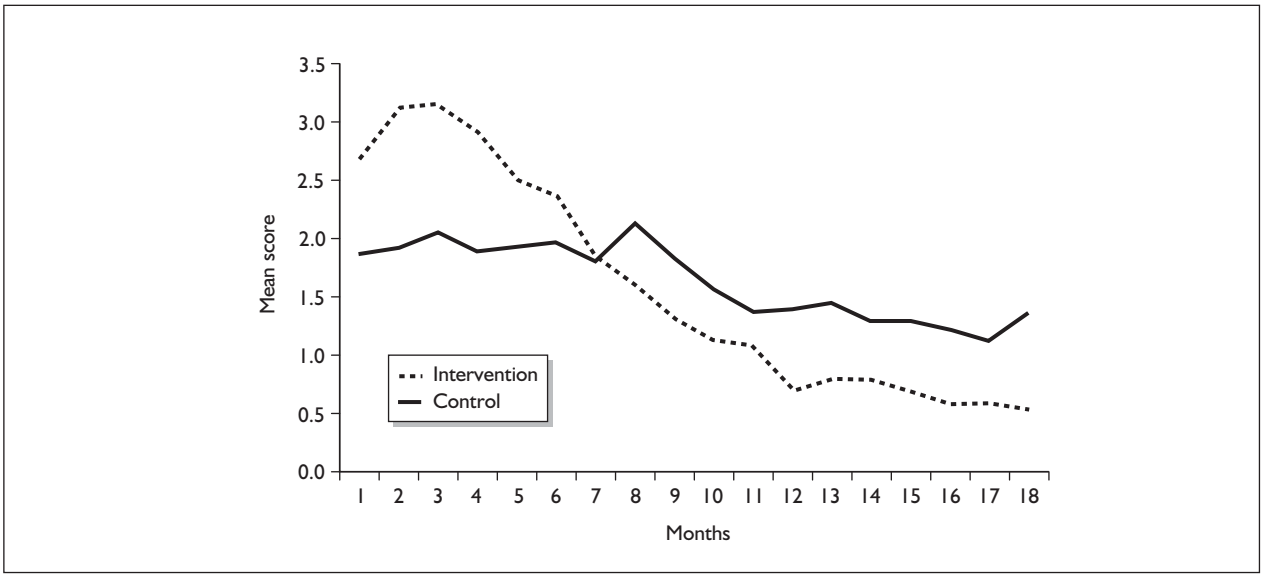

FIGURE 16 *Remission and relapse scores over 18 months for at-risk women, intervention vs control group.*

TABLE 27 *SCAN outcome: none, mild moderate or severe depression according to EPDS score at a threshold of 12*

	None		Mild		Moderate		Severe		
	n	%	*n*	%	*n*	%	*n*	%	Total, *n*
EPDS < 12	487	96	14	2.8	3	< 1	1	< 1	505
EPDS ≥ 12	239	67	66	19	46	13	4	< 1	355
Total	726	84	80	9	49	6	5	< 1	860

TABLE 28 *SCAN outcome: moderate or severe depression according to EPDS score at a threshold of 12*

	Moderate or severe, *n*		
	No	Yes	Total, *n*
EPDS < 12	501	4	505
EPDS ≥ 12	305	50	355
Total	806	54	860

TABLE 29 *Any SCAN outcome, according to EPDS score, at a threshold of 12*

	No outcome, *n*	Positive outcome, *n*	Total, *n*
EPDS < 12	471	34	505
EPDS ≥ 12	219	136	355
Total	690	170	860

TABLE 30 *Sensitivity and specificity of EPDS by SCAN outcome at a threshold of 12*

Detection of	Sensitivity	95% CI	Specificity	95% CI	Likelihood ratio +ve	95% CI	Likelihood ratio –ve	95% CI
Mild, moderate or severe depression	0.866 (116/134)	0.808 to 0.923	0.671 (487/726)	0.637 to 0.705	2.630	2.324 to 2.975	0.200	0.130 to 0.309
Moderate or severe depression	0.926 (50/54)	0.856 to 0.996	0.622 (501/806)	0.588 to 0.655	2.447	2.178 to 2.749	0.119	0.046 to 0.306
Any SCAN outcome	0.800 (136/170)	0.740 to 0.860	0.682 (470/689)	0.647 to 0.717	2.517	2.204 to 2.874	0.293	0.216 to 0.398

TABLE 31 *SCAN outcome: none, mild moderate or severe depression according to EPDS score at a threshold of 13*

	None, *n*	Mild, *n*	Moderate, *n*	Severe, *n*	Total, *n*
EPDS < 13	548	20	7	1	576
EPDS ≥ 13	178	60	42	4	284
Total	726	80	49	5	860

TABLE 32 *SCAN outcome: moderate or severe depression according to EPDS score at a threshold of 13*

	Moderate or severe, *n*		
	No	**Yes**	**Total, *n***
EPDS < 13	568	8	576
EPDS ≥ 13	238	46	284
Total	806	54	860

TABLE 33 *Any SCAN outcome, according to EPDS score, at a threshold of 13*

	No outcome, *n*	**Positive outcome, *n***	**Total, *n***
EPDS < 13	548	28	576
EPDS ≥ 13	178	106	284
Total	726	134	106

TABLE 34 *Sensitivity and specificity of EPDS according to SCAN outcome at a threshold of 13*

Detection of	**Sensitivity**	**95% CI**	**Specificity**	**95% CI**	**Likelihood ratio +ve**	**95% CI**	**Likelihood ratio –ve**	**95% CI**
Mild, moderate or severe depression	0.791 (106/134)	0.722 to 0.860	0.755 (548/726)	0.724 to 0.786	3.226	2.765 to 3.765	0.277	0.199 to 0.386
Moderate or severe depression	0.852 (46/54)	0.757 to 0.947	0.705 (568/806)	0.673 to 0.736	2.885	2.473 to 3.365	0.210	0.111 to 0.399
Any SCAN outcome	0.718 (122/170)	0.650 to 0.785	0.765 (527/689)	0.733 to 0.797	3.052	2.589 to 3.598	0.369	0.289 to 0.474

Intervention monitoring

At-risk women who returned a 6-month questionnaire

A total of 404 women who scored ≥ 12 on the 6-week postal EPDS were at-risk women, of whom 274 (67.8%) returned a 6-month questionnaire.

Health visitor administration of 8-week EPDS to at-risk women

The HV protocol stated that HVs should repeat the administration of the EPDS face-to-face at 8 weeks postnatally for all at-risk women to determine which women were eligible for the intervention. Of all of the 404 at-risk women, 70.8% (286/404) had an 8-week EPDS score and for 29.2% (118/404) the score was missing. Of those who had an 8-week EPDS score, for 60.5% of women (173/286) the score was < 12 and for 39.5% (173/286) the score was ≥ 12 (*Table 35*). Of the missing scores, 48% (57/118) were missing because the HV-administered face-to-face 6-week EPDS score was < 12. A further 27% (32/118) were missing for reasons to do with the women being absent or declining, and 20% (24/118) were absent for reasons to do with the HV being unavailable.

Health visitor psychological intervention sessions offered to at-risk women

For the 395 at-risk women for whom data were available, 50% (197/395) were offered a psychological intervention session and therefore 50% (198/395) were not offered a session. In total, 31% of all at-risk women (121/395) received at least one psychological intervention session and, of those offered, 39% (76/197) declined (*Table 35*). There were 259 intervention sessions delivered in the CBA group and 242 intervention sessions delivered in the PCA group.

Figure 17 illustrates that, of the at-risk women who returned a 6-month EPDS, 46% (125/274) were offered intervention sessions and 29% (80/274) accepted the intervention sessions. Among the 32% (130/404) of women who did not return a 6-month EPDS score and therefore were no longer included in the trial, 55% (72/130) were offered sessions and 32% (41/130) received sessions. *Figure 17* also illustrates that HVs offered sessions to women who had no 8-week EPDS score and who had an 8-week EPDS score < 12. Among all of the at-risk women, of whom according to the SCAN interviews most were not depressed, 197/404 (48.88) were offered sessions and 61% (121/197) accepted.

TABLE 35 *At-risk women with an 8-week EPDS score*

	All at-risk women ($n = 404$)	
	n	**%**
8-week EPDS: score < 12	173/296	60.5
8-week EPDS: score ≥ 12	113/286	39.5
8-week EPDS: score missing	118/404	29.2
HV offered sessions	197/395	49.9
Woman accepted sessions	121/395	30.6
Woman declined sessions	76/197	38.6
Prescribed antidepressants	84/380	22.1
Woman saw someone else	148/374	39.6

At-risk women receiving other support

About 22% (84/380) of the women had also been prescribed antidepressants, but not all of the women took these. Around 40% (148/374) were also receiving support apart from the HV. Most frequently (19.5%) the women received support from a GP (73/374); 8% of women were also in receipt of other mental health services and 6% attended a postnatal support group. Of possibly the greatest concern were the seven women who had an 8-week EPDS score ≥ 12 but who were not offered the psychological intervention sessions by the HV. *Table 36* indicates that these seven women were supported by a GP, counsellor or mental health worker or were not classified as depressed.

Preference for psychological intervention or antidepressants

There was no evidence that women preferred an antidepressant to the HV psychological intervention.

Six-month EPDS outcome for all women

Six-month EPDS outcome for all women: intervention versus control

At 6 months, among all of the women who had returned both a 6-week and a 6-month questionnaire, 16.4% in the CG scored ≥ 12 on the EPDS versus 11.7% in the IG. The absolute difference was 4.7% (95% CI 0.7 to 8.6). This effect was statistically significant ($p = 0.003$). After adjusting for covariates – 6-week EPDS score, living alone, previous history of PND and any life events – the point estimate of the odds ratio for the IG effect was relatively unchanged (at around 0.67) and this effect remained statistically significant (*Table 37*).

Figure 18 illustrates the change in EPDS score over time in the control and intervention groups for at-risk women and all women.

Intracluster correlation coefficient for all women

As recommended by the cluster CONSORT guidelines,[197] *Table 38* reports the observed ICC for the 6-month EPDS outcome.

TABLE 36 *Support received by women eligible for the psychological intervention according to SCAN outcome*

SCAN outcome	Health visitor description of support
Mild, $n = 1$	Long-standing migraine problems causing low mood. Closely supported by GP. On low dose of amitriptyline
Moderate, $n = 1$	Support from GP and counselling from surgery. Been taking antidepressants throughout pregnancy and postnatally, therefore not offered intervention sessions
No depression, $n = 3$	1. Attends clinic most weeks. Anxious. Own mother supportive
	2. GP prescribed fluoxetine
	3. On fluoxetine at 1 month postnatally
Other, $n = 1$	Generalised anxiety disorder – seeing mental health worker, prescribed antidepressants
Missed, $n = 1$	Health visitor said mother was coping well with children and commenced a 4-week baby massage course

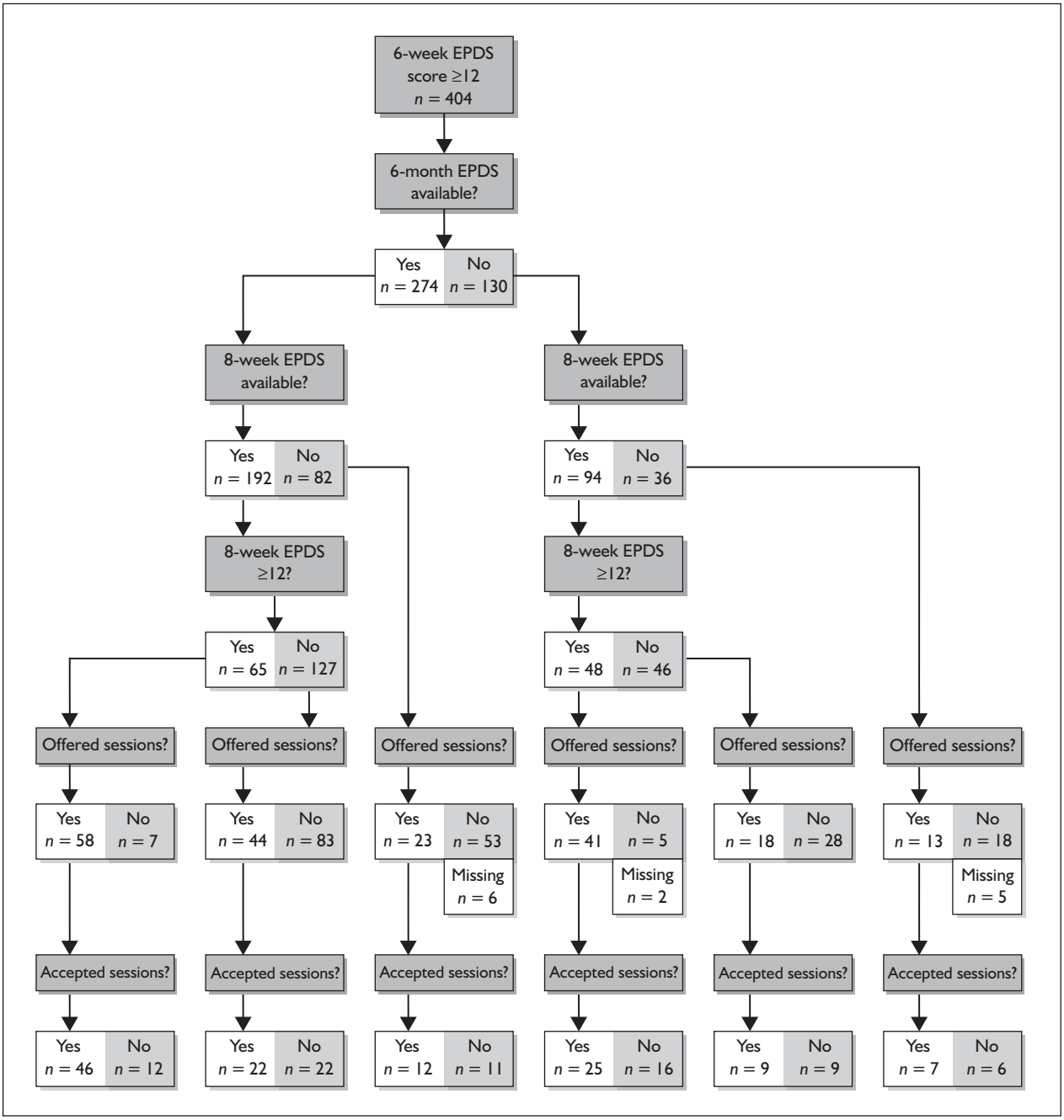

FIGURE 17 *Flow chart of at-risk women: 8-week EPDS assessment and intervention sessions offered.*

Six-month EPDS outcomes: all women in the CBA and PCA groups versus the control group

Examining the two IGs separately for all women, 11.6% (98/848) of those in the CBA group and 11.9% (107/897) of those in the PCA group scored ≥ 12 on the 6-month EPDS ($p = 0.80$) (*Table 39*).

Six-month secondary outcomes for all women

Six-month secondary outcomes for all women: intervention versus control

The mean EPDS score was 6.4 (SD 5.2) in the CG and 5.5 (SD 4.7) in the IG (*Table 40*). This small difference was statistically significant ($p = 0.001$). As with the secondary outcomes for the at-risk women, most of the mean scores for all women were statistically significant in favour of the IG.

TABLE 37 *Six-month EPDS outcome: proportion of all women with an EPDS score ≥ 12 at 6 months, by intervention or control (n = 2659)*

6-month EPDS score	Int group	Control group	All	Absolute difference (%)	95% CI	Odds ratio, int to control	95% CI	*p*-value
< 12, *n* (%)	1540 (88.3)	764 (83.6)	2304 (86.6)					
≥ 12, *n* (%)	205 (11.7)	150 (16.4)	355 (13.4)	4.7	0.7 to 8.6	0.67	0.51 to 0.87	0.003
						0.68[a]	0.52 to 0.88[a]	0.004[a]
						0.67[b]	0.52 to 0.86[b]	0.002[b]
Total, *n*	1745	914	2659					

Int, intervention.
[a]*n* = 2659, adjusted for 6-week EPDS score.
[b]*n* = 2624, adjusted for 6-week EPDS score, lives alone, history of postnatal depression, life events.

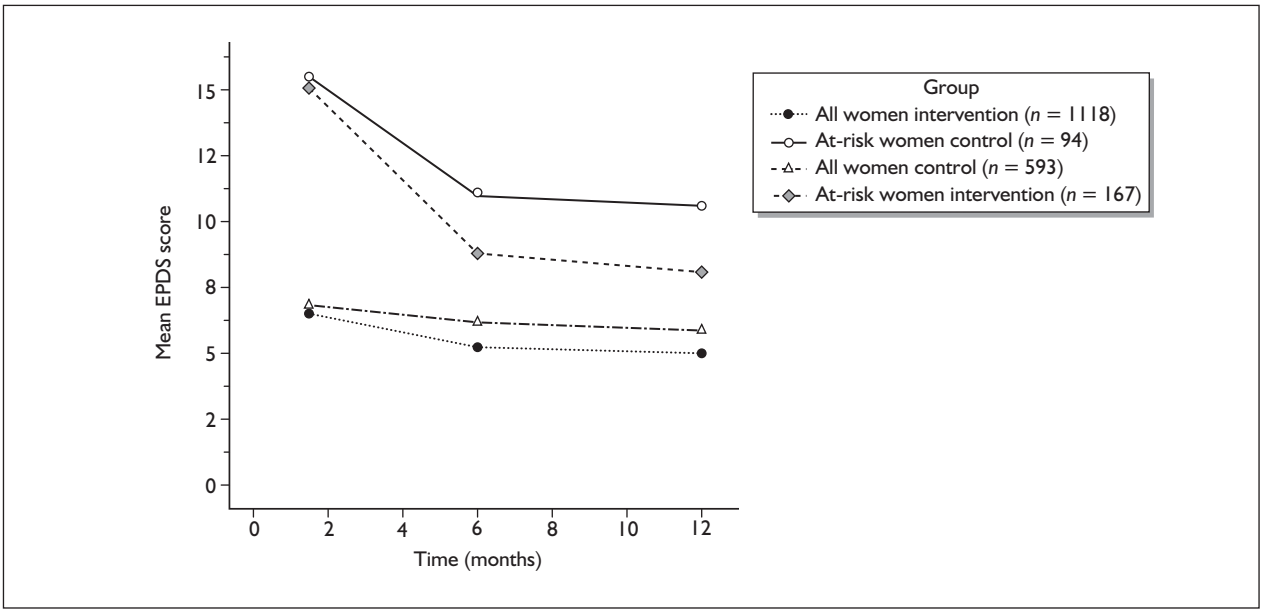

FIGURE 18 *Mean EPDS scores for at-risk women and all women from 6 weeks to 12 months by intervention and control group.*

TABLE 38 *Estimated intracluster correlation coefficients (ICC) for the 6-month outcome, the proportion of women scoring ≥ 12 on the EPDS*

	n	No. of clusters	Average cluster size	Min. to max. cluster size	ICC	95% CI lower	95% CI upper
At-risk women	418	86	4.9	1–15	0.037	0.000	0.114
All women	2659	100	26.6	1–101	0.009	0.000	0.022

TABLE 39 *Six-month EPDS outcome: proportion of all women with an EPDS score ≥ 12 at 6 months, by CBA, PCA or control group (n = 2659)*

6-month EPDS score	CBA group	PCA group	Control group	OR, CBA to control	95% CI	*p*-value	OR, PCA to control	95% CI	*p*-value
Score < 12, *n* (%)	750 (88.4)	790 (88.1)	764 (83.6)						
Score ≥ 12, *n* (%)	98 (11.6)	107 (11.9)	150 (16.4)	0.66	0.48 to 0.91	0.012	0.67	0.51 to 0.90	0.007
				0.65[a]	0.47 to 0.90[a]	0.009[a]	0.71[a]	0.54 to 0.94[a]	0.017[a]
				0.64[b]	0.46 to 0.89[b]	0.0007[b]	0.70[b]	0.53 to 0.91[b]	0.008[b]
Total	848	897	914						

CBA, cognitive behavioural approach; OR, odds ratio; PCA, person-centred approach.
[a]*n* = 409, adjusted for 6-week EPDS score.
[b]*n* = 2624, adjusted for 6-week EPDS score, lives alone, history of postnatal depression, life events.

Six-month secondary outcomes for all women: CBA and PCA versus control

The mean 6-month EPDS score was 5.5 (SD 4.7) for all women in both the CBA group and the PCA group ($p = 0.94$). There were no differences in the other secondary outcomes between the CBA group and the PCA group.

Six-month secondary outcomes for all women: CBA-F, CBA-P, PCA-F and PCA-P versus control

There were some differences between the unadjusted mean EPDS scores in the four IGs, which ranged from 4.9 in the CBA-F group to 6.0 in the CBA-P group (*Table 41*).

Twelve-month secondary outcomes for all women

Of the 741 questionnaires not sent at 12 months, 597 (81%) were not sent because the women had not reached the 12-month postnatal follow-up time. Twelve-month outcomes were therefore available for 593 CG and 1118 IG women.

Twelve-month secondary outcomes for all women: intervention versus control

The mean EPDS score was 5.9 (SD 5.2) in the CG and 5.0 (SD 4.6) in the IG. This difference (–0.9) was statistically significant ($p = 0.003$). Most of the differences in mean CORE-OM and STAI scores were statistically significant, in favour of the IG (*Table 42*).

Twelve-month secondary outcomes for all women: CBA and PCA versus control

The mean EPDS score was 5.1 (SD 4.8) in the CBA group and 4.9 (SD 4.5) in the PCA group. There were no differences in the other secondary outcomes between the CBA group and the PCA group.

Twelve-month secondary outcomes for all women: CBA-F, CBA-P, PCA-F and PCA-P versus control

There were some differences between the unadjusted mean EPDS scores, which ranged from 4.9 (SD 4.4) in the CBA-F group to 5.3 (SD 4.8) in the CBA-P group.

Eighteen-month secondary outcomes for all women

Eighteen-month secondary outcomes for all women: intervention versus control

Of the 2113 questionnaires not sent at 18 months, 1879 (89%) were not sent because the women had not reached the 18-month postnatal follow-up time. Eighteen-month outcomes were therefore available for 318 CG and 706 IG women.

At the 18-month follow-up for all women who returned a questionnaire there were some statistically significant differences between the IG and CG on the SF-12 PCS, the SF-6D, some of the CORE-OM subscales and all domains on the PSI (*Table 43*).

Secondary outcomes for women's partners

Partner outcomes for at-risk women at 6, 12 and 18 months

There appeared to be little difference between the two main groups regarding the outcome scores for the at-risk women's partners at 6 and 12 months. There was a pattern indicating some benefit in the IG partners versus the CG partners at the

TABLE 40 *Six-month secondary outcomes for all women (n = 2659): control vs intervention, unadjusted and adjusted*

	Control			Intervention			Unadjusted			Adjusted[a]		
6-month outcome	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	**Difference**	**95% CI**	***p*-value**	**Difference**	**95% CI**	***p*-value**
EPDS	914	6.4	5.2	1745	5.5	4.7	–1.0	–1.5 to –0.4	0.001	–0.8	–1.2 to –0.4	0.000
SF-12 PCS	885	54.5	6.8	1694	54.7	6.1	0.2	–0.3 to 0.7	0.469	0.0	–0.4 to 0.5	0.871
SF-12 MCS	885	47.6	10.5	1694	48.9	9.5	1.5	0.3 to 2.6	0.010	1.4	0.5 to 2.3	0.003
SF-6D	903	0.8	0.14	1712	0.8	0.13	0.0	0.0 to 0.0	0.001	0.0	0.0 to 0.0	0.000
CORE-OM well-being	907	0.8	0.82	1735	0.7	0.73	–0.1	–0.2 to –0.0	0.030	–0.1	–0.1 to –0.0	0.015
CORE-OM risk	906	0.1	0.20	1736	0.0	0.15	–0.0	–0.0 to 0.0	0.071	–0.0	–0.0 to 0.0	0.143
CORE-OM symptoms	907	0.6	0.61	1734	0.5	0.54	–0.1	–0.2 to –0.0	0.000	–0.1	–0.1 to –0.0	0.000
CORE-OM functioning	905	0.6	0.7	1735	0.5	0.6	–0.0	–0.2 to –0.0	0.002	–0.1	–0.1 to –0.0	0.001
CORE-OM total score	906	0.5	0.5	1736	0.5	0.5	–0.1	–0.1 to –0.0	0.001	–0.1	–0.1 to –0.0	0.000
State anxiety (STAI)	858	34.3	11.7	1634	33.2	10.9	–1.3	–2.7 to –0.1	0.042	–1.3	–2.5 to –0.1	0.033
Trait anxiety (STAI)	839	34.1	10.3	1635	33.1	9.6	–1.1	–2.3 to 0.0	0.059	–1.1	–2.1 to –0.1	0.032
PSI parenting distress	766	46.3	9.0	1422	47.4	8.6	1.1	0.2 to 2.0	0.014	1.2	0.4 to 2.0	0.003
PSI PCDI	776	56.9	4.8	1435	57.1	4.5	0.3	–0.1 to 0.6	0.199	0.3	–0.1 to 0.6	0.178
PSI difficult child	740	52.8	6.0	1365	53.3	5.6	0.5	–0.1 to 1.1	0.078	0.5	–0.0 to 1.1	0.054
PSI total stress	698	155.9	16.9	1310	157.9	15.3	2.1	0.3 to 3.9	0.021	2.3	0.6 to 3.9	0.007

CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; EPDS, Edinburgh Postnatal Depression Scale; MCS, mental component summary; PCDI, parent–child dysfunctional interaction; PCS, physical component summary; PSI, Parenting Stress Index.
[a]EPDS, SF-12, SF-6D and CORE-OM all adjusted for 6-week score, lives alone, history of postnatal depression, any life events.
Better health represented by a lower score in CORE-OM, EPDS and STAI. Better health represented by a higher score in PSI, SF-12 and SF-6D.

18-month follow-up. There was a trend for the SF-12 PCS scores to be higher in the IG partners at all time points. The scores for the partners are presented in *Table 44*.

Partner outcomes for all women at 6, 12 and 18 months

There appeared to be a little difference between the two main groups regarding the outcome scores for the partners of all women at 6 and 12 months. At 18 months postnatally there was a difference in the SF-12 PCS in favour of the IG partners. The mean SF-12 MCS, CORE-OM and DAS scores were also in favour of the IG partners at 18 months (*Table 44*).

Eighteen-month infant outcomes

Women's replies to infant outcomes

There was some evidence of benefit associated with the intervention in infant outcomes according to at-risk women's replies (*Table 45*). The IG at-risk women were more likely to say that they were not concerned about their child for 12 out of 15 questions. For the item 'being slow to catch on', 94.3% of IG at-risk women versus 76.6% of CG women said that they were not concerned ($\chi^2 = 11.98$, df = 3, $p = 0.007$). For the item 'temper tantrums', 59.8% of IG at-risk women versus 46.0% of CG women said that they were not concerned ($\chi^2 = 6.6$, df = 3, $p = 0.086$).

There was some evidence of benefit associated with the intervention in infant outcomes according to the replies of all women (*Table 45*). More IG women said that for 26 of the 29 behaviour questions their child had no problems. This was statistically significant for the management and discipline question and approaching significance for the temper tantrums question. The IG women were more likely to say that they had no concerns about 14 of the 15 aspects of their toddler's development. For the item 'paying attention', 91.4% of IG women said that there was no problem versus 88.4% of CG women ($\chi^2 = 8.086$, df = 3, $p = 0.044$); the results approached significance for the item 'being clumsy' ($p = 0.069$) and the item 'seeming unhappy' ($p = 0.053$). For the at-risk women the mean aggregate infant outcome concern score was 19.4 (SD 6.1) for 37 women in the CG and 16.5 (SD 5.4) for the 73 women in the IG. The mean difference was –2.9 (95% CI –5.0 to –0.7, $p = 0.008$).

Partners' replies to infant outcomes

Of the at-risk women for whom there was a full set of 6-week, 6-month, 12-month and 18-month data available, 87 IG partners and 47 CG partners replied to the 18-month questionnaire. There was no clear pattern in the responses from either group in the Toddler Growth and Development Questionnaire (TG&DQ) or the BSQ. For the concerns item 'sleeping at night', 80.6% of the IG women's partners versus 58.6% of the CG women's partners said that they were not concerned ($\chi^2 = 13.28$, df = 3, $p = 0.004$).

Of all women for whom there was a full set of 6-week, 6-month, 12-month and 18-month data available, 448 IG partners and 211 CG partners replied to the 18-month questionnaire. For the TG&DQ the IG partners were more likely to say that their child could do an activity for most of the questions. There was no pattern for partners' responses to the BSQ or concerns questions. For the CHAT, the IG women's partners were more likely to respond positively on most responses.

Immunisation data

Among the at-risk women for whom immunisation data were available, 54% (43/80) of infants in the IG versus 30% (9/30) of infants in the CG had received their measles, mumps and rubella (MMR) immunisation before 18 months ($p = 0.03$).

Among all women for whom immunisation data were available there were no differences observed between the groups in the number of infants who received immunisations up to 6 months. In total, 51% (277/540) of infants in the IG had received their MMR immunisation before 18 months versus 31% (59/190) of infants in the CG ($p = 0.001$).

Summary of infant outcomes

It appeared that, overall, for the women's replies there was some indication that the IG women perceived fewer problems with their infants than CG woman at the at-risk women level. The pattern for the partners' replies was more mixed.

Intervention process monitoring

PoNDER Adherence Rating Scale

Classification of audiotape recordings

The HVs were asked to audiotape intervention sessions to monitor adherence. A mean score ranging from 0 to 7 was calculated for the three PARS factors: GFC, PCA-specific items and CBA-specific items. Audiotapes for which the CBA-specific PARS scores were higher than the PCA-specific PARS scores were classified as being CBA. Tapes for which the PCA-specific PARS scores were higher than the CBA-specific PARS scores were

TABLE 41 *Six-month secondary outcomes for all women (n = 2659): four intervention groups vs control unadjusted group*

	Control		CBA-F				CBA-P		
6-month outcome	***n***	**Mean (SD)**	***n***	**Mean (SD)**	**Difference (95% CI)**	***p*-value**	***n***	**Mean (SD)**	**Difference (95% CI)**
EPDS	914	6.4 (5.2)	431	4.9 (4.6)	–1.9 (–3.6 to –0.3)	0.024	417	6.0 (4.8)	–2.2 (–4.0 to –0.5)
SF-12 PCS	885	54.5 (6.8)	414	54.8 (5.6)	0.31 (–0.4 to 1.0)	0.396	401	54.2 (6.6)	–0.3 (–1.0 to 0.4)
SF-12 MCS	885	47.6 (10.5)	414	49.8 (9.2)	2.2 (0.7 to 3.7)	0.005	401	48.1 (9.8)	0.6 (–0.7 to 1.9)
SF-6D	903	0.81 (0.14)	419	0.84 (0.13)	0.03 (0.12 to 0.51)	0.001	408	0.81 (0.14)	0.08 (–0.09 to 0.26)
CORE-OM well-being	907	0.8 (0.8)	429	0.6 (0.7)	–0.2 (–0.3 to –0.4)	0.008	413	0.8 (0.8)	–0.0 (–0.1 to –0.1)
CORE-OM risk	906	0.1 (0.2)	429	0.0 (0.1)	–0.0 (–0.0 to 0.0)	0.113	414	0.0 (0.1)	–0.0 (–0.0 to 0.0)
CORE-OM symptoms 6M	907	0.6 (0.6)	428	0.4 (0.5)	–0.1 (–0.2 to –0.1)	0.000	413	0.5 (0.6)	–0.1 (–0.1 to –0.0)
CORE-OM functioning	905	0.6 (0.7)	429	0.5 (0.6)	–0.1 (–0.2 to –0.1)	0.000	413	0.6 (0.6)	–0.1 (–0.1 to –0.0)
CORE-OM total score	906	0.5 (0.5)	429	0.4 (0.4)	–0.1 (–0.2 to –0.1)	0.000	414	0.5 (0.5)	–0.1 (–0.1 to –0.0)
State anxiety (STAI)	858	34.3 (11.7)	407	31.9 (10.8)	–2.5 (–4.0 to –0.9)	0.002	388	34.1 (11.0)	–0.4 (–1.8 to 1.0)
Trait anxiety (STAI)	839	34.1 (10.3)	396	32.1 (9.5)	–2.0 (–3.4 to –0.7)	0.003	383	34.0 (9.6)	–0.2 (–1.5 to 1.0)
PSI parenting distress	766	46.3 (9.0)	342	48.0 (8.8)	1.7 (0.7 to 2.7)	0.001	319	46.6 (8.4)	0.3 (–0.8 to 1.3)
PSI PCDI	776	56.9 (4.8)	342	56.9 (4.6)	0.0 (–0.4 to 0.4)	0.970	322	56.8 (4.9)	–0.1 (–0.7 to 0.5)
PSI difficult child	740	52.8 (6.0)	324	53.3 (5.9)	0.5 (–0.4 to 1.5)	0.237	302	53.2 (5.6)	0.4 (–0.4 to 1.1)
PSI total stress	698	155.9 (16.9)	313	158.5 (16.3)	2.7 (0.6 to 4.7)	0.011	288	156.7 (15.3)	0.9 (–1.2 to 2.9)

CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; EPDS, Edinburgh Postnatal Depression Scale; MCS, mental component summary; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group; PCDI, parent–child dysfunctional interaction; PCS, physical component summary; PSI, Parenting Stress Index.
Better health represented by a lower score in CORE-OM, EPDS and STAI. Better health represented by a higher score in PSI, SF-12 and SF-6D.

	PCA-F				PCA-P			
***p*-value**	***n***	**Mean (SD)**	**Difference (95% CI)**	***p*-value**	***n***	**Mean (SD)**	**Difference (95% CI)**	***p*-value**
0.014	432	5.3 (4.8)	–1.8 (–3.1 to –0.5)	0.007	465	5.7 (4.7)	–2.8 (–4.0 to –0.7)	0.005
0.453	426	55.0 (6.0)	0.5 (–0.3 to 1.3)	0.193	453	54.6 (6.4)	0.1 (–0.7 to 0.9)	0.760
0.366	426	49.3 (9.6)	1.9 (0.2 to 3.5)	0.025	453	48.6 (9.3)	1.3 (–0.00 to 2.5)	0.052
0.357	428	0.84 (0.13)	0.03 (0.02 to 0.05)	0.000	457	0.83 (0.13)	0.22 (0.06 to 0.40)	0.008
0.597	428	0.7 (0.8)	–0.1 (–0.3 to –0.0)	0.056	465	0.7 (0.7)	–0.1 (–0.2 to –0.0)	0.056
0.417	428	0.7 (0.8)	–0.0 (–0.0 to 0.0)	0.058	465	0.0 (0.2)	–0.0 (–0.0 to 0.0)	0.086
0.075	428	0.5 (0.5)	–0.1 (–0.2 to –0.1)	0.000	465	0.5 (0.5)	–0.1 (–0.2 to –0.0)	0.007
0.095	428	0.5 (0.6)	–0.1 (–0.2 to –0.0)	0.007	465	0.6 (0.6)	–0.1 (–0.2 to –0.0)	0.016
0.119	431	0.5 (0.5)	–0.1 (–0.2 to –0.0)	0.003	465	0.5 (0.5)	–0.1 (–0.2 to –0.0)	0.010
0.596	399	32.9 (10.9)	–1.7 (–3.2 to –0.1)	0.034	440	33.7 (10.7)	–0.9 (–2.3 to 0.6)	0.242
0.702	410	32.8 (9.7)	–1.4 (–2.8 to –0.0)	0.047	446	33.5 (9.6)	–0.7 (–2.1 to 0.6)	0.288
0.628	369	47.9 (8.4)	1.6 (0.5 to 2.7)	0.003	392	47.2 (8.6)	0.8 (–0.2 to 1.9)	0.125
0.809	374	(57.7) 3.8	0.9 (0.4 to 1.3)	0.000	397	56.9 (4.8)	0.0 (–0.5 to 0.6)	0.862
0.323	366	(53.9) 4.9	1.1 (0.5 to 1.6)	0.000	373	52.9 (5.9)	0.1 (–0.8 to 0.9)	0.846
0.404	348	(159.5) 13.6	3.6 (1.7 to 5.6)	0.000	361	156.9 (15.8)	1.1 (–1.2 to 3.4)	0.368

TABLE 42 *Twelve-month secondary outcomes for all women (n = 1711): control vs intervention, unadjusted and adjusted*

	Control			Intervention			Unadjusted			Adjusted[a]		
12-month outcome	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	**Difference**	**95% CI**	***p*-value**	**Difference**	**95% CI**	***p*-value**
EPDS	593	5.9	5.2	1118	5.0	4.6	–0.9	–1.5 to –0.3	0.002	–0.7	–1.1 to –0.2	0.003
SF-12 PCS	579	55.0	6.4	1099	55.0	6.0	0.1	–0.6 to 0.8	0.834	–0.2	–0.8 to 0.5	0.590
SF-12 MCS	579	48.7	9.8	1099	49.9	9.2	1.1	0.2 to 2.0	0.013	0.9	0.1 to 1.6	0.022
SF-6D	587	0.8	0.1	1110	0.8	0.1	0.0	–0.0 to 0.0	0.087	0.0	–0.0 to 0.0	0.521
CORE-OM well-being	593	0.7	0.8	1120	0.6	0.7	–0.1	–0.2 to –0.0	0.017	–0.1	–0.2 to –0.0	0.009
CORE-OM risk	593	0.1	0.2	1120	0.0	0.1	–0.0	–0.0 to 0.0	0.319	–0.0	–0.0 to 0.0	0.490
CORE-OM symptoms	593	0.6	0.6	1118	0.5	0.5	–0.1	–0.2 to –0.1	0.000	–0.1	–0.1 to –0.0	0.000
CORE-OM functioning	592	0.6	0.6	1119	0.5	0.6	–0.1	–0.2 to –0.0	0.001	–0.1	–0.1 to –0.0	0.001
CORE-OM total score	593	0.5	0.5	1120	0.4	0.5	–0.1	–0.2 to –0.0	0.001	–0.1	–0.1 to –0.2	0.001
State anxiety (STAI)	580	33.7	11.7	1097	32.4	10.7	–1.5	–2.7 to –0.2	0.019	–1.4	–2.5 to –0.2	0.020
Trait anxiety (STAI)	576	33.7	10.1	1091	35.4	9.5	–1.4	–2.5 to –0.3	0.014	–1.4	–2.4 to –0.3	0.009
DAS Likert	571	4.0	1.2	1077	4.1	1.2	0.01	–0.0 to 0.2	0.098	–0.0	–0.1 to 0.1	0.670
DAS	561	18.2	3.3	1058	18.1	3.1	–0.1	–0.4 to 0.2	0.527	–0.1	–0.4 to 0.2	0.574
PSI parenting distress	581	46.5	8.8	1087	47.8	8.2	1.2	0.3 to 2.0	0.009	–1.7	–5.4 to 2.1	0.377
PSI PCDI	588	57.2	4.7	1102	57.1	4.8	–0.1	–0.5 to 0.4	0.741	–0.1	–0.5 to 0.4	0.741
PSI difficult child	572	51.8	6.5	1076	52.1	6.0	0.3	–0.3 to 0.9	0.328	0.3	–0.3 to 0.9	0.293
PSI total stress	558	155.6	17.1	1055	157.0	15.6	11.3	–0.4 to 3.0	0.137	1.1	–0.3 to 2.7	0.123

CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; DAS, Dyadic Adjustment Scale; EPDS, Edinburgh Postnatal Depression Scale; MCS, mental component summary; PCDI, parent–child dysfunctional interaction; PCS, physical component summary; PSI, Parenting Stress Index.
[a]EPDS, SF-12, SF-6D and CORE-OM all adjusted for 6-week score, lives alone, history of postnatal depression, any life events.
Better health represented by a lower score in CORE-OM, EPDS and STAI. Better health represented by a higher score in DAS, PSI, SF-12 and SF-6D.

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TABLE 43 *Eighteen-month secondary outcomes for all women: control vs intervention, unadjusted and adjusted*

	Control			Intervention			Unadjusted			Adjusted[a]		
18-month outcome	***n***	**Mean**	**SD**	***n***	**Mean**	**SD**	**Difference**	**95% CI**	***p*-value**	**Difference**	**95% CI**	***p*-value**
SF-12 PCS	286	57.2	10.1	634	59.1	7.2	1.8	0.6 to 3.1	0.005	1.4	0.2 to 2.6	0.022
SF-12 MCS	286	40.1	5.7	634	40.0	4.8	–0.0	–0.6 to 0.5	0.875	–0.0	–0.5 to 0.4	0.846
SF-6D	289	0.82	0.14	641	0.85	0.13	0.03	0.01–0.05	0.003	–0.03	0.00 to 0.04	0.012
CORE-OM well-being	291	0.8	0.8	650	0.7	0.7	–0.1	–0.2 to 0.1	0.273	–0.0	–0.1 to 0.0	0.312
CORE-OM risk	291	0.1	0.2	650	0.0	0.2	–0.0	–0.0 to 0.0	0.440	–0.0	–0.0 to 0.0	0.996
CORE-OM symptoms	291	0.6	0.7	650	0.5	0.5	–0.2	–0.2 to –0.1	0.000	–0.1	–0.2 to –0.0	0.001
CORE-OM functioning	291	0.6	0.7	649	0.5	0.6	–0.1	–0.2 to –0.0	0.008	0.0	–0.0 to 0.1	0.159
CORE-OM total score	291	0.5	0.6	650	0.4	0.5	–0.1	–0.2 to –0.0	0.005	–0.1	–0.1 to –0.0	0.011
State anxiety (STAI)	281	34.0	11.8	631	32.6	10.8	–1.5	–3.4 to 0.4	0.116	–1.4	–3.1 to 0.3	0.105
PSI parenting distress	288	46.8	9.2	636	48.4	8.1	1.5	0.3 to 2.8	0.013	1.6	0.5 to 2.7	0.004
PSI PCDI	289	55.8	6.1	650	56.8	5.0	0.9	0.3 to 1.6	0.004	0.9	0.3 to 1.5	0.005
PSI difficult child	281	50.2	7.2	642	51.2	6.4	1.0	0.1 to 2.0	0.028	1.0	0.1 to 1.9	0.036
PSI total stress	276	153.0	19.4	628	156.3	16.5	3.3	0.8 to 5.8	0.009	3.2	0.9 to 5.6	0.007

CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; MCS, mental component summary; PCDI, parent–child dysfunctional interaction; PCS, physical component summary; PSI, Parenting Stress Index.
[a]EPDS, SF-12, SF-6D and CORE-OM all adjusted for 6-week score, lives alone, history of postnatal depression, any life events.
Better health represented by a lower score in CORE-OM, EPDS and STAI. Better health represented by a higher score in PSI, SF-12 and SF-6D.

TABLE 44 *Partner outcomes at 6, 12 and 18 months for at-risk women and all women: control vs intervention*

	6 months								12 months			
	At-risk women				All women				At-risk women			
	Control		Intervention		Control		Intervention		Control		Intervention	
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
SF-12 PCS	109	53.1 (7.8)	191	54.0 (6.1)	743	54.5 (6.1)	1384	54.6 (5.6)	50	53.4 (6.2)	111	53.7 (5.8)
SF-12 MCS	109	46.4 (10.8)	191	46.4 (9.9)	743	49.2 (8.7)	1384	49.7 (8.8)	50	48.9 (8.8)	111	48.1 (10.3)
SF-6D	110	0.80 (0.15)	192	0.80 (0.13)	747	0.84 (0.13)	1391	0.85 (0.13)	51	0.83 (0.14)	113	0.82 (0.15)
DAS Likert	22	4.3 (0.9)	30	4.1 (1.4)	150	4.3 (1.0)	247	4.2 (1.2)	53	4.0 (1.1)	113	3.9 (1.3)
DAS	22	17.4 (2.8)	30	16.9 (3.1)	150	16.6 (2.8)	247	16.4 (2.7)	53	17.4 (2.8)	113	16.7 (2.7)
PSI parenting distress	105	46.2 (7.4)	175	45.0 (7.8)	703	48.0 (7.5)	1251	48.2 (7.8)	52	46.8 (6.8)	112	46.3 (9.4)
PSI PCDI	104	54.7 (5.9)	177	55.0 (5.5)	701	56.2 (5.0)	1262	56.2 (4.9)	53	55.8 (5.2)	112	56.3 (5.6)
PSI difficult child	100	50.7 (5.7)	171	50.3 (7.3)	674	52.3 (5.5)	1218	52.0 (6.1)	53	51.1 (6.1)	112	51.0 (6.9)
PSI total stress	99	151.4 (16.5)	166	150.1 (17.7)	660	156.2 (15.4)	1180	156.3 (13.6)	52	153.6 (15.3)	112	153.7 (18.8)
CORE-OM well-being												
CORE-OM risk												
CORE-OM symptoms												
CORE-OM functioning												
CORE-OM total score												
State anxiety (STAI)												

CORE-OM, Clinical Outcomes in Routine Evaluation Outcome Measure; DAS, Dyadic Adjustment Scale; MCS, mental component summary; PCDI, parent–child dysfunctional interaction; PCS, physical component summary; PSI, Parenting Stress Index.
Better health represented by a lower score in STAI. Better health represented by a higher score in PSI, SF-12 and SF-6D.

18 months											
All women				At-risk women				All women			
Control		Intervention		Control		Intervention		Control		Intervention	
n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)
417	54.5 (5.7)	785	54.7 (5.4)	24	51.8 (8.0)	50	54.7 (6.9)	178	54.2 (6.5)	381	67.7 (6.4)
417	50.1 (8.4)	785	50.1 (8.9)	24	48.9 (10.4)	50	50.6 (10.0)	178	50.4 (8.4)	381	52.1 (8.3)
420	0.85 (0.13)	787	0.85 (0.13)	25	0.81 (0.16)	50	0.84 (0.14)	181	0.85 (0.13)	384	0.87 (0.13)
429	4.2 (1.1)	799	4.3 (1.1)	25	3.8 (1.3)	50	3.9 (1.3)	179	4.2 (1.2)	381	4.2 (1.2)
425	17.1 (2.5)	800	17.0 (2.7)	25	16.0 (2.5)	51	16.5 (3.1)	179	16.4 (2.4)	379	16.7 (2.7)
424	48.3 (7.3)	783	47.8 (8.2)	24	44.3 (9.1)	50	47.5 (10.0)	177	48.0 (8.1)	383	49.4 (8.0)
427	56.3 (4.9)	792	56.2 (5.2)	25	54.7 (5.2)	51	55.2 (5.9)	181	55.9 (5.4)	385	56.5 (4.7)
421	51.6 (5.9)	775	51.2 (6.2)	25	48.2 (5.4)	48	49.5 (8.0)	1196	51.3 (6.1)	367	51.1 (6.1)
415	156.4 (15.3)	765	155.0 (16.9)	24	146.9 (16.9)	48	151.7 (21.6)	173	154.4 (17.5)	366	156.9 (16.6)
				25	0.7 (0.9)	51	0.7 (0.8)	180	0.6 (0.6)	384	0.5 (0.7)
				25	0.1 (0.2)	51	0.6 (0.4)	180	0.0 (0.1)	384	0.1 (0.3)
				25	0.7 (0.8)	51	0.6 (0.7)	180	0.5 (0.6)	384	0.4 (0.5)
				25	0.7 (0.7)	50	0.6 (0.6)	179	0.6 (0.6)	383	0.5 (0.5)
				25	0.6 (0.6)	51	0.5 (0.6)	180	0.5 (0.4)	384	0.4 (0.4)
				25	36.0 (13.1)	49	32.9 (11.3)	174	32.9 (10.4)	374	31.1 (9.3)

TABLE 45 *Eighteen-month infant outcomes for at-risk women and all women: control vs intervention*

	Control group			Intervention group				
	n	Mean	SD	*n*	Mean	SD	Difference	*p*-value
At-risk women								
Growth and development rescaled (0–100)	43	34.17	12.92	84	32.12	12.61	2.05	0.396
Behaviour Screening Questionnaire rescaled (0–100)	42	28.10	10.02	78	26.23	9.68	1.86	0.328
Concerns rescaled (0–100)	46	10.29	12.11	85	6.43	7.80	3.86	0.055
CHAT rescaled (0–100)	47	4.96	5.58	87	2.94	6.22	2.03	0.057
Infant outcomes rescaled total	37	19.40	6.13	73	16.45	5.38	2.94	0.016
All women								
Growth and development rescaled (0–100)	318	33.44	13.07	706	32.16	12.49	1.28	0.143
Behaviour Screening Questionnaire rescaled (0–100)	303	25.42	10.41	658	24.04	10.30	1.38	0.056
Concerns rescaled (0–100)	340	6.17	7.52	739	5.03	5.68	1.14	0.013
CHAT rescaled (0–100)	340	2.84	6.41	742	2.29	5.62	0.55	0.172
Infant outcomes rescaled total	275	16.51	5.94	618	15.86	5.54	0.65	0.125

CHAT, Checklist for Autism in Toddlers.
Note: A higher score indicates more reports of development and behaviour problems, and more concerns about a toddler's growth and development.

classified as being PCA. In addition to completing a PARS for each tape, raters were also asked to use their professional judgement to indicate whether they believed that the tape that they had just rated belonged to a CBA or a PCA. This gave a second set of classifications based on expert judgement.

PARS rating procedure

The adherence assessment was limited because of the very small number of audiotapes that HVs submitted. HVs were asked to audiotape every intervention session so that a random sample of at least 10% of all sessions could be rated for adherence. In the event, only a very small number of audiotapes were submitted for rating, which limited the adherence assessment. In total, 46 session tapes were submitted for 46 sessions, which were delivered by just nine HVs. Additionally, 50% of the submitted tapes were inaudible and could not be rated. Therefore, tapes from 23 sessions were available for rating. Six of the 23 rated sessions were from the CBA intervention and 17 of the 23 tapes were from the PCA intervention. This was only 2.3% of the total number of CBA sessions delivered ($n = 259$) and 7.0% of the total number of PCA sessions delivered ($n = 242$). All 26 PARS items were randomly distributed throughout the rating scale. Raters were asked to rate each tape for the presence and extensiveness (but not the quality) of all 26 PARS items on a 7-point scale ranging from 1 'not at all present' to 7 'extensively present'.

Steps were taken to ensure rater blindness to the original 46 tapes. All 46 sessions were rerecorded and randomly coded, resulting in 46 separate coded tapes. Each rater was given a randomly generated number sequence of the order in which they were to rate their tapes, to minimise rating multiple sessions submitted by the same HV in session sequence and thus avoid contaminating ratings.

PARS raters

The three raters were experienced psychotherapists who did not have an allegiance to either CBA or PCA approaches, but who had some awareness of both approaches from training and professional experience. Raters also read the trial training manuals prepared for both trial interventions. Rater A (the principal rater) was a 47-year-old man educated to PhD level in a psychotherapy-related topic and a United Kingdom Council for Psychotherapy (UKCP)-registered psychotherapist, working as a research fellow and psychotherapist in an NHS specialist psychotherapy service. He was originally trained in transactional analysis

psychotherapy but was now practising, teaching, supervising and publishing, and had an allegiance to, psychodynamic–interpersonal psychotherapy.

Co-rater B was a 50-year-old man, educated to Masters level in psychotherapy-related topics and a UKCP-registered psychotherapist, currently working as a psychotherapist in an NHS specialist psychotherapy service as well as in an NHS specialist service for people given a diagnosis of personality disorder. He originally trained in both psychoanalytical psychotherapy and cross-cultural psychotherapy but was practising, teaching and supervising, and had an allegiance to, psychoanalytical psychotherapy.

Co-rater C was a 44-year-old woman educated to degree level and working as a university lecturer and visiting psychotherapist in an NHS specialist psychotherapy service. Originally trained in psychodynamic therapy she was now practising, teaching, supervising and publishing, and had an allegiance to, psychodynamic–interpersonal psychotherapy.

The aim was for rater A to rate all 46 tapes with raters B and C each co-rating half (expected to be 23 each). However, as 50% of the tapes were inaudible, rater A rated all 23 audible tapes and raters B and C co-rated 13 and 10 tapes respectively.

PARS results

There were no significant differences in group mean PARS scores for GFC between the two interventions. The number of tapes correctly classified by PARS score was:

- rater A – 20/23 (87%) tapes (kappa = 0.64, $p = 0.002$)
- rater B – 12/13 (92%) tapes (kappa = 0.81, $p = 0.003$)
- rater C – 9/10 (90%) tapes (kappa = 0.74, $p = 0.016$)

The inter-rater levels of agreement on classification using PARS scores were:

- raters A and B agreed on the classification of 11/13 (85%) tapes (kappa = 0.58, $p = 0.021$)
- raters A and C agreed on the classification of 9/10 (90%) tapes.

PARS conclusion

The method used to measure the quality of adherence by the HVs to the two interventions they were trained to deliver had some limitations. Only a small number of HVs involved in the trial submitted any tapes at all for rating. It may be assumed that these tapes were only submitted by HVs who felt the most confident about their ability to deliver the intervention they had been trained to deliver. Half of the submitted tapes were inaudible and could not be rated, further reducing the generalisability of the adherence results. The rated tapes cannot therefore be considered to be, as originally intended, a random sample of all interventions delivered during the trial.

Given these limitations, the results show that most of the tapes were correctly classified by raters who had no allegiance to either of the two psychological interventions. The PARS scores for tapes from both interventions suggest that both interventions, as expected, contained a similar degree of GFC, as well as a satisfactory amount of the specific factors expected to be associated with each intervention to enable them to be identified as two separate interventions.

Agnew Relationship Measure Short Form (ARM-SF)

Data from the ARM-SF were collected from 36 HVs and 103 women for a total of 355 sessions. In total, 20 of these HVs had received training in CBA and 16 had received training in PCA. ARM-SF data, from either the women or the HVs, were provided by the CBA group for a total of 190 sessions delivered to 63 women. Similarly, ARM-SF data, from either the women or the HVs, were provided by the PCA group for a total of 165 sessions delivered to 40 women. This compares with a total of 501 sessions delivered in the whole trial, with 259 CBA sessions and 242 PCA sessions; that is, ARM data were available from 71% of all sessions, and 73% and 68% of CBA and PCA intervention sessions respectively.

There were large amounts of missing data. Many sessions had ARM-SF data from either the HV or the woman rather than from both. Data for a complete set of eight sessions were only available for seven (6.8%) woman–HV dyads; 31 (30.1%) woman–HV dyads had data for only one session. The mean number of sessions for both IGs for which data had been submitted was 3.45 (SD 2.31). The mean number of sessions from the CBA IG and the PCA IG for which data had been submitted was 3.02 (SD 2.05) and 4.13 (SD 2.54) respectively. The mean number of sessions that were delivered was 4.27 (SD 2.17) and 4.68 (SD 2.49) for the CBA and PCA IGs respectively.

ARM-SF data for all sessions

The mean ARM-SF scales across all sessions and for both IGs combined are presented in *Table 46*. Because of the amount of missing data, mean ARM-SF scores were computed across sessions.

There were no statistically significant between-group differences on any of the women or HV ARM-SF scales. The women's scores were significantly higher than the scores of HVs for all ARM-SF scales ($p \leq 0.0001$) apart from total mean ARM-SF score. The numerical differences between these scores are generally quite small ranging from 0.35 (bond) to 0.72 (mean ARM-SF). The largest difference of 1.42 for confidence suggests that women perceived the HVs as being more confident in delivering the interventions than the HVs did themselves.

ARM-SF scores for the CBA and PCA groups

Mean ARM-SF scores averaged across all sessions were also calculated separately for the two IGs (*Table 47*).

Within both IGs, as with the results for all sessions combined reported above, there were statistically significant differences between the women and the HVs, with women scoring all ARM-SF scales higher than the HVs ($p = 0.002$ for the CBA intervention; $p = 0.025$ for the PCA intervention).

There were no statistically significant differences in either women's or HVs' scores between the two IGs. However, both women and HVs in the PCA IG scored higher than women and HVs in the CBA group, albeit small differences on a 7-point scale. There is some evidence in the literature that the quality of alliance measured in the first few sessions of therapy is a major predictor of clinical outcome.[213,214] To rule out the possibility of a type II error, ARM-SF data for the first three sessions only were compared by IG. There were no significant differences between the women in the two IGs ($t = < 1.8$, $df = 84$, $p = 0.100$). There was a marginally significant difference on the ARM-SF confidence scale with PCA HVs scoring higher than CBA HVs [PCA confidence mean = 5.37 (SD 0.91); CBA confidence mean = 4.98 (SD 1.01); $t = 1.91$, $df = 85$, $p = 0.059$]. There were no other significant differences between HVs ($t \leq 1.64$, $df = 85$, $p = 0.09$).

Comparative ARM-SF data

Having examined for differences between interventions and modes of delivery, the results were compared with other studies that have used

TABLE 46 *Mean (SD) ARM-SF scales averaged across all sessions (n = 355) for health visitors and women*

ARM-SF scale	Women ($n = 103$)	Health visitors ($n = 36$)
Total mean ARM-SF score	6.45 (0.49)	5.73 (0.64)
Bond	6.82 (0.36)	6.47 (0.47)
Partnership	6.58 (0.66)	6.13 (0.79)
Confidence	6.66 (0.54)	5.24 (0.91)
Openness	5.74 (1.18)	5.08 (1.15)

TABLE 47 *Mean (SD) ARM-SF scale scores for health visitors and women across all sessions by intervention group*

	CBA intervention ($n = 190$ sessions)		PCA intervention ($n = 190$ sessions)	
ARM-SF scale	Women ($n = 63$)	Health visitors ($n = 20$)	Women ($n = 40$)	Health visitors ($n = 16$)
Total mean ARM-SF score	6.43 (0.50)	5.65 (0.67)	6.51 (0.49)	5.84 (0.59)
Bond	6.79 (0.36)	6.42 (0.51)	6.87 (0.36	6.55 (0.39)
Partnership	6.56 (0.68)	6.11 (0.77)	6.61 (0.64)	6.16 (0.82)
Confidence	6.64 (0.53)	5.12 (0.94)	6.71 (0.56)	5.41 (0.86)
Openness	5.69 (1.24)	4.95 (1.14)	5.85 (1.06)	5.25 (1.16)

CBA, cognitive behavioural approach; PCA, person-centred approach.

the shortened version of the ARM-SF.[206,215,216] The Leeds Depression Project[215] offered CBT to a clinically representative sample (clients $n = 75$; therapists $n = 10$; sessions $n = 628$). The Second Sheffield Psychotherapy Project[216] compared CBT and psychodynamic–interpersonal psychotherapy (clients $n = 95$; therapists $n = 5$; sessions $n = 1120$). Comparative mean (SD) total ARM-SF scores from these studies are presented in *Table 48* below.

These data show that the mean total ARM-SF scores from the PoNDER trial are comparable with those from previous psychotherapy studies in the UK.

ARM-SF summary results

The data show that women across all sessions and within both interventions returned high scores on all ARM-SF scales. Scores were above 6.0 on a 7-point scale for all ARM-SF scales, apart from for openness (range 5.69–5.85).

Scores for the HVs across all sessions and within both interventions were lower than the women's scores on all ARM-SF scales. The scale with the largest differences between the women and the HVs was the ARM-SF confidence scale. The differences between women and HVs on confidence were 0.66 across all sessions, 1.52 in the CBA IG and 1.3 in the PCA IG. The openness scale was the lowest scoring scale for both women and HVs, across all sessions and within both interventions. The large SDs on this scale (1.06–1.24) for both women and HVs indicated substantial variation.

There were no significant differences in either HVs' or women's ARM-SF scores between the two interventions. There were significant differences across both interventions on HV scores only, depending on whether the EPDS was administered face-to-face or by post. HVs in both the CBA-F and the PCA-F groups who administered the EPDS face-to-face had significantly lower ARM-SF scores than HVs in both the CBA-P and the PCA-P groups in which the EPDS was administered by post. This difference was also significant when comparing the first three sessions with subsequent sessions. Total ARM-SF mean scores for both women and HVs were comparable with those of clients and therapists from the wider psychotherapy literature.

Health visitor pre-trial questionnaire

There were 128 pre-trial questionnaires returned by all of the HVs; 40 in each IG and 48 in the CG, before they were informed of their random allocation.

Most HVs (67%) who said that they had attended training about PND said that their training had taken place in the previous 5 years; three HVs said that they attended training in the 1980s. Most of this training (66%) lasted between half a day and 2 days. Most of the HVs who returned a questionnaire said that they already used the EPDS (79%), many with all postnatal women (47%). The EPDS was used by 60% of these HVs at 6 weeks postnatally. The HVs reported greater levels of confidence in identifying women with PND (85%) than in supporting women with PND (80%). Almost all of the HVs said that they had supported at least one woman in the previous 6 months who they felt was suffering from PND.

Pre-trial health visitor predispositions to psychological interventions and OPP

Table 49 indicates the mean OPP scores before the trial began of the HVs who completed a pre-trial questionnaire. The highest level of agreement among the pre-trial HV responses was with the humanistic group of questions. The lowest level of agreement among the pre-trial HV responses overall was with the organic and social economic group of questions. There appeared to be little difference between the three main groups, CBA, PCA and CG, in the pre-trial OPP scores, apart from the social economic scores for the PCA

TABLE 48 *Comparative mean (SD) ARM-SF total scores*

Study sample	Client total mean (SD) ARM-SF score	Therapist total mean (SD) ARM-SF score
PoNDER trial CBA intervention	6.43 (0.50)	5.65 (0.67)
PoNDER trial PCA intervention	6.51 (0.49)	5.84 (0.59)
PoNDER trial (all sessions)	6.45 (0.49)	5.73 (0.64)
Leeds Depression Project	6.13 (0.70)	5.47 (0.77)
Sheffield Psychotherapy Project	5.75 (0.85)	5.04 (0.89)

CBA, cognitive behavioural approach; PCA, person-centred approach.

TABLE 49 *Health visitor pre-trial OPP part 2: help for problems*

	Control group		CBA		PCA		
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*p*
Psychodynamic	46	0.58 (0.82)	39	0.57 (0.95)	37	0.44 (1.05)	0.750
Humanistic interpersonal	46	2.34 (0.57)	40	2.43 (0.42)	41	2.37 (0.51)	0.695
Behavioural	43	1.48 (0.84)	40	1.60 (0.73)	40	1.70 (0.90)	0.507
Cognitive	46	1.37 (0.81)	38	1.44 (0.79)	37	1.45 (0.89)	0.895
Organic	44	0.30 (1.02)	37	0.31 (1.10)	39	0.62 (1.10)	0.330
Social economic	44	0.04 (1.24)	40	0.37 (1.14)	37	0.70 (1.15)	0.046

CBA, cognitive behavioural approach; PCA, person-centred approach.
The OPP scores range from –3 to +3, with +3 representing the greatest agreement.

HVs and the CG HVs, which was of borderline statistical significance. Overall, the scores indicated a similarity between all of the HVs' views on what they thought could help people with psychological problems. This indicated that there were no strong predispositions among the HVs regarding the usefulness of a CBA or PCA, which could have adversely affected their willingness to be trained in either approach or the training outcomes.

Health visitor post-trial questionnaire

Post-trial training in identifying and supporting women

There were 135 post-trial questionnaires returned by all HVs, 42 in each IG and 51 in the CG. Most HVs (85%) said that they had attended training about identifying or supporting women at risk of PND, and 77% said that their training had taken place in the previous 5 years, with no HVs saying that they had attended training in the 1980s. Most of this training (80%) lasted between half a day and 5 days. Most of the HVs who returned a questionnaire said that they already used the EPDS (81%), many with all postnatal women (63%). The EPDS was used by all of these HVs at 6 weeks postnatally. The HVs reported slightly lower levels in confidence in identifying women with PND (71%) than in supporting women with PND (74%). All of the HVs said that they had supported at least one woman in the previous 6 months who they felt was suffering from PND.

Post-trial health visitor predispositions to psychological interventions and OPP

There were 60 OPP HV responses; 18 CBA, 24 PCA and 18 CG. *Table 50* indicates the HVs mean post-trial OPP scores. The post-trial replies show that 78% of the CG versus 88% of the IG attended training to identify or support all women with PND. The length of training received ranged from half a day to 5 days for 100% of the CG HVs and 93% of the IG HVs, with 60% of the CG and 87% of the IG indicating that the training had taken place between 2000 and 2004. In total, 90% of the CG HVs had used the EPDS on 61% of all of their postnatal clients, with 95% of the IG HVs using it on theirs. The EPDS was used at 6 weeks postnatally by 67% of the CG and 88% of the IG. Levels of confidence in using the EPDS to identify women at risk of PND were 53% in the CG and 79% in the IG.

Comparing the three groups, a post-trial difference emerged between the CBA group and the PCA group for replies to the behavioural, cognitive and organic groups of questions. This was statistically significant for the behavioural questions. The post-trial cognitive and behavioural scores were increased and highest in the CBA group and reduced and the lowest in the PCA group, with little change in the CG. The reduction in the PCA group could be interpreted as a development in these HVs' beliefs in the value of the PCA following the training and interventions. Post trial there was little change from baseline in the humanistic interpersonal scores, with a small rise in the PCA group and a small reduction in the CBA group and CG. The psychodynamic scores were lower in all three groups post trial, with greater reductions in the IG HVs who had been trained. The post-trial organic scores were higher in the CG and much lower in both of the trained groups.

The post-trial social economic scores in the CBA group dropped considerably, with only a very small reduction in the PCA group. This could be consistent with CBA HVs believing that people could think about and work through their problems, despite social and economic difficulties. The post-trial scores both within groups and

TABLE 50 *Health visitor post-trial OPP part 2: help for problems*

	Control group		Cognitive behavioural approach		Person-centred approach		
	n	Mean (SD)	*n*	Mean (SD)	*n*	Mean (SD)	*p*
Psychodynamic	17	0.29 (1.02)	19	0.02 (1.07)	23	0.03 (0.84)	0.628
Humanistic interpersonal	17	2.26 (0.54)	19	2.28 (0.75)	23	2.47 (0.48)	0.450
Behavioural	18	1.52 (0.99)	18	1.80 (0.61)	24	0.90 (1.02)	0.007
Cognitive	17	1.19 (0.93)	18	1.54 (0.59)	23	0.84 (1.06)	0.053
Organic	18	0.48 (1.25)	17	–0.47 (1.20)	20	0.03 (1.03)	0.062
Social economic	18	–0.10 (1.20)	20	0.08 (1.21)	22	0.64 (0.99)	0.101

The OPP scores range from –3 to +3, with +3 representing the greatest agreement.

between groups indicate that the HVs who had access to the trial training changed their views about what might help people with psychological problems and this could be attributed to the training that they received.

Health visitor training evaluation

Health visitor evaluation of the introductory day

The HV questionnaires indicated a high level of satisfaction with the introductory training day. In total, 83–92% of the HVs felt that the presentations for the background, EPDS, clinical interview, risk management and skills development were good or very good. These levels of satisfaction are reflected in the rest of the responses. One person in the CBA group provided a poor response for four of the items. The CBA group were between 77% and 100% positive about all of the items. The PCA group indicated that they were between 91% and 100% positive across all of the items.

Health visitor evaluation of the 5 core training days

The replies of the IG HVs who returned a training evaluation questionnaire following the 5 core training days indicated a high level of satisfaction with the content and methods of the training. Most HVs in both of the IGs replied very or extremely/excellent to all of the questions, on a 5-point scale, relating to the training, course objectives, theoretical content, pitch, structure and appropriateness of models. The two groups were equally likely to say that they were very satisfied with the 5 core training days (59% CBA versus 59% PCA).

There were some differences between the two groups in favour of the PCA group HVs who seemed more likely to reply at the extremely positive end of the scale than the CBA HVs on questions relating to relevance, appropriateness, usefulness, acceptability and interest for HVs supporting women with PND. They were also more likely to reply definitely to the two questions on whether the core training days had improved their understanding and skills in supporting women with PND. The PCA HVs were also more likely than the CBA HVs to reply that they would definitely recommend the course to other HVs (67% compared with 29%).

Conversely, 55% of the CBA HVs said that they felt very confident in applying the skills that they had developed compared with 33% of the PCA HVs, and 39% of the CBA HVs said that they felt moderately confident in applying the skills that they had developed compared with 51% of the PCA HVs.

As well as the evaluation after the 5 core training days the HVs were asked to complete 16 questions on their post-training self-assessed level and knowledge and skill, on a 1–7 scale in which 1 was very poor and 7 was excellent. The scores for most HVs who replied to the questionnaire were at the upper end of the scale for most questions. In both IGs for some questions, two HVs' replies were at the lower end of the scale. That is, they assessed their knowledge and skills as being poorer than those of other HVs in the same group.

Chapter 5
Economic analysis

Introduction

Psychological interventions for PND could have several important effects on costs and outcomes. The most obvious effects might be that HVs would be required to undertake more visits but that the prevalence of PND and its associated costs such as medication use would be reduced. Broader effects such as the impact on the baby, other children and the partner need also to be considered. An economic evaluation was undertaken alongside the study to capture any changes in resource use.

Economic evaluation methods

The economic evaluation followed the technology appraisal guidelines used by NICE[217] and, as such, takes the NHS and social service perspective. One issue that was relevant to defining the perspective for this intervention was which family members should be included in the cost-effectiveness analysis. It is feasible that the intervention could have had an impact on the baby, other children and even the partner (for all women where there was one). The primary analysis presented was based on the costs of the mother at 6 months with a further analysis based on mother and baby costs at 12 months.

Costs

The following cost components were included in the economic evaluation:

- HV contacts (including training if appropriate)
- baby immunisations
- GP contacts
- prescriptions
- social worker contacts
- mother and baby or psychiatric unit admissions
- other NHS contacts.

Resource use data from 6 weeks to 6 months were collected on a resource use log completed by HVs based on their own and GP records. For 6 months to 18 months, only HV and baby immunisation data were collected on the resource use log, with the remaining resources collected by way of the 12-month and 18-month questionnaires. Resource use was collected for the mother, baby, other children and the partner (if appropriate).

A set of unit costs (2003/4 prices) is given in *Table 51*. The main source of the unit cost data was Netten and Curtis,[218] with additional information on training costs collected from the sessions instigated for the trial itself. Costs and quality-adjusted life-years (QALYs) were not discounted as analyses were only presented for costs and outcomes within 1 year.

Training costs were gathered from the sessions undertaken as part of the trial and were primarily made up of trainer fees, travel and backfill health visiting (*Table 52*). Other sundries produce a cost of training of £1398 per HV. To use this within a unit cost of HV time it needed to be converted into an equivalent annual cost, based on a profile of training and supervision over the foreseeable future. Based on expert opinion (PS) we estimated that further training would be required 5-yearly, and 1 hour of clinical supervision would be required every month. This produced an annual equivalent cost of £988 per annum, assuming a 20-year working life and that annuity was charged at 3.5% and payable in advance (*Table 53*). This represented a 2.3% increase in the gross costs of a HV (£42,625 taken from Netten and Curtis[218]), which translated to a cost per hour of client time of £79 versus £77 in the CG.

All GP contacts and prescriptions were included within the economic evaluation. However, because of the huge range of medications prescribed it was thought necessary to simplify the analysis. Prescriptions were split down into their nine main indications (which amounted to 83% of prescriptions), plus 'other'. The most common prescription for each indication was then costed using the *British National Formulary*.[221] This was then combined to produce two unit costs, one for antidepressants and one for other prescriptions (*Table 51*).

TABLE 51 *Unit costs (£) of resources used*

Resource	Unit cost (2003/4)	Source
HV hour of contact without CBA/PCA training	77	Netten and Curtis, 2004[218]
HV hour of contact with CBA/PCA training	79	*Table 53*
GP contact[a]	30	Netten and Curtis, 2004[218]
Social work visit[b]	108	Netten and Curtis, 2004[218]
Community mental health contact[c]	29	Netten and Curtis, 2004[218]
Clinical mental health contact[d,e]	129	Department of Health, 2005[219]
Mother and baby psychiatric unit day[d]	458	Department of Health, 2005[220]
Fluoxetine prescription[f]	1.56	BNF, 2005[221]
Other prescription[g]	2.79	BNF, 2005[221]
DTwP and Hib vaccination per dose	20	BNF, 2005[221]
Men-C vaccination per dose	18	BNF, 2005[221]
Inpatient admission (infant)[d,h]	516	Department of Health, 2005[219]
A&E attendance[d,i]	73	Department of Health, 2005[220]
NHS direct contact[j]	25	Hansard and Department of Health, 2005[220]
Walk-in centre attendance[d,k]	39	Department of Health, 2005[220]

CBA, cognitive behavioural approach; HV, health visitor, PCA, person-centred approach.
[a]Includes surgery, home and telephone contacts. Unit cost based on most common type of contact, surgery contact.
[b]Assuming a 2-hour visit. No information was available on length of visit and unit costs do not estimate for the cost of a visit.
[c]Includes counsellor, community psychiatric nurse (CPN), community mental health team and mental health nurse contacts. Unit cost based on most common type of contact, CPN home visit.
[d]Prices adjusted using inflation indices given in Netten and Curtis.[218]
[e]Includes crisis service, psychologist, psychotherapist, psychiatric outpatient and mother and baby psychiatric outpatient contacts. Unit cost based on most common type of contact, psychiatric outpatient contact (specialty code 402).
[f]Based on most common drug and dosage for antidepressant prescriptions.
[g]Calculated as an average of the cost for prescriptions for the nine most common indications. Prescriptions for these indications covered 83% of non-antidepressant prescriptions.
[h]Specialty used was 'paediatrics'.
[i]Type of attendance used was 'discharged and minor investigation'.
[j]Taken from Hansard and Department of Health[220] for call volume (6,427,321) and cost (£161,900,000) respectively.
[k]Minor injury unit separate from A&E department.

TABLE 52 *Cost breakdown (£) for health visitor (HV) training*

Item	Cost (2004/5)	Source
HV backfill for training	63,832	Study records
HV travel	15,644	Study records
Trainer costs	42,089	Study records
Manual development	2000	Study records
Room rental for training	3072	Study records
Refreshments	940	Study records
Introduction day	3075	Based on £41 per professional chargeable hour for clinical psychologist
Administration	742	Based on 8 days of clerical time
Total	131,393	
Cost per HV	1398	

TABLE 53 *Equivalent annual cost (£) of training health visitors*

Year	Training[a]	Supervision[b]	Total	Discounted
0	1398	816	2214	2214
1		816	816	788
2		816	816	762
3		816	816	736
4		816	816	711
5	524	816	1340	1128
6		816	816	664
7		816	816	641
8		816	816	620
9		816	816	599
10	524	816	1340	950
11		816	816	559
12		816	816	540
13		816	816	522
14		816	816	504
15	524	816	1340	800
16		816	816	471
17		816	816	455
18		816	816	439
19		816	816	424
Net present value				14,527
Equivalent annual cost				988
Increase in PSSRU estimated health visitor gross cost (£42,625[218])				2.3%

[a]Training in year 0 taken from *Table 52*. Professional opinion identified the need for refresher training after 5 years equivalent to 3/8 of original course (i.e. £524 rather than £1398).
[b]Clinical supervision identified as 2 hours every 2 months with a clinical psychologist (at £41/hour plus health visitor time).

'Other NHS contacts' also included a vast array of contacts, mostly unrelated to PND or any likely somatisation. Therefore, we identified all mental health-related contacts and classified these as 'community mental health contacts', that is, counsellor, CPN, community mental health team and mental health nurse contacts, or 'clinical mental health contacts', that is, crisis service, psychologist, psychotherapist, psychiatric outpatient and mother and baby psychiatric outpatient contacts.

One minor complication with respect to the costing was that the recommended vaccinations for children changed in 2005; vaccines containing whole cell pertussis and the live poliomyelitis vaccine are no longer used in the UK for the childhood immunisation programme. Consequently, the immunisations at 2, 3 and 4 months now consist of two immunisations rather than three. Immunisations were costed using the new schedule, excluding the resource use information for polio (which is now included in the injection with diphtheria).

Outcomes

The SF-6D, from a subset of SF-36 questions, was calculated for all women at 6 weeks and 6, 12 and 18 months. SF-6D scores were estimated using the UK tariff.[222] QALYs were estimated by calculating the area of the trapeziums beneath the SF-6D scores with respect to time. For a baseline (6-week) utility of 0.8 and a 6-month utility of 0.9, the QALYs over this period were $[(0.8 + 0.9) \times 0.5] \times (20/52)$ years, or 0.33 QALYs. To

adjust for different baseline scores, QALYs gained were then calculated by subtracting the rectangle formed with the baseline score from the QALY.

Analysis

The primary comparison for the economic analysis was based on the at-risk women and compared intervention and control groups at 6 months. This was termed the at-risk women analysis. Further analysis comparing at-risk women in the CBA and PCA groups was also undertaken. Also, a comparison of all women in the intervention and control groups at 6 and 12 months was undertaken. A further analysis comparing all women in the CBA and PCA groups was also undertaken.

The main economic analysis was based around costs and outcomes at 6 months postnatally for the mother. Further analyses also considered the costs for the baby and cost-effectiveness at 12 months. Allowance for the clustering was made by using the xtgee procedure in STATA[196] for the women-level cost and QALY estimates. Covariate adjustment was not undertaken because of the negligible effect seen in the clinical analyses and the lack of a clear set of relevant variables for the adjustment of costs. Baseline costs were not collected within the study.

Cost and outcome data were to be combined to produce an incremental cost-effectiveness ratio, if appropriate. The main focus of the analysis was to plot data on the cost-effectiveness plane and their associated cost-effectiveness acceptability curves (CEACs). These plots were based on bootstrapped sample means, generated from cost–QALY pairs from the data. Interpretation of the CEACs was based around the probability of cost-effectiveness in the £20,000–30,000 per QALY range, to reflect the thresholds typically used by NICE to identify which interventions to fund.

For the estimation of CEACs the incorporation of clustering is more complex and is typically ignored within economic evaluations. CEACs were therefore based on crude means. Further subgroup analyses were also undertaken to identify differences between the different psychological therapies and the use of the postal versus face-to-face administration of the EPDS at 8 weeks.

The sensitivity analysis was based around the impact of different time frames and analytical perspectives on the cost-effectiveness results, in particular, changing the time frame from 6 months to 12 months, changing from the 'at risk' analysis to 'all women as randomised' analysis, and imputing missing data at 6 months.

Additionally, missing economic data were imputed to produce a data set that was comparable with that in the main clinical analyses ($n = 418$ at-risk women, $n = 2659$ all women). Multiple imputation using the 'Norm' software developed by Joseph Schafer was used.[223] Covariates used in the imputation were 6-week EPDS, age, receipt of state benefits, relationship with baby, health of baby, living alone, history of PND and life events. Given a missing data rate (γ) of around 30%, five data sets were generated in line with recommendations.[223] To allow the uncertainty associated with the multiple imputations to be fully incorporated into the analysis required standard errors across the five data sets. However, it was not clear how this could be achieved within STATA. Consequently, mean values across the data sets were used as a single imputed data set. Although losing the benefits of imputing multiple data sets, this still retained the properties of the Schafer imputation algorithm and was therefore considered a robust imputation method.

Results for at-risk women at 6 months (primary economic analysis)

Analysis of cost-effectiveness is bivariate in nature and, to capture the covariance between costs and effects, is best undertaken on paired data (i.e. using cases with both cost and effects data). This requirement, together with the use of multiple data sources, typically leads to attrition. *Table 54* demonstrates that, of the analysable 418 at-risk women in the primary clinical analysis, 35% were lost at the time of the 6-month economic analysis. As not all women were followed up to 12 or 18 months, 71% and 86% of the data were missing for these analyses respectively. As it is prudent to give less emphasis to their associated results, we have placed the 12-month results, which also include costs associated with the baby, in Appendix 2 and an 18-month economic analysis was not reported.

There were 63 clusters in the 6-month analysis, having from one to 12 cases (mean 4.3). The ICC for total cost at 6 months was 0.17 (95% CI 0.05 to 0.30) and for QALYs gained at 6 months it was 0.01 (95% CI 0.00 to 0.10). The distribution of costs showed the typical skew seen in most economic studies (*Figure 19*).

TABLE 54 *Data available for economic analysis from at-risk women (n = 418)*

	Costs estimate available	QALY estimate available	Paired cost and QALY available	Cumulative paired cost and QALY available
6-month analysis	284	402	273	273
12-month analysis	197	253	132	123
18-month analysis	115	117	65	58

QALY, quality-adjusted life-year.

TABLE 55 *Resource use for at-risk women at 6 months*

Item	Control mean (*n* = 78)	Intervention mean (*n* = 195)	Mean difference	95% CI of the difference
HV total contacts[a]	8.5	7.8	–0.7	–2.9 to 1.5
HV contacts for baby[a]	6.8	6.1	–0.7	–2.3 to 1.0
HV contacts for mother[a]	5.3	2.8	–2.5	–4.0 to –1.1
HV contacts for PND[a]	0.7	1.4	0.7	0.1 to 1.3
Total HV minutes	202.4	185.6	–16.8	–90.1 to 56.4
GP contacts	3.3	2.7	–0.6	–1.2 to 0.1
Mother and baby unit days	0.0	0.0	0.0	
Community mental health contacts	0.0	0.0	0.0	–0.1 to 0.1
Clinical mental health contacts	0.0	0.0	–0.0	–0.0 to 0.0
A&E attendances	0.0	0.0	0.0	
Social services contacts	0.0	0.0	–0.0	–0.1 to 0.0
Antidepressant prescriptions	0.5	0.3	–0.2	–0.5 to 0.1
Other prescriptions	1.8	1.5	–0.3	–0.9 to 0.4

HV, health visitor; PND, postnatal depression.
[a]Number of baby, mother and PND visits sum to greater than the total number of visits because of some visits being for more than one purpose.

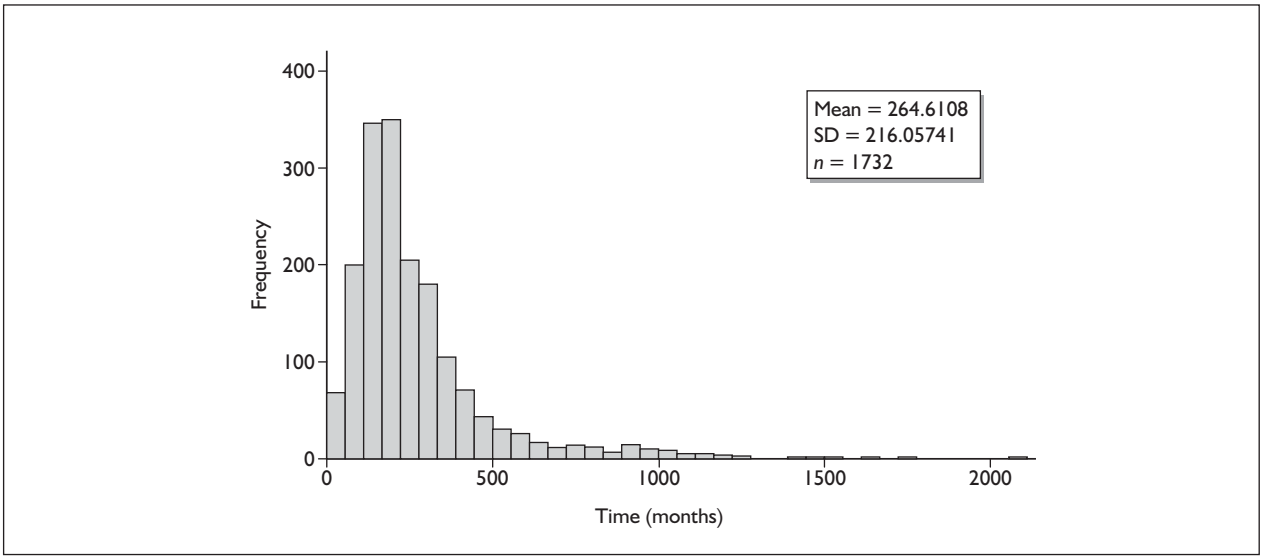

FIGURE 19 *Distribution of women's costs at 6 months across all groups.*

At 6 months there was no statistical difference in the total number of HV visits between the control and intervention groups (mean 8.5 versus 7.8, respectively) (*Table 55*). There was evidence that the content of the visits differed, with a reduction in the mean number of visits for the mothers in the IG (excluding those relating to PND); the IG women had a mean of 2.5 fewer visits. Also, the IG had double the number of visits for PND (mean 0.7 versus 1.4). Overall, the total mean time spent with the mother/baby by HVs was around 17 minutes lower in the IG, although this difference was not statistically significant.

There were no A&E attendances or admissions to mother and baby psychiatric units within the sample, and other mental health contacts and social worker visits were rare. When combined with unit costs the overall cost of care for mothers at 6 months was £35 less in the IG although this difference was not statistically significant (*Table 56*). Mean costs in the CBA group were the lowest, followed by those in the PCA group, with the CG being the most costly (*Table 57*). The levels of significance of these differences were not tested statistically.

The number of QALYs gained was greater in the IG (*Table 58*), although this was not statistically significant; comparing all groups the number of QALYS gained was greatest in the CBA group (*Table 59*). The position by which costs are lower and outcomes better in one group is often referred to as 'dominance'. However, this does not take into account the sampling uncertainty associated with the cost and QALY pairs.

This uncertainty is best illustrated in the cost-effectiveness plane shown in *Figure 20*. At the centre of the cloud of points are the mean incremental cost and QALYs gained for the IG from *Table 58* (–£35 and +0.003). This shows that other combinations of costs and QALYs, which were consistent with the data, produced sample means in all four quadrants (i.e. positive and negative costs and QALYs in every combination). However, the preponderance of points were in the 'south-east quadrant' (i.e. lower costs and greater QALYs gained), and very few were in the 'north-west quadrant' (i.e. higher costs and fewer QALYs gained). For the other two quadrants the cost-effectiveness of the intervention is determined by how much we are willing to pay for a gain in QALYs.

This information is summarised in a CEAC, shown in *Figure 21*. This shows the probability that the intervention was cost-effective at various 'threshold values' of a QALY. Even if we had placed no value on health gains, the intervention would have had a 65% chance of being cost-effective; this reflected the fact that 65% of observations in *Figure 20* were in the southeast quadrant. In the range of QALY values between £20,000 and £30,000, the probability of the intervention being cost-effective was just over 80%.

Comparing the CEACs for the control, CBA and PCA, the CBA had the highest probability of being cost-effective (*Figure 22*). In the range of QALY values between £20,000 and £30,000, the probability of CBA being cost-effective was just over 70%. Again, this reflected lower mean costs

TABLE 56 *Costs (£) for at-risk women at 6 months: control vs intervention*

Item	Control mean (*n* = 78)	Intervention mean (*n* = 195)	Mean difference	95% CI of the difference
HV contacts	260	245	–15	–110 to 79
GP contacts	100	83	–17	–36 to 3
Mother and baby unit admissions	0	0	0	
Community mental health contacts	1	1	+0	–2 to 2
Clinical mental health contacts	2	1	–1	–4 to 3
A&E attendances	0	0	0	
Social services contacts	3	2	–1	–6 to 5
Antidepressant prescriptions	1	1	–0	–1 to 0
Other prescriptions	5	4	–1	–3 to 1
Total cost	374	339	–35	–137 to 67

HV, health visitor.

TABLE 57 *Costs (£) for at-risk women at 6 months: control vs CBA and PCA*

Item	Control mean (*n* = 78)	CBA mean difference from control (*n* = 116)	PCA mean difference from control (*n* = 79)
HV contacts	259	–27	+2
GP contacts	100	–14	–21
Mother and baby unit admissions	0	0	0
Community mental health contacts	1	–0	+1
Clinical mental health contacts	2	–1	–0
A&E attendances	0	0	0
Social services contacts	3	+0	–1
Antidepressant prescriptions	1	–0	–0
Other prescriptions	5	–1	–1
Total cost	374	–45	–21

CBA, cognitive behavioural approach; HV, health visitor; PCA, person-centred approach.

TABLE 58 *Costs (£) and quality-adjusted life-years (QALYs) gained for at-risk women at 6 months: control vs intervention*

Item	Control mean (*n* = 78)	Intervention mean (*n* = 195)	Mean difference	95% CI of the difference
QALYs gained	0.023	0.026	+0.003	–0.004 to 0.010
Total costs	374.185	339.426	–34.759	–137.145 to 67.628

and higher mean QALYs gained. *Figure 23* shows that the CBA-F group is the most likely to be cost-effective, although the difference between the curves is less prominent than before.

The imputation of missing data used a selection of covariates describing the baseline health of the mother and the baby and sociodemographic characteristics. Baseline EPDS scores were not different between at-risk women in the economic analysis subsample ($n = 273$) and those in the clinical analysis sample ($n = 418$) who had missing economic data (15.2 versus 15.2 respectively). Women in the economic analysis subsample were younger on average (30.4 years versus 31.7 years, $p = 0.03$) and there was also weak evidence of lower rates of previous PND (16.7% versus 24.5%, $p = 0.07$). Following imputation, the statistical analysis of total costs and QALY gains were repeated in STATA and the results are shown in *Table 60*.

All women at 6 months

A larger sample was available for the all-women economic analysis, although, again, many cases were lost to the analysis (*Table 61*). For the all-women analysis there were 70 clusters, having a

TABLE 59 *Costs (£) and quality-adjusted life-years (QALYs) gained for at-risk women at 6 months: control vs CBA and PCA*

Item	Control mean (*n* = 78)	CBA mean difference from control (*n* = 116)	PCA mean difference from control (*n* = 79)
QALYs gained	0.023	+0.004	+0.002
Total costs	374	–45	–21

CBA, cognitive behavioural approach; PCA, person-centred approach.

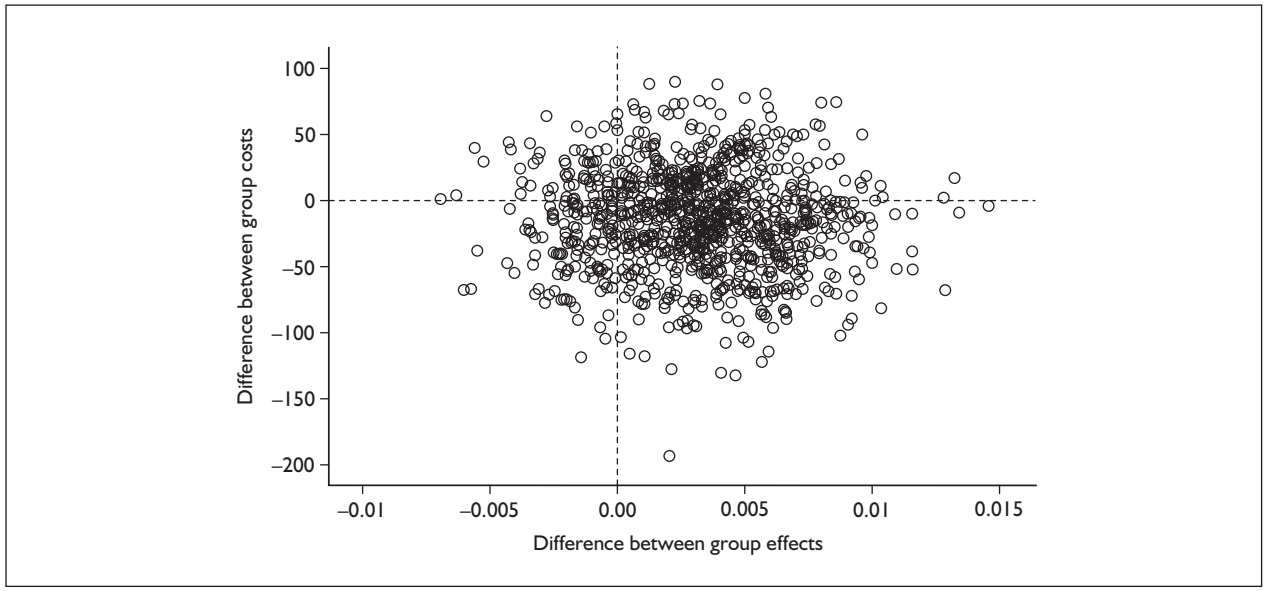

FIGURE 20 *Plot of bootstrapped sample mean cost and quality-adjusted life-year (QALY) differences for at-risk women at 6 months. Note that positive values show the intervention group to be more costly or more effective in terms of QALYs.*

range of 1–77 cases (mean 24.7). The ICC for total cost at 6 months was 0.20 (95% CI 0.13 to 0.28) and for QALYs gained at 6 months it was < 0.001 (95% CI 0.00 to 0.03).

The IG had a lower mean number of HV contacts, although this was not statistically significant (*Table 62*). The IG women had a mean of 1.7 fewer visits per woman and, overall, the IG women used 10 minutes less HV time (95% CI –51 to 31). No significant differences were seen in the other cost components. Overall, the IG had lower mean costs and higher mean QALYs gained (*Table 63*), although neither was statistically significant. The CEAC showed a 99% chance of the intervention being cost-effective.

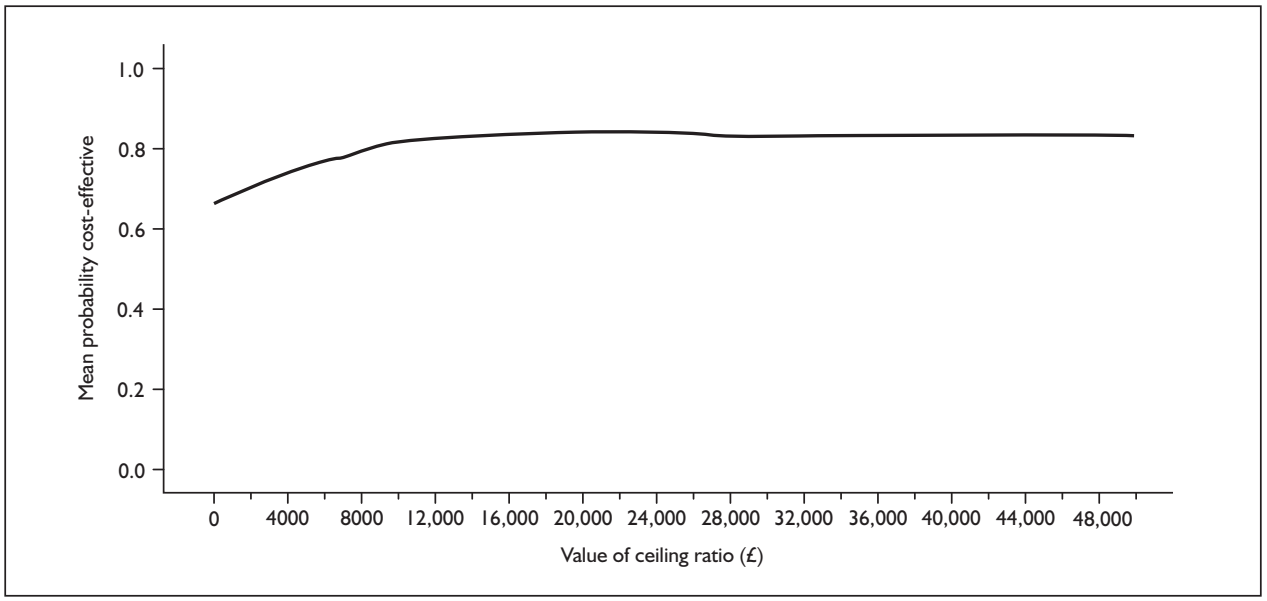

FIGURE 21 *Cost-effectiveness acceptability curve for the intervention group at-risk women at 6 months. The y-axis shows the probability that the new treatment is cost-effective.*

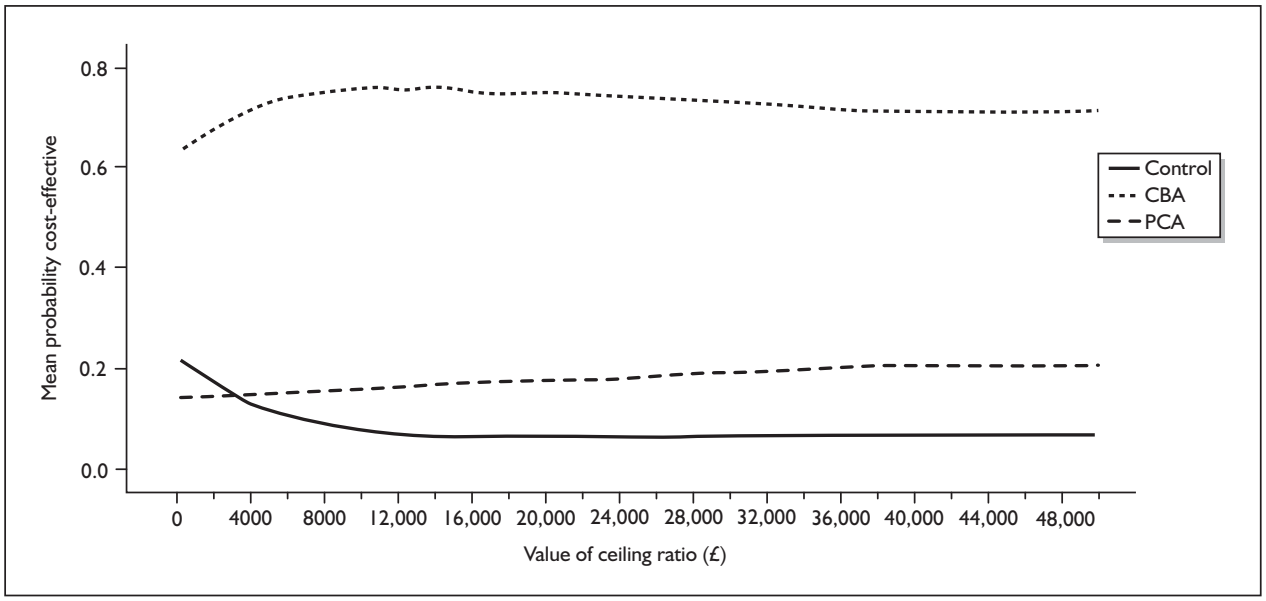

FIGURE 22 *Cost-effectiveness acceptability curves for at-risk women at 6 months: control vs CBA and PCA. The y-axis shows the proportion of simulations favouring each treatment. CBA, cognitive behavioural approach; PCA, person-centred approach.*

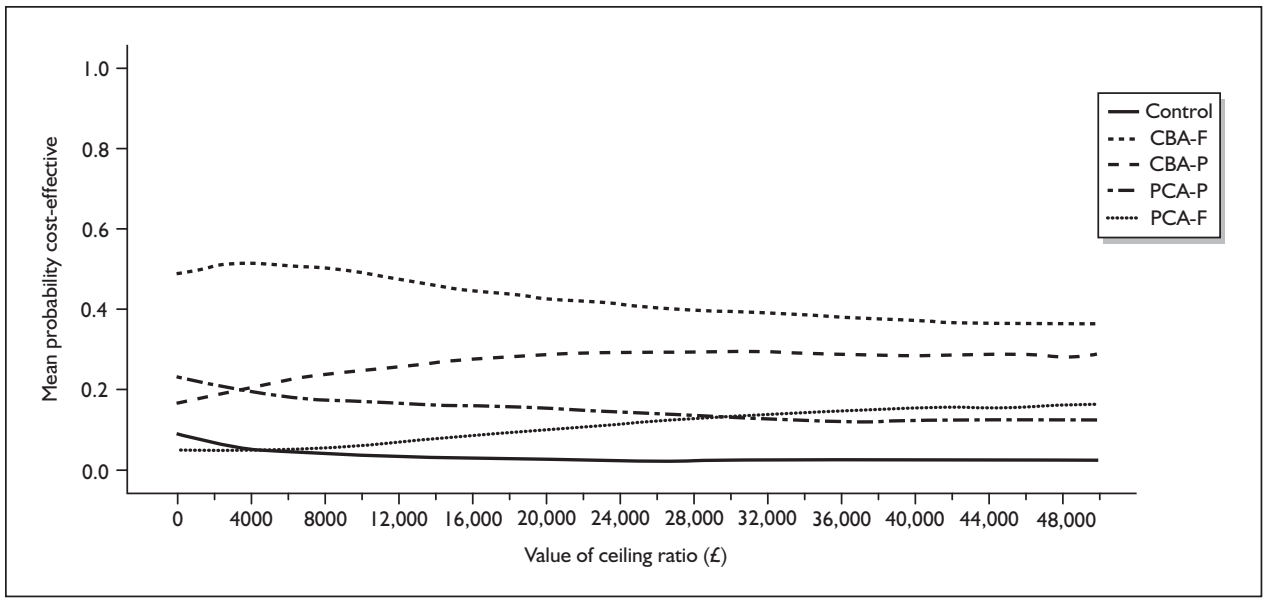

FIGURE 23 *Cost-effectiveness acceptability curves for intervention group at-risk women at 6 months: control vs CBA-F, CBA-P, PCA-F and PCA-P. The y-axis shows the proportion of simulations favouring each treatment. CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group.*

TABLE 60 *Actual and imputed costs (£) and quality-adjusted life-years (QALYs) gained for at-risk women at 6 months*

Item	Actual data, mean difference	95% CI of the difference	Imputed data, mean difference	95% CI of the difference
QALYs gained	+0.003	–0.004 to 0.010	+0.004	–0.001 to 0.009
Total costs	–34.759	–137.145 to 67.628	–40.088	–99.300 to 19.124

When looking at the individual therapeutic approaches there appeared to be very little difference between the CBA and PCA groups in terms of costs and QALYs gained (*Table 64*). *Figure 24* shows the CEAC at 6 months for all IG women, indicating that the cost-effectiveness of the intervention was close to '1' for all reasonable QALY valuations. However, the CEAC in *Figure 25* showed a marked difference. This result should be treated with caution as it is likely to be heavily influenced by clustering; this is accounted for in the univariate analysis of costs and QALYs shown in the tables but not in the bivariate analysis of cost-effectiveness shown in the figures.

The imputation of missing data resulted in only slight differences in the costs and QALYs gained compared with the economic subsample (*Table 65*).

TABLE 61 *Data available for economic analysis for all women (n = 2659)*

	Costs estimate available	QALY estimate available	Paired cost and QALY available	Cumulative paired cost and QALY available
6-month analysis	1797	2560	1732	1732
12-month analysis	1279	1669	934	882
18-month analysis	754	818	425	380

QALY, quality-adjusted life-year.

TABLE 62 *Resource use for all women at 6 months*

Item	Control mean (*n* = 495)	Intervention mean (*n* = 1237)	Mean difference	95% CI of the difference
HV total contacts[a]	7.2	6.7	–0.5	–2.1 to 1.1
HV contacts for baby[a]	6.6	6.2	–0.4	–1.8 to 1.0
HV contacts for mother[a]	4.0	2.3	–1.7	–2.9 to –0.6
HV contacts for PND[a]	0.3	0.3	+0.0	–0.2 to 0.2
Total HV minutes	143.9	133.9	–10.0	–51.3 to 31.4
GP contacts	2.7	2.4	–0.3	–0.8 to 0.1
Mother and baby unit days	0.0	0.0	0.0	–
Community mental health contacts	0.0	0.0	+0.0	–0.0 to 0.0
Clinical mental health contacts	0.0	0.0	+0.0	–0.0 to 0.0
A&E attendances	0.0	0.0	0.0	–
Social services contacts	0.0	0.0	+0.0	–0.0 to 0.0
Antidepressant prescriptions	0.1	0.0	–0.1	–0.1 to 0.0
Other prescriptions	1.3	1.3	+0.0	–0.3 to 0.3

HV, health visitor; PND, postnatal depression.
[a]Number of baby, mother and PND visits sum to greater than the total number of visits because of some visits being for more than one purpose.

TABLE 63 *Costs (£) and quality-adjusted life-years (QALYs) gained for all women at 6 months: control vs intervention*

Item	Control mean (SD)	Intervention mean (SD)	Mean difference	95% CI of the difference
QALYs gained	0.028	0.030	+0.002	–0.001 to 0.005
Total costs	271.868	251.900	–19.968	–75.729 to 35.792

TABLE 64 *Costs (£) and quality-adjusted life-years (QALYs) gained for all women at 6 months: control vs CBA and PCA*

Item	Control mean	CBA mean difference from control	PCA mean difference from control
QALYs gained	0.028	+0.002	+0.002
Total costs	271.856	–18.450	–21.830

CBA, cognitive behavioural approach; PCA, person-centred approach.

The results of the cost-effectiveness analysis of the intervention at 12 months were severely weakened by the level of missing data, shown in *Tables 54* and *61*, and so they are shown in Appendix 2. No 18-month economic analyses are presented.

Discussion

The results show a consistent pattern of psychological approaches being cost-effective at funding levels used by NICE. This was achieved by lower mean costs and higher mean QALYs gained in the IG. Although these aggregate differences are not statistically significant in isolation, in combination they produce a high probability of the intervention being good value for money.

The findings were consistent across both the at-risk women and the all-women cohorts, and at the 12-month follow-up. CBA appeared to be the most cost-effective across all analyses when interpreting the CEACs, although these may be confounded by the clustering present within the trial (see Clustering, below).

To fully appreciate these results, however, we must consider the problems inherent in them. Three issues are of particular note: the impact of missing data, clustering and costing methods.

Missing data

There was a great deal of missing data as a result of several factors. First, the economic data collection depended on the HVs taking time away from work to manually abstract information from medical records. Second, to maximise the achievement of the required sample size for the 6-month primary analysis, the recruitment and 6-month follow-up phase was extended within the existing trial resources and time frame. Therefore, not all recruited women had reached their 12-month follow-up time and even fewer had reached their 18-month follow-up time before the trial closed and so they were not sent 12- and 18-month

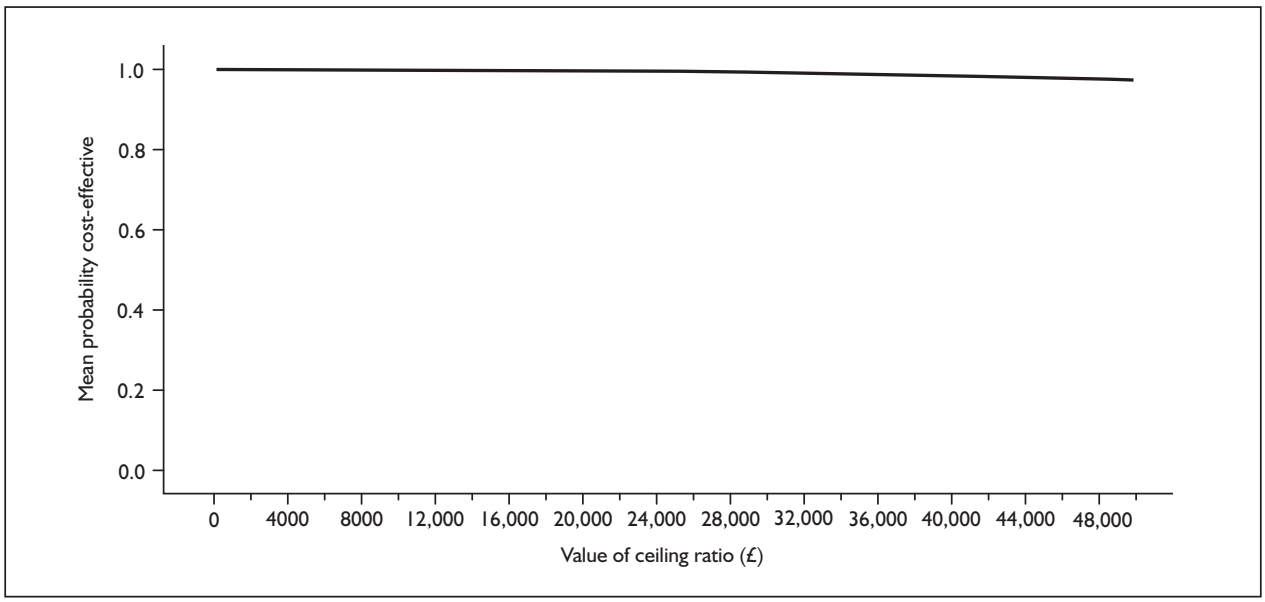

FIGURE 24 *Cost-effectiveness acceptability curves for all intervention group women at 6 months. The y-axis shows the probability that the new treatment is cost-effective.*

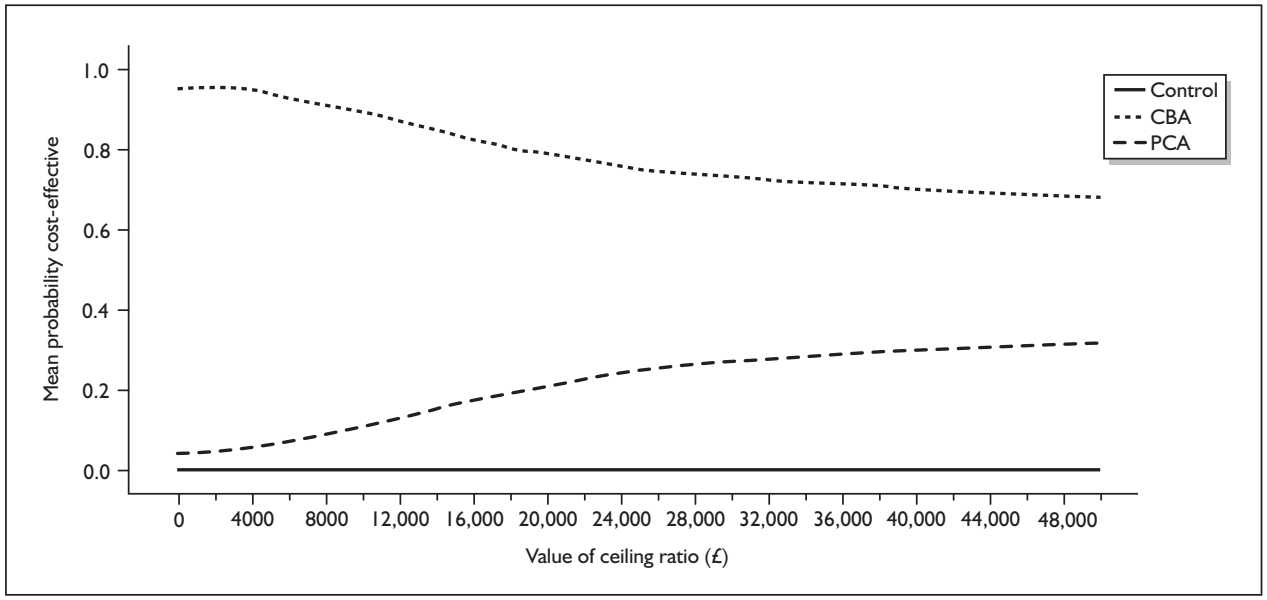

FIGURE 25 *Cost-effectiveness acceptability curves for all women at 6 months: control vs CBA and PCA. The y-axis shows the proportion of simulations favouring each treatment. CBA, cognitive behavioural approach; PCA, person-centred approach.*

TABLE 65 *Actual and imputed costs (£) and quality-adjusted life-years (QALYs) gained for all intervention group women women at 6 months*

Item	Actual data, mean difference	95% CI of the difference	Imputed data, mean difference	95% CI of the difference
QALYs gained	+0.002	–0.001 to 0.005	+0.003	+0.001 to 0.006
Total costs	–19.968	–75.729 to 35.792	–36.035	–68.423 to –3.646

questionnaires. This effectively removed them from the complete-case cost-effectiveness analysis. Third, the economic data were produced from many individual observations; 6-month QALYs were produced from two utility estimates, 12-month QALYs were produced from three utility estimates, and 18-month QALYs were produced from four utility estimates. Cost data were even more susceptible, with total 6-month costs produced from nine cost components. In addition, cost-effectiveness estimates were calculated using pairs of cost and QALY data.

These problems have led economists to look at data imputation as a way of ameliorating such effects. Of these, multiple imputation appears to be the most promising approach, as it takes into account the uncertainty around the imputed data and can be adapted to incorporate the covariance between costs and QALYs. This approach was adopted in the PoNDER trial and applied to the 6-month data to generate results that were consistent with the main clinical analysis. These analyses showed few differences between those included and those excluded from the cost-effectiveness analysis and, in turn, did not change the economic results noticeably. This conferred greater confidence in the 6-month results as illustrated in the CEACs.

However, two issues remain. First, imputation was not undertaken for the 12- and 18-month analyses as it was considered that the higher rates of 'missing data' may have been more likely to reflect a non-random process. Given that imputation cannot account for systematic causes of missing data, it was thought that imputing data for the 12- and 18-month analyses would give undue credibility to these analyses. Second, imputation was used to generate data sets that were consistent with the main clinical analyses (at-risk women, $n = 418$, and all women, $n = 2659$). It would have been possible to impute a much larger data set based on all women randomised and for whom baseline data were available. This was not undertaken as it was thought that the interpretation of the results of the study as a whole

was more robust when the basis of the economic and clinical analysis was consistent. It should be noted, however, that, as with the clinical analysis sample, those included in the economic sample had lower EPDS scores than those excluded (not shown).

Clustering

Within the economic analysis we took into account the inherent clustering of the data using cluster procedures available in STATA, and other economic evaluations based on cluster randomised controlled trials that have ignored this.[224] The high ICCs relating to costs in this study show that this is an important issue.

However, the cost-effectiveness analyses embodied within the CEACs presented do not take into account this clustering. No cluster randomised trial to our knowledge has carried this out, despite adjusting for clustering at the univariate level.[225,226] How this bivariate adjustment for cluster can be undertaken is not clear. Although it is possible to produce cost-effectiveness ratios for individual cases and estimate an ICC (which we have shown to be less than 0.001), this is of the average cost-effectiveness ratio and not the incremental cost-effectiveness ratio. Likewise, CEACs based on cluster means could be produced but they would need to be weighted and the basis of this weighting is open to debate.

Consequently, the CEACs may be biased by any cluster effect relating to cost-effectiveness. When considering this it is worth noting that the results shown in *Table 58* and *Figure 20* appear totally consistent in terms of the mean differences and the location of the sampled incremental cost-effectiveness ratio plots. This is also reflected in the shape of the CEAC, which reflects a 'dominant' intervention. Likewise, the results shown in *Figure 22* appear to generally reflect the results shown in *Table 59*. It is only in the case of *Table 64* and its associated CEAC in *Figure 25* that large differences are noticeable between the cluster-adjusted results and the unadjusted cost-effectiveness analyses.

Finally, it should be noted that the mean estimates shown in the tables did take into account the clustering, and so the headline figures of (statistically insignificant) lower mean costs and higher mean QALYs gained in the IG remain unbiased.

Cost of training

The estimation of the cost of training in *Table 52* is straightforward and, although there were assumptions regarding the intensity and frequency of retraining and clinical supervision, the estimate of equivalent annual cost in *Table 53* was robust. The more uncertain aspect of training costs was how they were incorporated into the unit costs of the HVs.

The approach taken in this study was to allocate this cost in the same way as pre- and post-qualification training. This produced a cost per hour that was £2 higher for HVs trained in CBA versus PCA. This effectively allocated the cost across all women contacts, even those not related to PND.

An alternative approach would have been to allocate the cost of training only to visits related to PND. We did not adopt this approach, first, because the HV training also developed skills in systematically detecting depression, and so these were used outside the 'therapeutic' psychological intervention sessions. Second, there was some anecdotal evidence that the skills of HVs were used other than for women with PND. *Table 62* shows that, among all women, an impact is identifiable on consultation numbers for problems relating to the mother, supporting our belief that the skills were being used in such a way that they had an impact on the broader HV caseload. This is consistent with our costing approach.

One important aspect of the HV training was that it appeared to have altered the pattern of health visiting contacts with the women in the IG. In particular, the overall level of visits reduced (although this was not statistically significant), with the greatest reduction in the visits relating to the mother that were not focused on PND. The level of visiting focused on PND was the same in both the intervention and control groups. This makes it difficult to identify an effect that is specific to the delivery of care relating to PND. Although the training seemed to have altered visiting patterns we can only speculate about why these changes occurred and their related therapeutic effects. So, although these changes were consistent with a hypothesis of training being associated with more targeted visiting and better quality of PND care, the study can not lend any evidence in support of this.

Other considerations

The economic analysis focused entirely on the differences in means, and consequently we used parametric tests. However, *Figure 19* shows that the data were not normally distributed and so such parametric tests may have been prone to bias, especially in small samples. Alternative approaches, based on bootstrapping or non-linear transformations of the costs, are possible. However, the integration of these approaches with the cluster-adjusted analysis presented here is not straightforward and, also, with samples in excess of 200 (at-risk women) and 2000 (all women) the parametric tests should produce reasonably robust estimates. We felt that these sample sizes were such that a cluster-based analysis using parametric tests was the best approach to be adopted. Also, the CEACs were produced from (non-parametric) bootstrapped samples and therefore were not affected by the shape of the underlying distributions.

The focus on means may not help with other questions, which may be better tested using other methods, for example differences in the proportions of babies receiving full vaccinations or mothers receiving antidepressants. These issues were beyond the scope of the economic evaluation.

The tables of resource use show some interesting differences between the groups in terms of the nature of visits undertaken by HVs – more PND visits but fewer mother visits in at-risk women (see *Table 55*). Other analyses, not presented here, also show more specific differences between the CG and the IGs, and even between the CBA and PCA groups. The importance of these differences, and the reasons for them, are considered to be beyond the scope of this economic evaluation.

Although the main focus of the economic analysis was the costs and outcomes associated with the mother, with secondary analyses of costs associated with the baby, resource use and SF-12 data were collected for partners as well. It was envisaged that this would form a further sensitivity analysis around the analytical perspective of the study. However, incorporating these data into a 'family-based' analysis further compounded the missing data problems and so these analyses have not been presented.

Chapter 6
Qualitative interviews

Introduction

The purpose of the qualitative evaluation was to encourage women to discuss their experiences, attitudes and views in relation to the support that they received from their HV.

There has been a limited amount of research conducted to investigate how women perceive the support that they receive postnatally.[227] Having a baby changes a woman's life and practical and social support from health professionals and family, friends and other mothers can reduce physical and emotional stress. Whether it is in the form of emotional, practical or simple reassurance, the way in which support is offered and delivered affects how it is perceived and experienced.[227]

A woman may see her HV antenatally or they may meet for the first time around 11 days after the baby is born. Expectations about what the HV's role will be and the characteristics of an ideal HV differ greatly. New mothers may have a broad range of expectations regarding the availability of advice on baby care, information about local services, help to deal with social problems, support for emotional problems and information about child protection or welfare issues.

The in-depth interviews

Semistructured interviews were carried out to supplement the quantitative data from the study by exploring in further detail women's experiences of the care that they received during the postnatal period. An interview schedule was designed to elicit information about how the women were feeling and on how PND was assessed and discussed by health professionals and support was accessed and offered, and whether the women felt that the support that they received was beneficial or could be improved.

Method

Women who scored ≥ 12 on the EPDS were at risk of developing PND. As we had no systematic information on two successive administrations of the EPDS for the treatment as usual group, an inclusion score of ≥ 18 on the 6-week postal EPDS was selected to increase the equivalence of all groups. All women who scored ≥ 18 on the 6-week EPDS were sent a letter when their baby was 6 months old to invite them to take part in an interview at home. They were informed of the purpose of the interview and reassured about the confidentiality of the interview and that all transcripts were to be completely anonymised and no individual information was to be relayed back to the HVs, and then they were asked to sign a taping consent form. Transcriptions were imported into NVivo (QSR) software, which aids qualitative researchers to organise and examine large amounts of textual data.

Each woman was contacted at 6 months postnatally by a LC (AR, JS, KR, JF) to discuss the interviews and arrange a LC visit if the woman was interested in taking part. Women were reassured of confidentiality and advised that the interview would take about 30 minutes.

A total of 39 women were invited to participate, of whom six declined (too busy) and three could not be contacted as their address or phone number had changed. In total, 30 women agreed to take part; nine women from the CG and 10 and 11 from the CBA and PCA IGs respectively (*Table 66*). All women who agreed to participate were asked if they had a partner and, if so, if their partner would be willing to be interviewed. Sixteen partners agreed; five from the CG and four and six from the CBA and PCA IGs respectively. All participants were compensated for their time with a £15 voucher.

Template analysis

A qualitative 'template analysis' approach was used[228] in which themes are elicited from the data through an iterative process. This method was the most appropriate as it allows an a priori template of particularly important themes to be applied to a subsample of the data, to answer specific questions first and then to allow further, richer detail to emerge from the data. Templates are made up of

TABLE 66 *Characteristics of the in-depth interview sample by group (n = 30)*

	PCA	CBA	Control	Total
n	11	10	9	30
Age 18–25 years, *n*	2	2	3	7
Age 26–35 years, *n*	6	5	4	15
Age 36–45 years, *n*	3	3	0 (missing *n* = 2)	6
Single parent	1	1	1	3
Partnered	6	3	1	10
First child	7	8	6	21
GP prescribed antidepressant	6	5	7	18

CBA, cognitive behavioural approach; PCA, person-centred approach.

hierarchically organised codes; the highest level codes are the broad themes whilst lower level codes are more narrowly focused aspects of the broader theme. The prespecified template focused on the original themes of women's experiences of the EPDS and interventions (*Figure 26* and *Box 1*).

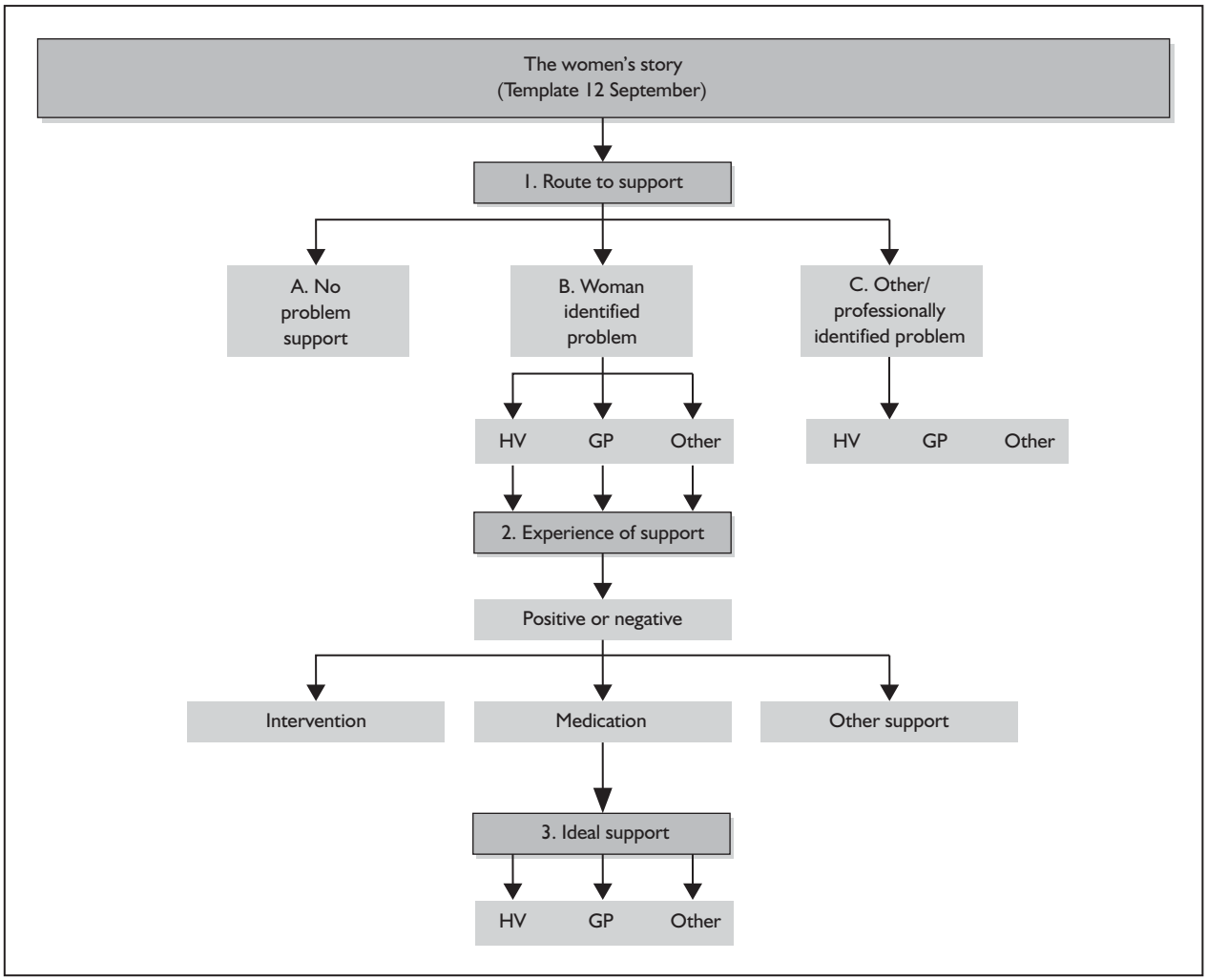

FIGURE 26 *Initial analysis template for the PoNDER trial*

Final template

BOX 1 *Detailed content of template themes*

1. Experience of depression
   - (a) Past history:
     - (i) previous depression (ii) previous postnatal depression
   - (b) Severity of current subjective depression:
     - (i) no low mood (ii) baby blues (iii) postnatal depression
   - (c) Assessment:
     - (i) EPDS (ii)other
   - (d) Life circumstances:
     - (i) feeling isolated
2. Experience of postnatal support
   - (e) Communication:
     - (i) inconsistent information from health visitors (ii) raising awareness of postnatal depression and what help is available
   - (f) Health visitor:
     - (i) practical
     - (ii) structured intervention:
       - (a) cognitive behavioural approach
       - (b) person-centred approach
   - (g) GP – medication:
     - (i) time taken (ii) how helpful it was (iii) breastfeeding, reassurance
   - (h) Other:
     - (i) partner (ii) other family members (iii) friends (iv) Sure Start
   - (i) Help-seeking behaviour:
     - (i) contacting GP (ii) contacting health visitor (iii) reluctant to admit problems to health visitor
   - (j) Ideal support

Three researchers developed the codes collectively and modified them after each successive reading of the interview transcripts. They then produced a final structured representation of themes, and the relationships between them, which adequately reflected the whole data set (*Box 2*).

BOX 2 *Final analysis template*

- Theme 1 – Women's experiences of the postnatal period
  - 1.1 Adapting to the new baby
  - 1.2 Pressures of motherhood
  - 1.3 Breastfeeding
- Theme 2 – Help seeking
  - 2.1 Help-seeking styles
  - 2.2 Barriers to help
    - 2.2.1 Presenting a coping image
    - 2.2.2 Perception of the health visitor
    - 2.2.3 Perceived role of the health professional
- Theme 3 – Professional roles
  - 3.1 Completing the EPDS
  - 3.2 Information on postnatal depression
  - 3.3 Relationship between the woman and the professional
  - 3.4 Woman's perception of the professional role
- Theme 4 – Intervention or support
  - 4.1 Person-centred approach
  - 4.2 Cognitive behavioural approach
  - 4.3 Treatment as usual intervention
  - 4.4 Non-intervention support
  - 4.5 Informal support
  - 4.6 Ideal support

Results

The interviews were extremely successful in producing rich, complex and often lengthy accounts of women's experiences of the postnatal period. The results concentrate on the key findings relating to the themes in the coding template. The 'intervention or support' theme addresses the central research question. All of the women have been given a unique identifying number (id) to protect their anonymity. As is clear from other sections of the report, typically the women who were not offered the intervention were in receipt of other services or support (*Table 67*).

The central focus of the interviews was the women's reported accounts and views of the support that they had received from their HV during the 6-week to 6-month postnatal period. In the following sections the following abbreviations are used: I, received PCA/CBA intervention; NI, no PCA/CBA intervention offered; DI, declined PCA/CBA intervention; control, treatment as usual. The first theme emerged as a result of the interviewees discussing how they were feeling physically and emotionally.

Theme 1: Women's experiences of the postnatal period

The theme describes how the women were feeling when their babies were 6 weeks to 6 months old, including reported signs that all was not well. *Table 68* shows the nature of the reported negative feelings. Some women reported multiple symptoms. There were other factors affecting mood for some women, including physical illness, for example infected episiotomy and mastitis, the July 2005 bombings in London, illness of an elderly parent and a child's ill health. Two of the women mentioned recent bereavements:

> *I lost my mum in the January and found I was having him in the June … . I think that is what it was.*
>
> PCA–NI, id 8

> *Yeah, deaths and that in t' family.*
>
> Control, id 9

Adapting to the new baby/loss of identity

Many women across all of the groups made comments about adapting to having a baby, commenting on their new role and new set of circumstances. This often emerged as a loss of role and identity. This was more frequent among first-time mothers. A sense of finality to the 'change' of becoming a mother also emerged from the data:

> *You suddenly turn into [baby's names] mum instead of a human being.*
>
> CBA–I, id 10

> *That's when I started crying for no reason … that I just couldn't cope anymore and that life wasn't fun and I wasn't getting no enjoyment out of life at all and all it seemed to be is the chore of like housework, looking after the baby, sleepless nights, not getting to see friends anymore, not going out and just being a mother and a completely different life to what I'd had.*
>
> CBA–I, id 10

> *I did feel like I can't cope … . You know you sort of feel like you might lose that part of you which is really you because suddenly you're just changing nappies and just looking after this thing that you produced.*
>
> PCA–DI, id 11

> *I was a bit worried, I think all women think this, that it was a mistake in having a baby, because now my life is dramatically different, I couldn't walk properly and I had this little thing to look after and I was thinking 'Crumbs, what have I done?', and there's no way back.*
>
> PCA–I, id 13

Women, who already had a child, or children, also mentioned themselves and older siblings having to adapt to the newborn: '*A few problems with me other child … she's had a lot of attention and it was the backlash on that which I found hard to cope with*' (CBA–I, id 12).

Pressures of motherhood

Closely related to the above topic, many of the women felt that they had to conform to some sort of 'ideal' of motherhood and felt under pressure if they did not feel that they were achieving this 'ideal':

> *I wanted to be so perfect and I wanted to do everything well and I didn't know how to do it or what to do.*
>
> PCA–DI, id 11

> *I suppose my anxiety sort of came out like that really … wanting to be perfect and not really being able to cope at times.*
>
> PCA–DI, id 11

Breastfeeding

Another frequently mentioned issue was breastfeeding. Many women reported that it affected their self-esteem and views of themselves as a mother:

> *I've got to be there to feed her all the time so I never get a break from her.*
>
> CBA–NI, id 15

> *I found that quite worrying that they wanted to keep an eye on her [the baby], I felt like it was my fault. I couldn't feed her enough and it was my fault that she wasn't putting on enough weight.*
>
> PCA–I, id 3

> *I was struggling with breastfeeding because I had mastitis twice and so feeding her was really very*

TABLE 67 *Intervention group (n = 21) by CBA or PCA and support received*

	PCA (*n* = 11)	CBA (*n* = 10)	Total
Offered intervention	5 (4 antidepressants)	5 (4 antidepressants)	10 (48%)
Not offered intervention	5 (3 antidepressants)	3 (0 antidepressants)	8 (38%)
Declined intervention	1 (0 antidepressants)	2 (1 antidepressant)	3 (14%)

CBA, cognitive behavioural approach; PCA, person-centred approach.

difficult and consequently she was quite unhappy … so she was feeding every 2 hours and 1 hour of that 2 hours she was feeding so I was physically absolutely exhausted, in pain and obviously that leads to being quite emotional.

CBA–I, id 16

You're constantly in demand.

CBA–I, id 17

I really struggled, I was miserable, mainly to do with breastfeeding.

CBA–NI, id 18

For example, on the subject of breastfeeding, I never found [it] very easy … . And because I didn't do it for as long as obviously is recommended … I did feel like I'd failed in lots of ways.

Control, id 14

Every feed was an actual nightmare so I don't think that helped cos I wasn't getting any sleep at all either so I just think of them as my very dark days.

Control, id 7

This woman also highlighted how having a difficult time breastfeeding affected her mood and her relationship with her son: '*Sometimes I feel like I could just hate him and I just want to get away from him because just constantly so difficult to feed*'.

Theme 2: Help seeking

Help-seeking styles

There appeared to be several processes underlying help-seeking behaviour for some women, in particular (1) self-recognition – women who were aware that they needed help and sought help, (2) those that responded to advice to seek help from others and (3) those that sought help for various other things, that is, their children's illnesses, as a 'way in' to seeking help for themselves.

Because I was so desperate that I admitted that I needed help and I received it.

PCA–I, id 20 (this woman had had PND with a previous child)

I was starting to think, you know, hurt him rather than myself because you just want him to shut up

TABLE 68 *Signs of emotional distress among the interviewed women*

Signs	Example
Crying	'*There were days or a couple of weeks when I would be crying all the time*' (CBA–NI, id 1)
Feeling unable to 'cope'	'*Not being able to cope if he was crying*' (PCA–NI, id 2)
Lack of sleep	'*If you're not getting any sleep everything gets on top of you and that's how I felt*' (PCA–I, id 3)
Low mood	'*I felt really, really depressed*' (CBA–NI, id 4)
Worrying	'*Worrying about things that are totally irrelevant*' (PCA–I, id 5)
Anger/irritability	'*You're being angry and violent and this isn't like you*' (CBA–I, id 6)
Feeling isolated	'*I didn't know anybody in the area, I did feel quite isolated I must say*' (PCA–I, id 3)
Feeling unsupported	'*And I was really upset about that [partner referring to her hormones] and I thought "he doesn't really understand at all"*' (Control, id 7)

CBA, cognitive behavioural approach; PCA, person-centred approach.
I, received PCA/CBA intervention; NI, no PCA/CBA intervention offered; DI, declined PCA/CBA intervention; control, treatment as usual.

and then you think about shaken baby syndrome and you think … oh, God that could be me. I can understand how people do that now. It's not that they're a bad parent. It's just that they're not coping and if I started to think badly of him then … I need help.

PCA–I, id 17

Driving on the M25 and I've actually had the thought as regards 'Wouldn't it be easier if I just drove off?' and at that point I thought 'No, something's not quite right here, don't be an idiot'.

Control, id 21

Women also accessed help via their children, indicating a difficulty in being explicit to health professionals and using other reasons to initiate contact.

I'd had a Caesarean section … so I couldn't drive for 6 weeks … so I called him [GP] out … I called him for [baby's name] but I did want to talk to him at the same time … but I used the excuse of him coming to see [baby].

CBA–NI, id 22

I had to take the children to the doctor … and she picked up that I wasn't well or she said 'How are you?' and then of course it all came out.

CBA–NI, id 5

It was most frequently reported by women that other people's prompting initiated the help-seeking behaviour:

It was sort of my partner saying to me 'Right if you don't go I'm basically making you an appointment, you are going, don't sweep it under the carpet, you know you can't just keep feeling like this'.

CBA–I, id 12

Only two women mentioned health professionals:

Oh yeah, I think if I hadn't spoken to my health visitor when I did I perhaps wouldn't have ended up going to the doctors and realising what was wrong.

Control, id 14

She [midwife) got me an appointment with the GP.

Control, id 25

Barriers to help

Presenting a coping image

One of the main barriers seems to be that the women wanted to present a 'coping' image, having a fear of seeming unable to look after their child and of what others might think:

You worry that you think that the health visitor might think you're not coping.

CBA–I, id 10

I didn't want anyone's help to be honest after I had [previous child]. I was so frightened that people would think I couldn't cope and take her off me.

PCA –I, id 20

I remember thinking 'I don't want her to think I'm not coping', which is stupid really because I wasn't.

CBA–I, id 17

This woman went on to say:

*Especially … you're stood in the middle of the surgery, with like six mums around you with six newborns and you just think well I'm hardly gonna turn round and go, you know, 'I'm really not f***ing coping, help'.*

I felt like terrible for the way I was feeling and I thought if I go tell somebody they must think, 'She can't look after her children'.

Control, id 24

Before when I was stressed out I didn't want to speak to anybody about it because I didn't want people to think, 'I can't do this'.

CBA–NI, id 1

Perception of the health visitor

Sometimes a major barrier to help was the woman's perception of a particular health professional. This highlighted the importance of the professional's openness to emotional issues:

So I think she wasn't as person-centred and she didn't really have the people skills to manage, you know, she could have, sort of offered advice and support in a much more supportive way instead of 'Well, you haven't done this, you haven't done that' and her tone was all wrong as well.

PCA–DI, id 11

One woman found that her particular HV was the barrier to support:

I did ask for support but I didn't really get any. The HV responded, 'Well you seem like you're doing alright', which kind of closes it off doesn't it then.

Control, id 7

For some women their perception of their HV led them to decline the offer of a formal intervention: '*I didn't feel like talking to her. I didn't really know her that well so …*' (CBA–DI, id 4).

Perceived role of the health professional
Women commented on the perceived role of the health professional:

> *I didn't feel it was something I wanted to discuss with the GP … I look at GPs as practical, physical health not, and I never used a GP in an emotional way … I just perceive them to be factual scientists.*
>
> CBA–I, id 16

Theme 3: Professional roles (experience of care from professionals)

Completing the EPDS

The interviewers asked the women about the 'questionnaire' (i.e. the EPDS) that the HVs used. However, there was no consensus and this seems to reflect a range of administrative styles:

> *I think it took us about an hour going through it, but I think the reason for that was because I was very low at that point and so she was making sure that she was understanding what was going on and how I was feeling.*
>
> CBA–I, id 16

> *She definitely came out and did a questionnaire but it was very informal … I don't think I realised she was doing a questionnaire until I saw she was ticking boxes or whatever.*
>
> CBA–NI, id 22

It would appear that it is not always clear that a questionnaire is being administered, as no explanation had been given.

Only one woman was entirely negative about the scale: '*I just felt it was stupid because … I just said sort of yes, no, yes, no, didn't go into any detail, couldn't be bothered*' (PCA–I, id 5).

Another woman commented on the same issue: '*I think if they do pick you on the wrong day I think you do get a crazy score*' (PCA–NI, id 8). She went on to say:

> *I think it's quite difficult to open up, to admit that you're feeling that bad and at least when [HVs name] came with the Edinburgh scale, at least somebody knows that at that particular moment you feel dreadful.*

This highlights the utility of the EPDS as a chance for the women to discuss their feelings if they choose to do so. Some women may not realise how low they are until they complete the questionnaire:

> *I started to do the questionnaire and that's when I realised … . It told me that day when I sort of answered the questions as truthfully as I could that, you know, I just wasn't feeling very good at all.*
>
> CBA–I, id 12

One woman from the CG did not do the EPDS and commented the following: '*No nothing, I don't think there were ever any real focus on how I were coping or not coping*' (Control, id 7).

These comments demonstrate that the interviewees also appreciated the EPDS because it shifted the focus onto their feelings rather than concentrating on the baby.

Information on postnatal depression

The women and their HVs were involved in a trial on PND and so the women were asked about the sort of information that they were given by their HVs and in some cases their GPs. Variations in how well informed women were about PND range from it being well defined to having no information at all:

> *At the antenatal classes that we had … she did mention it … she did say it was quite normal and it does happen and it happens generally to the most unlikely people, but she didn't necessarily dwell on it but made us aware that it was something that people do naturally suffer from.*
>
> CBA–I, id 16

> *She [HV] did give me a leaflet which told me the signs to look out for if you were suffering from postnatal depression.*
>
> PCA–I, id 13

> *She [HV] did tell me exactly what it was all about [PND].*
>
> Control, id 24

> *Well she gave me leaflets on it, talked to me about how common it is and you mustn't punish yourself for having this. You can't help how you are, it's just one of those things that unfortunately happens. And if you've got a predisposition to be depressed like I already have then you are a lot more likely to get it.*
>
> PCA–I, id 20

One of the women (id 12) had good information from both her GP and her HV. Other women had little or no information from health professionals and some professionals were reported as using the terminology 'baby blues':

> *I didn't really know much about it to be honest … nothing from a … professional point of view.*
>
> PCA–I, id 3

> *No … I'm pretty sure they didn't [explain about PND].*
>
> CBA–NI, id 22

This woman's GP called it 'baby blues' even though she was prescribed antidepressants.

> *Erm, she [HV] didn't say much really [about PND].*
>
> Control, id 9

> *She (GP) really didn't explain much about it … I explained my feeling, and she says, 'Right, well, sounds like you've got postnatal depression' and put me on some medication. And really that was it. She didn't explain or anything really.*
>
> PCA–I, id 26

One woman reported that she was told by her HV, '*Oh, you've got baby blues. Pull yourself together. Get on with it*' and the woman thought it was '*Just disgraceful*' (PCA–DI, id 28). This may have contributed to the woman declining the intervention. However, this woman did get the support she needed from her GP.

Relationship between the woman and the professional

The perceived 'personality characteristics' of professionals were crucial in determining whether women had a positive or negative experience of the postnatal period.

Positive comments on the relationship

Those women who had received an intervention were extremely positive about their relationship with their HV and were encouraged to comment on how this relationship had changed over the time span of the intervention:

> *Very good, absolutely like a really good honest relationship and I feel very like I trust her [HV] and that, you know, that I can confide in her and talk to her really about everything that's sort of like going on since I've had the baby.*
>
> CBA–I, id 10

> *So she [HV] was like supportive and kept in contact quite a lot, ringing me to see if I was ok and if I needed to talk, she was there sort of thing.*
>
> PCA–NI, id 30

This woman felt that continuity was important:

> *I always ask to speak to [HV] because I know her and it's easier really if you know somebody.*
>
> PCA–NI, id 30

> *Before [intervention] I was really quiet and I owe so much to her [HV] and its really brought out of me to be open and everything.*
>
> PCA–I, id 31

A positive comment from a CG woman who was well supported by her HV: '*I felt I could talk to her because I'd built a relationship with her when I'd had previous child*' (Control, id 24).

Negative comments on the relationship

All of the negative comments on the relationship with the HV were from women who had not been offered formal sessions of support or had declined and from women in the CG who perceived that they had received little or no support from their HV. All of these women were more positive about their relationships with their GP:

> *I don't feel I had any support either as a new mum or emotionally or whatever else, I don't think there was a relationship, to the point where both [partner's name] and I would dread her coming out to weigh him … and as I say, at the point where we were told … that we'd had a new HV, thank God for that, hooray.*
>
> Control, id 21

> *If I had another problem I would go to the doctor rather than see the health visitor. I did find the doctor more sympathetic but then I did open up more to the doctor.*
>
> PCA–NI, id 8

> *At first I was using them [HVs] as I thought they were meant to be used, which was asking questions all the time and checking things out with them to make sure I was right, you know basic people to talk to as some kind of support. To at least make me feel as though I was doing things right, and if I wasn't how to change it and do it slightly different. But then I soon realised that they weren't giving me any help whatsoever.*
>
> PCA–DI, id 28

This woman went on to describe HVs as being '*more like your Nanna telling you what to do*', and was very positive about the support from her GP.

Another woman also preferred the support of her GP: '*She is alright to say she is a HV but she is not the best I'd say*' (CBA–NI, id 4).

Woman's perception of the professional role

This section looks at how the role of the HV is perceived by women and it is particularly interesting to note the comments by the women who have had the intervention on how their preconceptions had changed.

One woman said:

> *I thought it was just snooping … that's what I thought health visiting was. It's trying to see if you're doing anything wrong with your children for social services … I didn't realise that it's … not about that, it's about keeping families together, not tearing them apart.*
>
> PCA–I, id 20

This view was echoed by another woman (CBA–I, id 10) who stated that before she would not have approached a HV for help because, '*You worry … you think the HV might think you're not coping*'. She highlights the fact that going to her doctor felt more '*comfortable … cos obviously I've been to him all my life*'. However, following the intervention she goes on to say, '*Had I known the support I would have got from the HV I know I would have done things differently*'.

Another stated:

> *Oh I think before the visits you don't really know them … if your baby's alright and you're alright … you only see them at assessments and things … I now know in the future if I've got any concerns, you know, I could just pick up the phone … yeah more confident towards them.*
>
> CBA–I, id 12

However, one woman would have liked more information about the role of the HV to facilitate appropriate access to the service.

There were comments on not knowing the function of the HV:

> *I don't really know what their job is … . Nobody gave me like the parameters of this role of the HV and so, I think if that happened then you'd … know what the function was … and sort of be able to use them better.*
>
> PCA–DI, id 11

The reported comments suggest that perhaps women should be given clearer information on the role of the HV.

Theme 4: Intervention or support

The women who received one of the two psychological interventions reported very positive experiences overall, placing particular emphasis on the importance of having the opportunity for one-to-one discussions with the HV. It appears that from the women's point of view the interventions have not only been 'acceptable' but also very successful.

Person-centred approach

Three of the five women made a comment on the nature of the approach. The HVs and the women tended to refer to them as 'listening visits'. For one woman it was very appropriate for her:

> *Yeah … she did help me through; she made me understand why I was feeling like that … I don't think I would be feeling like I am now if [HV] didn't have come … because I have mainly talked I think it's helped me in the fact that I can understand what I'm feeling rather than, er getting suggestions from other people … . It's helped me work out what I should do to make myself feel better.*
>
> PCA–I, id 29

Other women commented on the benefits of the intervention:

> *I owe so much to her [HV] and it's really brought out of me to be open and everything.*
>
> PCA–I, id 31

> *I think if my HV hadn't been phoning me frequently and coming to visit me, I think it made the difference between tipping over into being depressed and just being a little bit miserable and eventually pulling myself together. So I did think it made a huge difference.*
>
> PCA–I, id 13

> *[I] was grateful for that one-to-one time … [it] was very valuable for me and [baby].*
>
> PCA–I, id 3

This woman went on to describe the one-to-one time as being: '*For a purpose, specific, and an opportunity to talk about my issues*'.

However, one woman found the approach more difficult:

> *She [HV] explained about listening visits … but I actually struggled to talk cos I'd rather be challenged. I'd rather be asked questions … so I did explain to [HV] after the seventh one [visit] that I'm struggling to talk so it's not benefiting me … even though [HV] were ever so good.*
>
> PCA–I, id 26

This final comment perhaps shows the need for tailoring of any therapeutic approach to the needs of the individual.

The two women who were not offered the intervention had the same HV. One woman (PCA–NI, id 32) reported that she was told, '*If you don't feel any better, go and see your doctor*', whereas the other woman (PCA–NI, id 8) found the HV '*helpful*' when it came to practical advice but didn't see her as someone she would turn to for help with regards to '*feeling low*'.

Cognitive behavioural approach

The CBA group who received the intervention commented more on the specific components of the approach and how they interpreted the strategies being used, as well as making positive comments on the effect of the intervention:

> *But it was just talking about the relationship with my boyfriend and how I felt about baby and just talking through my week. What had helped. What hadn't helped. What I could try and do to make myself feel better. Just looking on positives rather than negatives … . Find the thought patterns that led down the wrong way.*
>
> CBA–I, id 17

This woman went on to describe the sheets she had to fill in at home:

> *there was … thought pattern sheets, like three a week. When you go angry think what's led you there, kind of thing, and work it backwards and then try and identify when it comes up again and try and intercept it before you get to the point of sitting and crying your eyes out.*
>
> CBA–I, id 17

Another woman commented that: '*We've analysed all the reasons why I've been down and depressed, how to sort of, challenge negative thoughts*' (CBA–I, id 10). She also describes how the HV helped her:

> *The worst time … I couldn't think about anything logically, whereas she sort of like focused me … it was also important that I don't feel like I'm being judged at all.*
>
> CBA–I, id 10

One woman (CBA–I, id 17) reported that, '*Just to have someone to sit and listen so you can just go "rah, rah, rah" and they go "right ok*" '. She described the sessions by saying '*it was more of a talk with a friend than a counselling session … it was really informal*'. She went on to comment that, '*Every time she left the house I always felt that bit brighter and that bit better*'.

Finally, another woman commented that, '*It's been absolutely brilliant*' (CBA–I, id 10).

Those women who were in the IG but who were not offered the intervention had very different experiences. This depended on whether they perceived themselves as being depressed. Overall they were positive about the support they received, which tended to be more practical in nature and focused more on the baby:

> *My HVs been really good for me … I used to go down to the baby clinic every 2 weeks to get [baby] weighed and whilst I was there I would say 'He's got a little bit of a cough, is that alright?' … and she was very good.*
>
> CBA–NI, id 22

Another woman (CBA –NI, id 18) had a more negative experience as she reported saying to her HV: '*We've coped with it fine, I needed your help then not now*'. She also went on to say: '*You know, you need the contact, somebody to talk to face to face, this is me, this is what's happening to me now*'.

One of the two women who declined the intervention stated: '*I didn't feel like talking to her. I didn't really know her that well so …*' (CBA–DI, id 4). She went to her GP for support. The second woman had an illness in the family and was too busy to have an intervention.

Treatment as usual – the control group

The CG experienced usual health visiting practice and their comments reflected the varied patterns

of practice. Those women who had experienced support from the HV, for example home visits and encouragement from the HV to phone when they needed to, reported the most positive experiences:

> *I can talk to her. I'm not frightened to say anything in front of her. It's not that she is going to judge me for how I'm feeling.*
>
> Control, id 24

> *She is very supportive and really it's good having someone that you can talk to about how you really feel.*
>
> Control, id 14

This woman goes on to comment that, '*She is not critical in anyway*' and '*She always made another appointment with me so I always knew that I was going to be seeing her again fairly soon*'. The HV also encouraged the woman to '*just ring*' if she had any worries or concerns.

Another woman commented that, '*And we just carried on talking and I were getting better as weeks went on*' (Control, id 19).

There were three women who received little or no support at all even though they reported that their HV was aware that they were having difficulties. It also seems that, for some, it depended on the personality and professional approach of the HV as one woman (Control, id 21) saw two HVs. The first she felt had dismissed her feelings and put it down to her '*being a new mum*'. The woman felt that she had a more positive experience with the second HV that she saw:

> *In fact she did what she said she was going to do. She said she'd get back to me and she did you know, she gave us alternatives … so for the three times I've seen her … she's been consistently thorough and I think she's done her best.*
>
> Control, id 21

Three women from this group reported that they had informed the HV that they were having difficulties but had little or no response.

One woman (Control, id 9) reported having very little contact even though she was on antidepressants and had told the HV about problems from her past. The woman seems to have been '*let down*' after confiding in her HV. She commented: '*They're always having to rush off*' and felt that there was no time for her. She had told the HV:

> *How I were feeling and things like that, and I told her what had happened in t'past and erm, she said a few things and that were about it and I haven't heard nowt from her since.*
>
> Control, id 9

One woman (Control, id 25) had burst into tears in front of the HV but felt she had little sympathy and commented, '*And I went out feeling twice as bad as when I went in*'. Another woman (Control, id 7) from the same practice stated, '*I did ask for support but I didn't really get any*', and goes on to say that she felt '*closed off*' by her HV:

> *I didn't really feel like the HV was very sympathetic really … and she didn't really pick up on indicators I was trying to give her. Because I said to her at one time, 'You know, I feel like I really can't cope' and she said, 'Oh you're doing alright'. I thought, 'I'm not actually', and that's even quite difficult to admit to yourself isn't it, that you're not coping with your baby?*

She also commented that she felt that the HV was '*too judgmental*'. This statement contrasts with some of the more positive comments from the group who received the intervention or who had a positive experience. It was important for them that the HV did not judge them and that they could feel free to say how they were feeling (see above).

Non-intervention support

Two women who had not been offered the intervention found support in new mums' groups:

> *I found it better … to go to the support group for the mums and talk to other mums … I found that by helping other people [with depression] that I was actually helping myself figure it out as well.*
>
> PCA–NI, id 28

> *Just to be able to talk to other mums and say, 'Yes I know what you mean'.*
>
> CBA–NI, id 1

Informal support

Often the informal support complimented the support that the women received from health professionals as it was more likely to be practical and often allowed the women time away from the baby/children.

> *My mum has been brilliant … she's sort of like had the baby for a couple of hours and let me sort of like get some sleep, so my mum in particular has been … my rock kind of thing.*
>
> CBA–I, id 10

He [partner] just been there for me every step of the way.

CBA–I, id 12

This woman also goes on to say that her parents and in-laws have been very supportive by having the children.

Other women mentioned sisters and friends and this informal type of support was most important to the women who were receiving little or no support from health professionals: '*She [HV] kept asking me how I were feeling, how I were coping but I just bottled all me feelings up*' (PCA–I, id 26).

Ideal support

All of the women in the IGs and those who received support in the CG thought that the support they had received was close to the ideal: '*There is no fault with the support I've had at all*' (Control, id 14). This woman felt that she had good support from both her HV and her GP.

Another woman commented that:

I think the HV is one of the best resources by far, erm, I think any kind of, form of counselling because although the tablets have definitely helped me I think the counselling side and the talking things through with the HV has been as good without a doubt for me personally.

CBA–I, id 10

She goes on to say that:

Something sort of like to make people aware that you know you can go to your health visitor and you can ask for help if you need it and … you know, just get over that stigma thing.

Other comments included:

I just hope from this trial that health visitors will be able to visit as they did me and more if needed, cos I do think it's important.

PCA–I, id 3

She was there from the first time she came round … I can't say I would have changed it

PCA–I, id 31

I think the same as what I've had really. You know, got support from your health visitor, GP, if you want that but I think the one-to-one would work.

PCA–I, id 29

The support my health visitor gave me was excellent, it really was, it made an enormous difference.

PCA–I, id 13

Only one woman from the IG commented that she would like the option of counselling:

Counselling … I think that would be brilliant. That is what, when I went to my doctor, that is what I would have preferred rather than giving me pills. I would have rather gone and talked to somebody and been able to sit and try and work through it rather than 'here, take a happy pill'. Because I didn't want to go on the antidepressants, I really didn't, but, it was a case of if I didn't my son was gonna suffer. So it was the only option. If I'd have had the option of a non-drug way rather than a drug way I would have gone for counselling rather than going on pills.

CBA–I, id 6

This woman had a positive intervention but felt that it was not 'proper' counselling as the intervention sessions were so informal.

Another woman (PCA–I, id 20) made an important point about getting to know the HV antenatally: '*I maybe think it would be a good idea if you met your HV more while you were pregnant to be honest*.' She goes on to explain:

10 days you're discharged from your midwife and that's the person you see in the community for 9 months and then suddenly it's someone else and everything's changed, everything's completely changed.

PCA–I, id 20

For those women who were not offered the intervention it was suggested that a form of counselling could be offered:

It would have been better for me if someone had said, 'I think we need to talk about this, do you want to speak to somebody?', or maybe some counselling … or maybe to get it off my chest with [HV's name], she's pushed for time a lot, we do questionnaires and that but obviously didn't have the time for me to sit there and say oh this has happened and that has happened, I think that would have helped, if I had just someone I could scream at.

CBA–NI, id 1

Health visitors who aren't like your Nanna, they like have counselling training and … they're able to listen to you … . All you want is someone to actually listen to what you're saying, even if it's complete

> *crap and it's all coming out wrong. You just want someone to say, 'It's alright, sit down and I'll listen to what you've got to say'. That would do you the world of good and I think it would actually stop people from developing worse symptoms because people just won't talk about it.*
>
> PCA–NI, id 28

This woman also suggested that evening visits would be helpful as this was often the worst time of day for her.

Another woman commented that:

> *I think what I would have liked is an opportunity to go and talk to some counsellor, probably. To go to somebody away from t'children … maybe gone to see somebody at the clinic or whatever, just not here, not with the kids and just have an opportunity to, say, 'actually' be honest about what I felt about 'em without fear of it being, you know, a child protection thing because that also … it's hard to admit to somebody that you hate your kids.*
>
> Control, id 7

Two women just wanted:

> *More support from my HV.*
>
> CBA–NI, id 4

> *If she'd [HV] just probably visited more often or was just more understanding and easier to talk to.*
>
> Control, id 25

One woman wanted to have more information about the HV role in advance and thought that women should be more informed about the service: '*I didn't know they can come to your house really*' (PCA–DI, id 11).

Two women did not mention the HV at all and wanted their support to come from the GP:

> *For them [GPs] to gi' ya more advice and actually listen to ya. Talk about things, I mean, I know they've only got a short time erm, but just be a bit more supportive.*
>
> PCA–I, id 26

> *I would want what I got from my GP.*
>
> CBA–NI, id 22

Postnatal groups were mentioned frequently by women as an 'ideal': '*I think more advice about groups, erm, postnatal groups or whatever*' (PCA–I, id 26). This woman also mentions family support.

One woman (PCA–I, id 3) would have liked to meet up with other mums and another was very enthusiastic about her experience in a group:

> *The absolutely fantastic thing about that surgery is they do a new mum group, which turned me around, it totally saved us, without a doubt, it was absolutely fantastic, I think it should be mandatory for all that they have to go to a group.*
>
> CBA–NI, id 18

Another woman commented that:

> *I think that something like the Sure Start PEEPS groups where you're going as a play thing anyway to meet other mums and if that was … more accessible then I think that I perhaps would have admitted or realised that something wasn't quite right earlier on.*
>
> Control, id 21

More specifically, several women stated that they would like to see groups for women with PND (CBA–I, id 12, and PCA–DI, id 11). One woman (PCA–NI, id 28) also suggested more support for those with existing mental health problems. Another thought: '*Talking to other mums that have gone through it and come out of it at the other end*' would be most helpful (Control, id 19).

One woman reported: '*I found it really good to listen to and to talk to other women*' (PCA–DI, id 11). This woman also suggested that perhaps antenatal classes should give women more time to discuss issues around PND so that they may feel more comfortable with them after the birth. In addition to this, one woman (PCA–NI, id 8) added that she would have liked there to be '*someone who had been through it [PND] before*' in attendance at her postnatal group. This view was supported by another woman although she thought that the information should be given antenatally:

> *I think it needs to be brought up before you have the child … to get somebody to talk about it who had had it … I'd love to go somewhere and speak to a group of people and tell them how I feel and that it can happen to you … . If somebody had come and spoke to me when I was pregnant with her [baby] I'd still probably think, 'I'm not going to get it', but it's nice to listen.*
>
> Control, id 24

One woman (CBA–NI, id 15) had previous episodes of depression and thought that there should be more information about the risk factors for PND. Other suggestions included having the

baby taken off her hands once a week, '*so you've got space to be yourself*', and she would have liked someone to '*come and talk to me*' and not to be given repeat prescriptions.

One woman (PCA–NI, id 30) would have liked someone to phone her, perhaps once a week, to ask her how she was doing, as she herself would find it difficult to make a call and ask for help. Another woman (PCA–NI, id 32) wanted a 24-hour helpline for when she was feeling really low.

Another woman commented that:

> *Make it a bit more personal if possible … maybe bit more spontaneous phone calls [from HV] or yer know, 'I've got half an hour free, can I just pop round?' or something.*
>
> CBA–DI, id 5

In fact, a key aspect of ideal support was the availability of someone to talk to, and those women who had been offered very little had low expectations. Support could come from either the GP or the HV: '*Just like, being on end of t' phone if you need to talk to them*' (Control, id 9).

Discussion

The qualitative aspect of this trial was intended to illuminate and add texture to the women's experiences of the HV support. The interviews produced rich data from a subsample of the overall data set representing the three main groups and the qualitative analyses were carried out without knowledge of the quantitative outcomes of the trial. Most of the interviewees reported some form of negative feelings and signs of distress. However, women experiencing depressive symptoms in the postnatal period appear reluctant to seek help as they have specific problems and fears and feel 'pressure' placed on them to cope.[229] This makes it intrinsically problematic for women to access help and for health professionals to identify when help is required.

Another barrier to help was women's perceptions of the HV and their relationship with the HV. It is widely accepted that empathy, acceptance and a non-judgemental attitude are important in establishing good therapeutic relationships.[230] The women in this study commented that aspects of the 'character' of the HV and a good relationship with the HV were influential in whether they revealed their feelings. Therefore, the outcomes of the support or intervention offered could also be affected by the 'personality' of the HV and the relationship between the HV and the woman. The women from the treatment as usual group were more likely to be positive about their HV if they had positive perceptions of the HV and the HV's role in supporting them.

The importance of the relationship with the HV was again apparent when HVs were using assessment measures such as the EPDS. The EPDS was generally well received by the women as it shifted the focus from the baby on to their own feelings. Women perceived the EPDS as an opportunity to talk about how they were feeling if they wanted to. It seems from these interviewees that the perception of the role of a HV and the relationship between the woman and her HV were key factors in whether they would open up. Many women felt that a HV was there for the baby and did not 'trust' their HV enough to open up to them. In fact, having an established relationship based on trust and a non-judgemental attitude seemed extremely important. This relationship could be with the HV, GP, partner or other mothers in postnatal groups. Understanding the role of the HV as someone who is there for them as well as their baby is therefore a key aspect.

For those women who had a good enough relationship with their HV to accept formal support, both the cognitive behavioural and person-centred approaches were very well received. A mother in the PCA arm did state in her interview that she would have preferred a more 'directive' approach but she completed seven sessions and appeared to have benefitted. There is no way of knowing if the improvements would have been greater if she had been offered a different approach. Despite opportunities for considerable HV input, and positive views of what they received, there was clearly a demand from some women for additional psychological input.

Conclusion

The interviews gave women the opportunity to tell their stories in their own words and generated valuable information about the acceptability of psychological interventions for PND. Those women who received the intervention felt that it was beneficial as a result of having time allocated specifically for them to talk about their feelings

and experiences. Women who had not been offered any support identified 'having someone to listen' to them as their ideal. The results suggest that greater clarity around the role of the HV in relation to the well-being of new mothers and not just their babies would be helpful. HV training may need to emphasise how difficult it may be for new mothers to be open about their feelings and provide information around the nature of the fears that impede their expression. Actively acknowledging these sorts of difficulties and common fears in a proactive way may facilitate more open expression. It is also the case that women's perceptions of the professional's personal characteristics are crucial, and an emphasis on training in the development of empathy and a non-judgemental approach may be of great benefit.

Chapter 7
Discussion

This study was a pragmatic cluster randomised trial of a complex intervention. This study has generated evidence of the pragmatic effectiveness of a package of training for HVs in primary care to identify depressive symptoms and provide a psychologically informed intervention.[231] We found a reduction in depressive symptoms among IG at-risk women as measured by the EPDS and a difference in secondary outcomes at 6 and 12 months postnatally among at-risk women.

We also found a difference in depressive symptoms between intervention and control group women in the follow-up of all consented women at 6 months and 1 year postnatally.

In addition, there was some evidence of a benefit in favour of the IG women for some of the secondary outcomes at 18 months' follow-up. Fewer women were followed up to 18 months, and the wide confidence intervals for the differences between the groups indicate that more uncertainty surrounds these outcomes.

Previous research

The trial has good internal and external validity and, considering all international publications on psychological interventions for women with PND,[148,232] this trial provides the most robust evidence of benefit, which previous studies in the treatment of PND were unable to provide. Previous studies of postnatal psychological interventions performed in Edinburgh,[1] Cambridge[2] and Manchester[3] showed positive short-term benefits for women but failed to provide good evidence to guide treatment recommendations. Small, non-representative sample size, attrition and brief follow-up limited these studies. The PoNDER trial has addressed these limitations and had more than twice as many participants as the previous largest study.[2] This is the only rigorously performed trial that followed up postnatal women to 18 months, as the final outcome in most previous studies of PND was measured at 1–3 months postnatally.[3] Furthermore, it is the only trial to incorporate an economic evaluation. As such, it is the first major investigation of this type.

Clusters

The trial achieved the required number of clusters as determined by the pre-trial sample size calculation. The IMD scores and other characteristics of recruited clusters showed that the collaborating GP practices were representative of those in the former Trent region and England as a whole, indicating good external validity.

The HVs who took part in the trial were interested in PND, research and accessing the training provided as part of the research. As such they were not all highly skilled in assessing women and offering effective support. The pre-trial HV questionnaire indicated a wide range of previous training in identifying and supporting women with PND, and a range of experience in administering the EPDS. This reflected varying activity among HVs and PCTs seeking to address the problem of PND. The HVs in the PoNDER trial had perhaps less access to training and other formal mechanisms for managing PND than the HVs who provided data for an audit of the wider CPHVA membership.[96] However, it is unclear how well the CPHVA or the PoNDER trial HVs' responses represented HVs nationally. As we have no suitable comparison with the wider HV population to comment accurately on external validity for this aspect, a national survey of HVs to assess their knowledge and skills and beliefs concerning the causes of psychological problems[203] would clarify the generalisability of the results. However, we believe the HVs represented a range of individual and professional characteristics, which were distributed equally among all groups.

Individual women

The pre-trial sample size calculation estimated that 50% of women might consent to take part. Over the recruitment phase 4084 (53.3%) eligible women did consent to take part and 3436 completed a 6-week postal questionnaire.

The women who did complete and return all of the instruments in the postal questionnaires at 6 weeks and 6, 12 and 18 months postnatally provide

a possibly unique insight into the natural history of symptoms of depression and postnatal health over time in the CG. The return rates at all follow-up time points indicated that the participating women were highly committed to the research and willing to offer their time to support the trial.

Because the HVs collected demographic details of all pregnant women on their caseload, we could compare the features of the women who consented with those of the women who declined to participate and with those of women in England and Wales in 2001.[212] The characteristics of women in the study were broadly similar to those of women in England and Wales, where 91% of the population were recorded as white British versus 94.2% of respondents versus 93.0% of the 8716 who were eligible. In total, 69% of women in England and Wales lived in owner-occupied accommodation[212] versus 71.8% of eligible women. Women from culturally diverse groups, those not fluent in English and women who had difficulty responding to a postal administration of EPDS or assessment of PND were not wholly represented.

Some HVs thought that women who had been previously affected by PND might not consent to take part in the trial, but this was not the case. A total of 17.3% (595/3449) of postnatal women in the PoNDER study compared with 18% (48/266) of CG postnatal women in an earlier trial of postnatal care[146] had a 6-week EPDS score ≥ 12. We believe that the PoNDER study women were representative of women experiencing PND in real-world primary care. The similar characteristics of the at-risk women in the IG and CG indicated that the stratified randomisation process was very effective, imparting good internal validity.

Six-month primary outcome

The primary objective of the study was achieved by identifying a group of at-risk women with a 6-week EPDS score ≥ 12. The pre-trial sample size calculation was based on detecting an absolute difference of 15% (this is approximately equivalent to an odds ratio of 0.54) in the proportions of at-risk women with a 6-month EPDS score ≥ 12 [i.e. a minimum clinically important difference (MCID) of 15%]. We observed a statistically significant but smaller absolute difference (11.7%) than our anticipated MCID between the intervention and control group at-risk women in the proportions with a 6-month EPDS score ≥ 12 (the primary outcome). The 95% confidence interval suggests that the true treatment difference lies between 0.4% and 22.9%. Therefore, it is consistent with the data that the true treatment effect, although statistically significant, may be small and potentially not very clinically important. We are therefore unable to confirm or exclude our a priori clinically important effect of 15%.

Secondary outcomes

At 6 months the difference in the mean EPDS scores and other secondary outcomes, apart from the SF-12 PCS and the CORE-OM risk scores, reflected the results from the primary analysis. Most of the differences between the IG and CG at-risk women observed at 6 months postnatally were maintained over time, with some 'plateauing' towards 18 months postnatally. In addition to an enduring positive impact on the woman's health, there appears to have been a positive impact on the woman's interaction with her infant, as measured by the PSI.

Secondary outcomes were also measured in the follow-up of all women who consented to take part in the study at the same time points as those studied in the at-risk women. An interesting, unexpected finding was that the effect of the intervention was demonstrated not only in the at-risk women but also in the group of all women followed up as randomised, at 6 and 12 months postnatally, indicating some non-specific effect from the HV intervention extending beyond the at-risk women.

Contrasting benefits of the two psychological approaches

There was a 2.2% difference between the CBA (32.9%) and the PCA (35.1%) groups in the proportion of women who had a 6-month EPDS score ≥ 12 (95% CI –14.2% to 10.1%, $p = 0.74$). This type of finding is consistent with findings from the literature on psychological therapies, that different models of intervention result in broadly similar outcomes despite differences in theoretical bases and the style of intervention delivered. This is known as the equivalence paradox.[233] For example, a primary care trial for patients with depression comparing brief NDC and CBT[7] found no significant difference in outcomes at 4 months leading to the conclusion that both interventions were equally effective in this setting to this follow-up point. Similar effects have been found in large

data sets comparing person centred therapy and CBT in routine NHS primary care settings.[234]

Economic analysis

The economic evaluation found that for the at-risk women the HV intervention was cost-effective over the HV usual care, and as such might be recommended by NICE.[217] The CBA had the highest probability of being cost-effective. In the range of QALY values between £20,000 and £30,000, the probability of CBA being cost-effective was just over 70%.

Administration of the EPDS face-to-face or postally

Just as no real difference was observed between the CBA group and the PCA group, there was no evidence to suggest that there was a benefit in outcome for any of the four separate CBA-F, CBA-P, PCA-F and PCA-F groups. Further disaggregations in the economic evaluation indicated that the face-to-face administration, in conjunction with the CBA intervention, might be more likely to be cost-effective.

Infant outcomes

With new mothers the earlier any benefit in postnatal health can be achieved, the sooner any potential negative impact on the infant can be ameliorated. We planned to use the Ainsworth[235] and Bailey[236] scales to monitor infant outcomes but were advised that the videotape analysis would be too costly and so this element of the trial was not funded.

From the women's responses to the questions on infants, we observed some evidence that women in the IG had fewer concerns about the development of their infants than those in the CG at 18 months. For the at-risk women, the mean aggregate infant outcome concern score (where a higher score indicates greater concern) was 19.4 (SD 6.1) for 37 women in the CG and 16.5 (SD 5.4) for the 73 women in the IG. The mean difference was –2.9 (95% CI –5.0 to –0.7, $p = 0.008$).

It is important to note that the infant outcomes were based upon maternal self-report without any independent observations. Women with depression may perceive their infants differently, or an infant may interact differently with a mother who has been depressed. The infant behaviour may also indicate a two-way interaction. The instruments used to monitor infant outcomes were not well-validated tools, but the BSQ has been used in a previous study of infant outcomes,[39] in which the greatest effect appeared to be in reducing the mother's perception of her infant's temper tantrums. The suggestion of a positive effect on the IG women's perceptions of their infants at 18 months postnatally compared with the CG was not confirmed by the partners' responses.

Partner outcomes

There appeared to be little difference in partner outcomes between the IG and the CG except in some domains at 18 months postnatally. This corresponds to the time when partners are more likely to take an active role in interacting with and caring for the infant. The partner outcomes were not straightforward but provided some evidence of a benefit. This may simply reflect the benefit we observed in the IG women.

p-Values

Some caution should be applied in the interpretation of the statistical *p*-values, particularly for the various secondary outcomes and end points because of the number of tests. As there is no general consensus on what procedure to adopt to allow for multiple comparisons[198] we have reported unadjusted *p*-values and confidence limits.

Intracluster correlation coefficient

The ICC derived from the stratified clusters for the at-risk women in the trial (0.037), although higher than the estimate (0.006) used in the original sample size calculation, indicated little clustering. The number of at-risk women needed to treat, derived from the absolute risk, was moderately good in this context.[237]

Potential sources of bias

The trial was designed specifically to minimise the effect of chance, contamination and bias. In a cluster randomised trial, in which there can be differential recruitment to clusters, it is vital to

address the question of selection bias. In the trial the possibility of selection bias was minimised as the coded random allocation list was prepared by a statistician who was unaware of the identity of the HVs and the GPs, and the allocation to group was concealed from the participating HVs and GPs until they had signed their consent forms.

Blinding

Blinding of the intervention was not possible, but the statistician and the health economist were initially blinded to the women's allocation to group for the data analysis. The SCAN interviewers were blinded to both the women's EPDS scores and group.

Differential loss to follow-up

The 30% of women lost to follow-up were evenly distributed across the clusters and there was a limited dropout of the clusters. In total, 101 clusters were randomised and 86 clusters provided data for the primary analysis of 418 at-risk women. The average cluster size was 4.9 women, ranging from one to 15 at-risk women per cluster, and 85% (86/101) of clusters recruited to the trial were still included in the final primary analysis.

We explored the possibility that the higher reply rate among the CG at-risk women may have exerted a bias at the 6-month follow-up. A comparison of the 6-week EPDS scores of the women who did not return a 6-month EPDS with the 6-week EPDS scores of those who did showed that the mean EPDS was 16.2 (SD 3.6) in the IG and 15.1 (SD 2.9) in the CG, suggesting that the difference in non-reply rate may have biased the unadjusted results. However, we adjusted the 6-month comparisons for the 6-week EPDS scores.

Sensitivity analysis

Overall the sensitivity analysis and imputation of the missing 6-month EPDS scores for the 177/595 (29.7%) women who were lost to follow-up suggested that there may be a possibility of attrition bias, although the regression imputation method suggested that this bias on the estimated treatment effect may not be too large.

Potential effect of SCAN interviews

Unlike the IG at-risk women, none of the CG at-risk women were invited for a SCAN interview until 18 months postnatally. Although there is no reported evidence of a therapeutic benefit[238] from SCAN interviews, we explored the possibility of potential bias introduced by a therapeutic effect of the SCAN interviews in the IG lasting 1 year. There were no differences in the mean scores of at-risk women who had or did not have a SCAN interview, making any SCAN therapeutic effect unlikely.

Potential effect of antidepressants

For the 31 IG at-risk women who had an outcome of moderate or severe depression on the SCAN interview, 26 accepted the psychological intervention sessions, one declined and 45% (14/31) also had a prescription for an SSRI. However, this was not exclusive to the IG, as the resource use logs indicated that CG women were also offered antidepressants. In total, 36.8% (46/125) of CG women said that they had been prescribed an antidepressant versus 28.5% (61/214) of IG women, suggesting that the greater improvement in the IG was not attributable to a higher rate of prescriptions for antidepressants.

Six-week EPDS scores and the SCAN

A secondary objective was to use the SCAN[168] data to correctly classify IG at-risk women as having none, mild, moderate or severe depression. It was also possible to investigate how well the EPDS administered in a primary care setting identified depressive symptoms in women who were depressed according to the SCAN classification. In total, 3.6% (18/505) of lower-risk women with a 6-week EPDS score of < 12 were classified as depressed, indicating that a single administration of the EPDS did not identify all at-risk women. Unexpectedly, 67.7% (239/353) of at-risk women who had a SCAN interview were not classified as depressed, confirming the value of an 8-week second administration of the EPDS. We were aware before the trial began that the EPDS needed to be evaluated for routine use in primary care.[57] However, we were not aware of any other tool at the start of the trial that could confer advantages over the EPDS.

The identification of women with anxiety and depression, generalised anxiety disorder, depersonalisation syndrome, nightmares, non-organic insomnia, or panic disorder or other diagnostic outcomes highlighted that postnatal women experience other distressing mental health conditions postnatally and not just symptoms of depression.

The sensitivity of the EPDS in the PoNDER study, using the SCAN data, was lower than in the original validation study.[178] The positive predictive value was also lower than the positive predictive values in both of the other validation studies (*Table 69*).[8,9] The first study was based on a sample of women who were believed to be depressed.[8] The other larger study[9] was on a community sample of 702 primiparous women in Cambridge and compared the EPDS scores with the outcomes of a Standardised Psychiatric Interview. The PoNDER study data are derived from a larger sample ($n = 860$) of women from a geographically and socioeconomically broader sample of not only primiparous women.

At a threshold of 12 the EPDS at 6 weeks picked up symptoms that were self-reported as being present in the previous week and that were perhaps transient according to the SCAN interview at 7 weeks (which explores the previous 4 weeks in a clinical semistructured interview assessment of depressive symptoms). When the SCAN has been used in general population surveys, the prevalence of depression (mild, moderate or severe) is 2–3% (higher in women), whereas the threshold of 12 recommended for the EPDS typically classifies about 12% of women. Further evaluation using receiver operator characteristic (ROC) analysis is planned for the PoNDER study EPDS data and SCAN data to establish an optimal cut-off point.

Sensitivity and specificity are usually fixed properties of a test and do not change with the sample or population and the underlying prevalence of the disease. Positive predictive values and negative predictive values (predictive value of a negative test result) vary according to the prevalence of a disease in a population and therefore do change. In the trial, women with an EPDS score ≥ 12 had a 33% chance of being depressed (as indicated by the gold standard SCAN interview). In contrast, the negative predictive value was about 93%. Therefore, women who scored < 12 were highly likely to be not depressed. The EPDS is not an ideal outcome measure for comparing the incidence of true depression; however, the comparison between the groups was not affected by this, as the EPDS cut-off was the same for all groups.

Within the trial we needed to use the results from the first administration of the EPDS to identify a group of women with whom a direct comparison could be made in the intervention and control groups without contaminating the usual care provided in the CG. No pragmatic evidence was available on the proportions of women who would score < 12 on a second administration of the EPDS. What the results probably mean for everyday practice is that HVs should readminister the EPDS 2 weeks after the first administration, to select out those who are not depressed. Administering once only at 8 weeks postnatally would limit the possibility of early intervention for women who are moderately or severely depressed.

Health visitor training

The IG HVs were satisfied with the introductory day training and felt that the presentations for the background, EPDS, clinical interview, risk management and skills development were good. The IG HVs were also very positive about the 5 core training days, although the CBA HVs seemed to find the training more difficult than the PCA

TABLE 69 *Sensitivity, specificity and positive predictive value of the EPDS for the PoNDER trial compared with other validation studies*

Study and EPDS threshold	Sensitivity	Specificity	Positive predictive value
The PoNDER study, EPDS ≥ 12	0.791	0.755	32.7%
The PoNDER study, EPDS ≥ 13	0.866	0.671	37.3%
Validation study, EPDS ≥ 12.5[8]	0.86	0.78	78%
Validation study, EPDS ≥ 12[9]	0.677	0.925	66.7%

HVs. In anticipation of little difference in clinical outcomes between the two main IGs, we aimed to capture important differences where they existed to supplement the data. The changes in the OPP scores from baseline to post trial indicated that the CBA and PCA group HVs had assimilated the principles of their training.

The HVs reported marked differences in their approach following the training in providing psychological sessions; they said that they had become more confident and more perceptive within any setting. They believed that both the CBA and the PCA training had been excellent. It is not easy to determine which aspects of psychological sessions are effective, as when interventions from efficacy studies are transferred to a real-world situation other non-specific variables may modify the effect. There is, for example, variability in the practitioner offering a psychological intervention, the context and the natural course of the condition in each client receiving psychological sessions.

One important aspect of the HV training was that it appeared to have had an impact on the pattern of health visiting. In particular, the overall level of visits reduced (although this was not statistically significant), with the greatest reduction seen in the visits to the mother that were not related to PND. The level of visiting relating to PND was the same in both the intervention and control groups. This made it difficult to identify an effect specific to the delivery of care relating to PND. Although the training seemed to have altered visiting patterns we can only postulate as to why these changes occurred and their related therapeutic effects. Therefore, although these changes are consistent with a hypothesis of training being associated with more targeted health visiting and better quality PND care, the study can not lend any evidence in support of this.

Agnew Relationship Measure Short Form

The completed ARMs indicated that the women felt confident in their HVs and developed a facilitative relationship with them. Moreover, the high ARM scores, compared with those from other studies, indicated that following a brief training the HVs in both IGs were good at establishing a high-quality, warm, therapeutic relationship as rated by the women, with no significant differences between the two groups. This is despite evidence suggesting that CBT interventions are associated with a stronger alliance than psychodynamic–interpersonal interventions.[239] The ARM Short Form scores being lower for HVs than for women mirrors results from the wider psychotherapy literature showing divergence between client and therapist ratings using the ARM Short Form.[240] A meta-analysis of 79 studies[214] showed a modest but consistent relationship between therapeutic alliance and clinical outcome ($r = 0.22$). Clients' rather than therapists' ratings seem to be the most predictive of outcome.[241]

Adherence and audiotapes

Health visitor sessions were audiotaped to allow an independent assessment for treatment adherence. HVs providing intervention visits were generally reluctant to tape record their intervention visits because they felt uncomfortable doing so, were protective of their clients and also felt that the tape recording might adversely affect the nature of the intervention session. Some women chose not to consent to have their sessions tape recorded. We might assume that the HVs who submitted completed tapes were more confident than others who did not do so, but there were no differences between the CBA and PCA groups in this respect. We cannot extrapolate the results beyond those who submitted tapes. Despite the possibility of a bias towards the more confident HVs, it seems that HVs who submitted tapes did deliver two distinct identifiable interventions, in line with their original training. These results offer some indication that, following brief training, HVs delivered two distinct psychologically informed interventions and adhered to the intervention that they were trained to deliver. The failure to obtain enough tapes suggests that those providing psychological intervention sessions in a research context should be better prepared. There should be further work to explore the barriers to their use within psychological therapy trials more generally, such as perceived threats of exposure. This could be improved in future HTA trials by assessing implementation intentions.

Eight-week EPDS administration

The HVs failed to deliver the protocol as required, for many reasons. Despite the best efforts of the LCs and the principal investigator to implement the HV protocol, the HVs were not all obliging. The absence of 29% of the 8-week EPDS scores

in the research context was clearly an undesirable consequence of a pragmatic trial.

This was not an explanatory trial and it is likely that in a real-world clinical context HVs would not always be able to administer a repeat EPDS for a range of practical reasons. Some of the at-risk women in the PoNDER trial chose not to complete it as they were feeling better or were unavailable, for example in hospital or staying away with their own mother. When a HV was absent on holiday or on sick leave, if they did not have a colleague trained in the use of the EPDS, the ideal follow-up assessment time was missed.

The aim of identifying depression at 6 weeks postnatally is to intervene as soon as possible for the benefit of the mother, infant and family. The SCAN data supported the finding that around 67% of at-risk women were not depressed. The HVs' focus group feedback was that they felt that this was because at 6 weeks postnatally the EPDS picked up some transient symptoms. The HVs suggested that administering the EPDS for the first time at 8 weeks postnatally, once the women had begun to recover from some early postnatal exhaustion, then repeating it after 2 weeks, might more correctly indicate the women who were truly depressed. This time point would coincide with some improvement in postnatal physical health symptoms associated with depressive symptoms.[242] The association between physical postnatal disorders and depressive symptoms should be systematically evaluated in the context of identifying true depression postnatally.

Psychological intervention sessions

The SCAN outcomes and the proportion of at-risk women who had an 8-week EPDS < 12 indicated that, at 6–8 weeks postnatally, fewer at-risk women than expected were depressed. Overall, about half (197/404) of all of the IG at-risk women were offered sessions, and when there was a raised 8-week EPDS, 88% (99/113) of women were offered sessions.

Health visitors were able to use the combination of the women's EPDS scores and their own assessment skills in their decisions to offer sessions to those IG women who, in their clinical judgement, were assessed as being likely to benefit from the sessions, as opposed to the requirements of the protocol for two EPDS scores ≥ 12. Rather than to increase the acceptability of the trial to HVs, this was because the HV training highlighted the limitations of the EPDS and that it was likely that some women with an EPDS score < 12 would be depressed. The study SCAN data confirmed this likelihood. It would have been unethical to withhold from a women a potentially effective intervention when a specially trained HV had identified clinical symptoms. When there was no 8-week EPDS, 31% (36/118) of women were offered sessions. That is, the absence of the 8-week EPDS score suggests that the HV 8-week face-to-face clinical assessment dominated the decision to offer the sessions. When the 8-week EPDS was < 12, 36% (62/173) of women were still offered sessions.

Of the women who had a SCAN interview, there were 6% (20/315) with an outcome of depression who were not offered sessions. Five of these women were prescribed an antidepressant, three attended a postnatal group and all of the others had a face-to-face administered 6-week or 8-week EPDS score < 12. This indicates some possible error due to a reliance on the face-to-face administered EPDS score.

Some women were not offered sessions as they were accessing other support. The HVs remained in close contact with the women and continued to see them when they attended well-baby clinics or accessed other supportive mothers via a baby massage or postnatal support group. This is perhaps a unique feature of the intervention, that the HVs could continue to observe the women's progress, were generally aware of facilitating and impeding features and changes in the women's lives, such as the departure of an abusive partner, and had an understanding of some factors affecting the women's moods. That is, the HVs could still see the women as part of their usual care, rather than having to plan to see women in a formal session, as indicated in the protocol.

For those women who declined the sessions, the knowledge that the HV was aware of their problem and had offered sessions may in itself have been perceived as support. The HVs did explain to the women that they were able to return at any time to access further support when they felt that they required it, and many HVs reported that this happened 4–6 months postnatally, and sometimes later too.

The sessions offered to women may not have been acceptable for several reasons. Having a professional to talk to is regarded by women

internationally as being important in helping them to recover from PND (for those who believe that professional help is appropriate).[243] However, reviews of women's views on treatments for PND,[244] and the impediments to women seeking help,[245] provide consistent accounts that: women are reluctant to accept that they have a problem with depression; they avoid approaching health-care professionals for help; and they are reluctant to tell health-care professionals that they have a problem. Women remain concerned about stigma, and they perceive other social pressures and particularly a threat that their infant will be removed from them if they admit to being depressed.[245] An important influence on whether a woman accepts treatment is the nature of the relationship between the woman and the health professional.[245] The importance of a trusting relationship with the HV was identified during the qualitative interviews. In practical terms, postnatal women also find appointments inconvenient or they do not have time because of childcare responsibilities.[244]

Qualitative interviews

These interviews indicated that, when they were received, the women valued the HV sessions. Although different models have specific effects, all models of therapy contain non-specific effects or common factors, such as warmth and feeling supported. The interviews indicated that the women were more likely to accept the intervention if they felt that they had a trusting relationship with the HV. The importance of the HV as a 'known' individual implies the desirability of antenatal contact. Future HV training should also include approaches to ensure that mothers perceive them as empathic and non-judgemental. HVs should also be trained to: present the role of the HV more clearly in relation to the well-being of mothers (not just the baby); discuss expectations of HVs by new mothers; and acknowledge the common fears of new mothers and how frequently mothers find it difficult to reveal their true feelings.

Interpretation

Six-month data were available for 395 IG at-risk women and, although it is likely that many of these women were not depressed, 50% (197/395) were offered psychological sessions. Of the 197 women who were offered sessions, 61.4% (121/197) accepted and 38.6% (76/197) declined. There were 259 intervention sessions delivered in the CBA group and 242 intervention sessions delivered in the PCA group.

The positive effect on the primary outcome arose in the IG despite the small number of psychological sessions accepted by the IG at-risk women and even fewer received by the lower-risk women. It is important to recognise that psychological interventions are not dichotomies in the context of continuing care. The positive effect overall may have been the result of a general improvement in HV care for women with PND.

The actions of some HVs in not uniformly following the protocol as required, that is, not administering the 8-week EPDS or not offering the sessions as indicated by the protocol, may have diluted some of the potential overall effect of the sessions and compromised the interpretation about the effectiveness, uptake and acceptability by the women (some qualitative data on this issue are provided). However, HVs, as with other clinicians, hold clinical autonomy and there is no degree of external control and, as a pragmatic trial, the HVs' actions may have been representing what would happen in real-world primary care.

For the reasons stated below, one interpretation of this effect is that the IG HVs were operating differently overall to the CG HVs to produce the positive outcomes in the IG women and that the non-specific effect enhanced the effect of the small number of psychological sessions accepted by the at-risk women. Again, although the outcomes are consistent with the hypothesis of a non-specific effect we cannot provide direct evidence for this.

That is, the effect may have arisen in association with the package of IG HV training, comprising many components that are difficult to separate, any of which might affect the emotional status of pregnant women and new mothers. The HV intervention comprised all the newly acquired skills that the HVs developed as part of the pre-trial training in assessing women, identifying depressive symptoms and delivering the psychological intervention sessions.

The IG HVs also reported that they felt that PND had become destigmatised in their practices, generating a lot of discussion among the whole practice team. Taking part in the research included an antenatal contact for recruitment (which was common to the CG as well as the IG). The IG HVs felt that this established an early relationship for the 6-week postnatal assessment in the woman's

home and meant that women were more receptive. The HVs also felt that the professional–client role had been enhanced, as a better rapport developed with the women during the home visits to administer the EPDS at 6 and 8 weeks postnatally. The importance of this was echoed in the women's replies in the qualitative analysis.

The HVs explained their role in PND so that the women would feel that attention was given to them rather than solely to the baby. The HVs said that the women felt that they were concerned about them as the focus had shifted from the baby to the mothers themselves. Also, the HVs felt that women were more able to ask for support and accessed more support than they may have done in the past.

The non-specific effect suggested by the results for the cohort of all women could be due to measurement bias or the delivery of a small number of psychological intervention sessions to a few women who were not at-risk women.

We believe that the training enhanced the IG HV role and it is also feasible that HVs in the CG were affected by participating in the trial. This may have been as a result of their additional reading or accessing additional training whilst collaborating in the trial, but we are unable to confirm this.

Summary of the strengths and weaknesses

The strengths of the study are related to the sample size achieved, the good internal validity and the precision of the results. The trial was conducted in a pragmatic setting and used a combination of quantitative and qualitative methods and an economic evaluation. There was support from participating HVs and an apparent measurable effect of the intervention on the primary outcome.

However, there are weaknesses, many beyond the control of the investigators. These include non-adherence to the protocol by HVs not administering the 8-week EPDS and loss to follow-up at 6, 12 and 18 months postnatally. This is distinct from the absence of 12- and 18-month follow-up data due to censoring by an end to the funding of the trial.

A further weakness was that, by not adhering to the protocol and offering the sessions as required, fewer women than expected were offered sessions, compounded by the number of women who declined the formal sessions. Furthermore, some HVs failed to complete the audiotapes of all of the sessions which took place.

Recommendations for further research

There are gaps remaining in the evidence about the assessment of postnatal women and the identification and management of depressive symptoms. The following areas should be investigated:

1. As a priority, further research should explore how to improve HVs' accurate identification of symptoms of depression, anxiety and other mental health problems experienced by postnatal women. This might include further analysis of our existing data set, the revision of guidance on the use of the EPDS or the development of a new instrument, to be validated in a primary care setting and confirmed with a clinical interview.
2. Further analysis of our existing data set is needed to explore the features of women who declined HV psychological sessions, followed by qualitative work to understand what postnatal women perceive as being the requirements of HVs for the development of high-quality, warm, trusting and therapeutic relationships.
3. The trial was not designed to detect the unexpected non-specific effect of the HV intervention on all women as randomised. This observation should be tested in a trial focused on this issue to determine the mechanism of the effect by comparing the outcomes for all pregnant and postnatal women who receive usual HV care, with a brief intervention provided antenatally for all women in one group and a brief intervention provided postnatally for all women in another group, using a clinical interview at follow-up.
4. There should be a detailed study to find out whether women's partners and their own mothers can help in the identification of depression and anxiety symptoms and whether non-professional support networks or other facilitating features can help minimise the development of postnatal mental health problems or help postnatal women with these problems recover more quickly. This could be a trial and economic evaluation of the provision of information and skills to the families of antenatal women compared with usual care.

5. The results presented here showed that the HV intervention was cost-effective with the main provisos relating to missing data and the treatment of clustering in the analysis. Our approach in the economic evaluation was consistent with the clinical analysis in this report and typical of most published economic evaluations. However, other viewpoints are possible and alternative approaches feasible. For example, adopting a Bayesian approach within WinBUGs could address the missing data and clustering issues. We propose that these analyses should be the subject of future research.
6. One further approach would be the reformulation of the economic evaluation into a cost-effectiveness model to allow a more structured approach to address policy questions, with the improved ability to look at longer-term costs within a modelling framework. This could form the basis of a value of information analysis that could identify systematically the areas of key importance to the policy decision and hence the priorities for future research.

Summary

The PoNDER study recruited the number of clusters and postnatal women required by the trial. The GP clusters and HVs were representative of those in England and Wales. A cohort of postnatal women representative of women experiencing postnatal depressive symptoms in real-world primary care was followed up from 6 to 18 months postnatally.

The HVs did not all adhere to the trial protocol requiring a repeat 8-week EPDS for all at-risk women and the provision of psychological sessions for all women with an 8-week EPDS score ≥ 12.

The SCAN data and the available 8-week EPDS scores indicated that more than half of the at-risk women were probably not depressed. This partly explains why HVs did not provide psychological sessions to all at-risk women. Using a threshold of 12 on the EPDS alone cannot be recommended for routine use at 6 weeks postnatally to determine which women might be offered psychological sessions.

At 6 months the trial observed a statistically significant difference between the proportions of CG women (45.6%) and IG women (33.9%) who had a 6-month EPDS score ≥ 12 (difference 11.7%, 95% CI 0.4 to 22.9%, $p = 0.036$). The point estimate is statistically not clinically significant, although the confidence interval includes a difference that would be clinically significant, and we are unable to confirm or exclude our a priori clinically important effect of 15%.

In total, 32.9% of CBA group women had a 6-month EPDS score ≥ 12, compared with 35.1% of PCA group women (difference 2.2%, 95% CI –14.2% to 10.1%, $p = 0.74$).

There were statistically significant differences between the intervention and control group at-risk women in mean secondary outcome scores.

In the cohort of all consented women followed up, 16.4% of CG women had a 6-month EPDS score ≥ 12, compared with 11.7% of women in the IG (difference 4.7%, 95% CI 0.7 to 8.6%, $p = 0.003$).

The unexpected non-specific effect of the HV intervention is suggested by the results for the cohort of all women who consented to take part in the study. Also, a non-specific effect is suggested by the results for the at-risk women, of whom less than one-third received the psychological sessions, and could indicate that the HVs offered enhanced postnatal care to the women in the study.

There was an indication of a benefit in the IG women's perceptions of some of their infants' behaviour at 18 months postnatally and some indication of a difference in the partners' mean scores at 18 months postnatally.

Conclusion

This is the only large trial of a HV intervention for PND based in routine primary care. Brief training for HVs to both systematically identify women with symptoms of PND and deliver psychologically based sessions appeared to benefit postnatal women in their care.

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Appendix 1

Participant flow charts

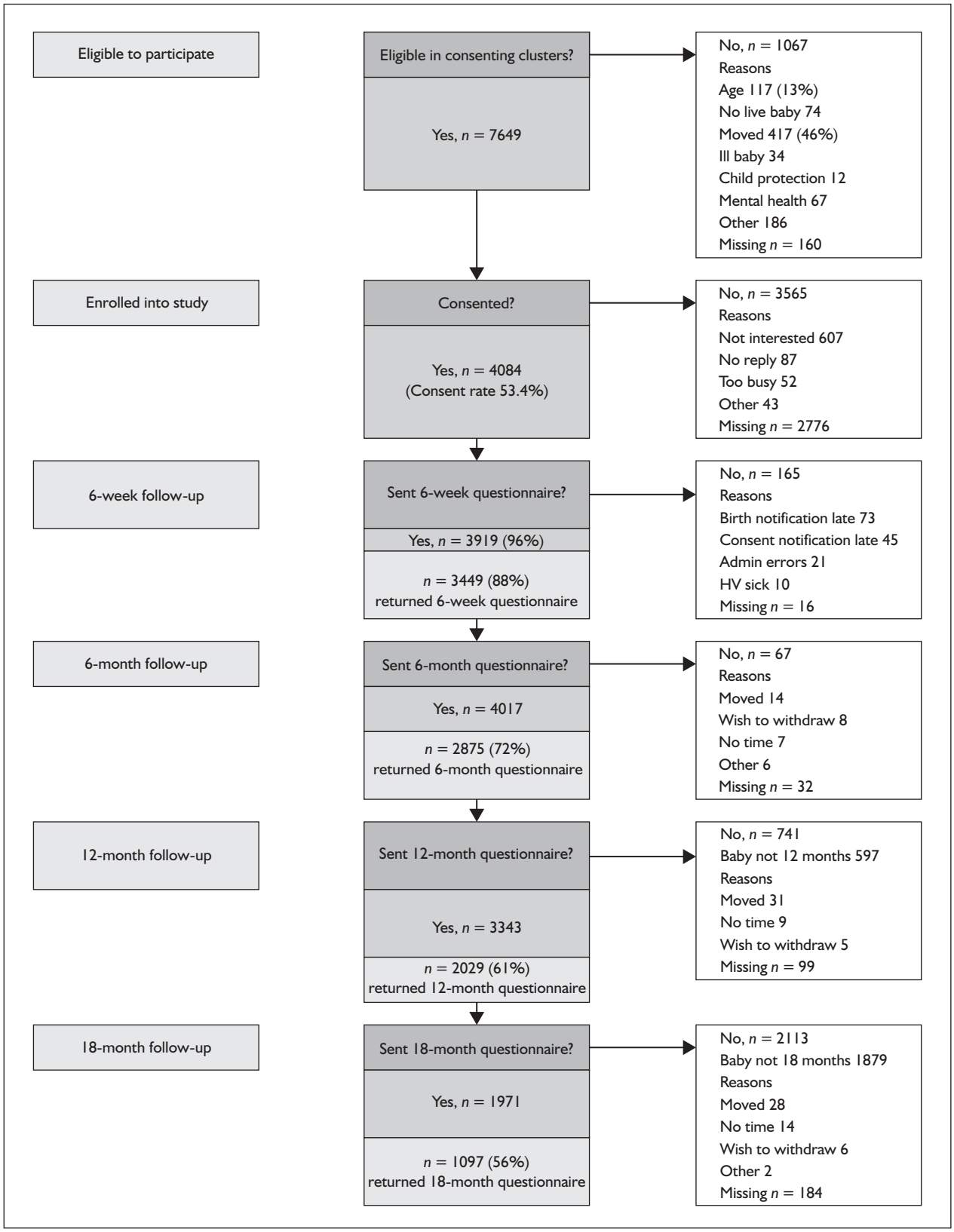

FIGURE 27 *Overall participant flow chart for 8716 pregnant women in all clusters.*

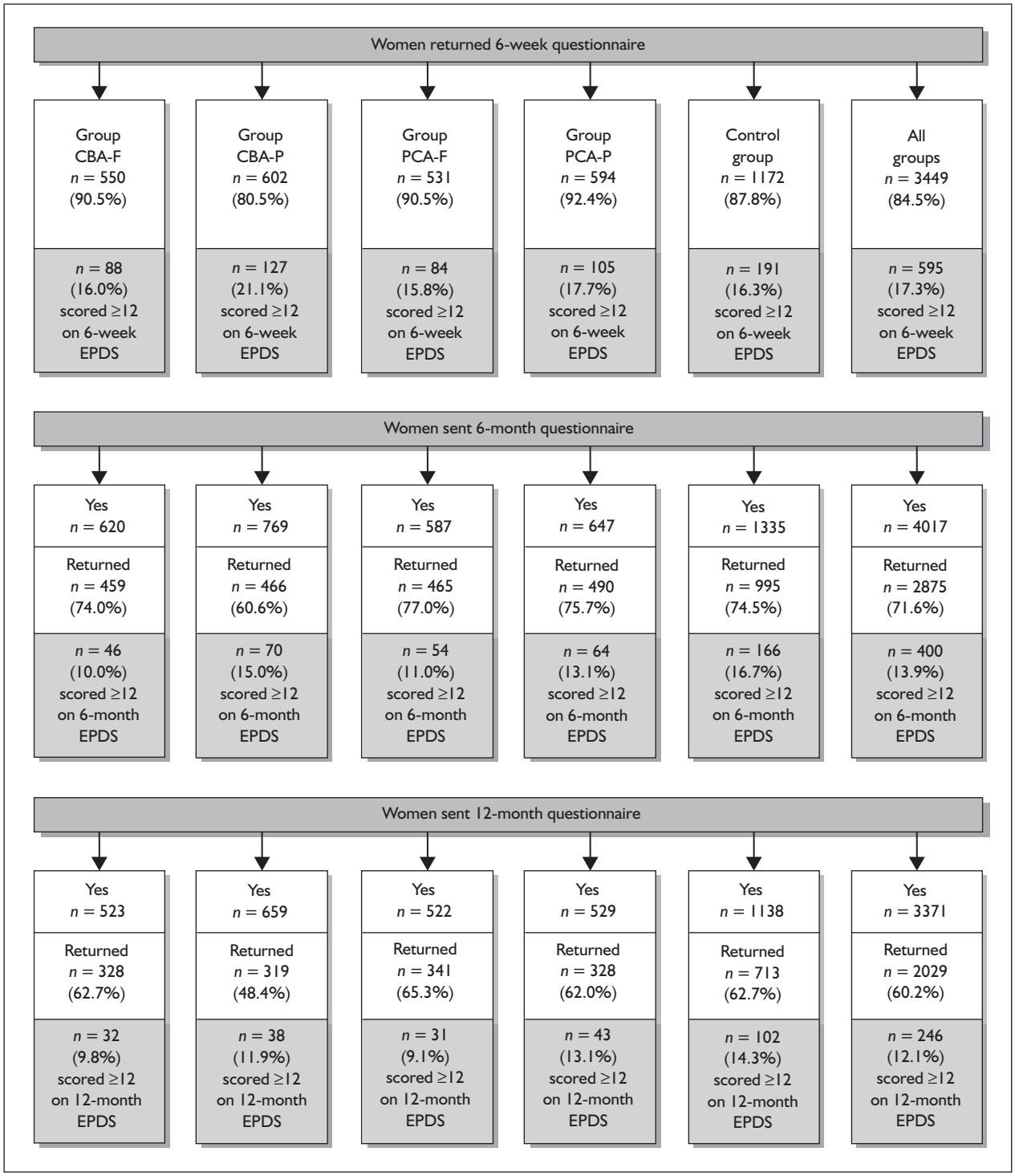

FIGURE 28 *Flow chart for the population of consented women who returned a 6-week questionnaire by group. CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; EPDS, Edinburgh Postnatal Depression Scale; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group.*

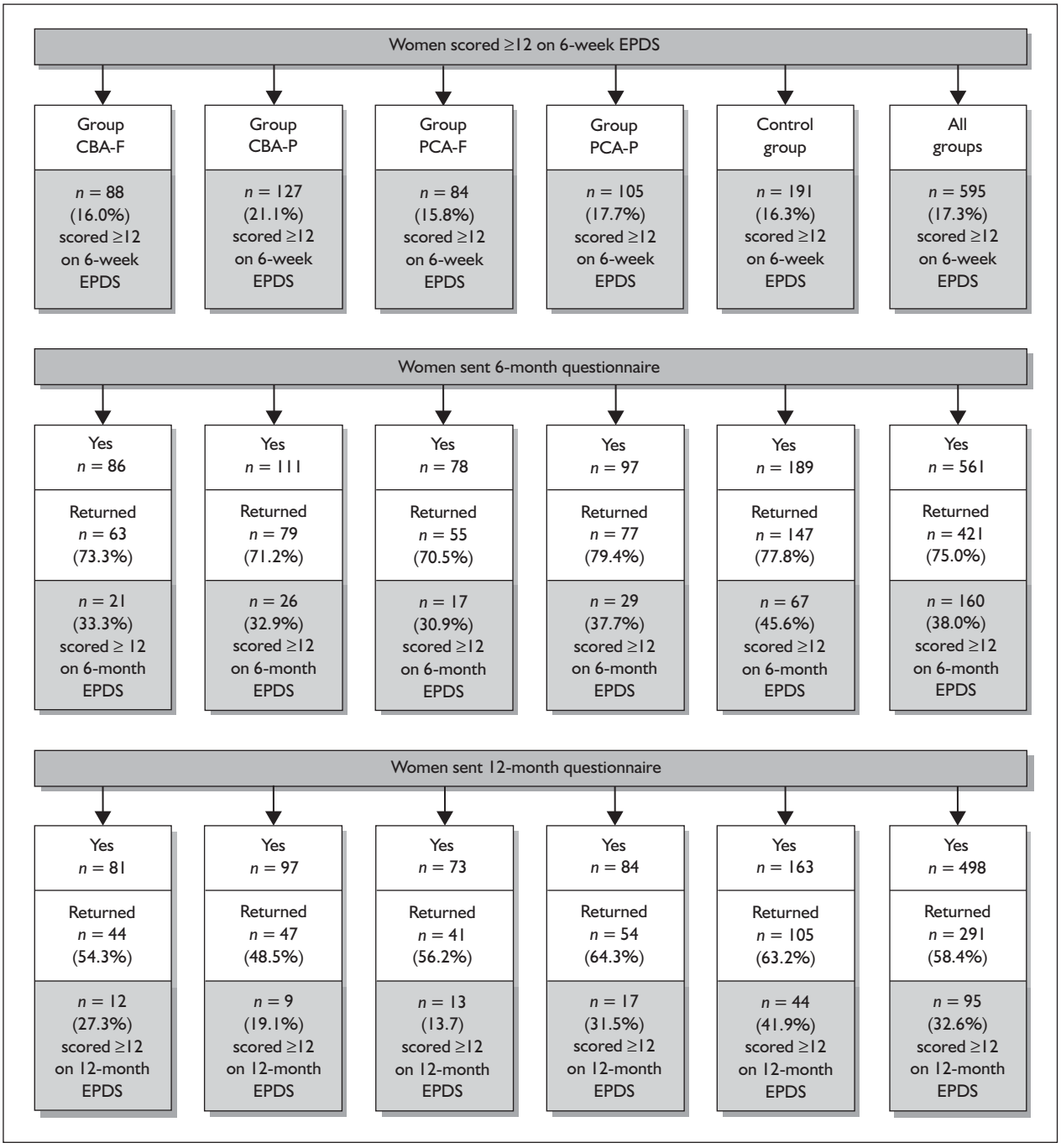

FIGURE 29 *Flow chart for at-risk women by group (n = 595). CBA-F, cognitive behavioural approach face-to-face group; CBA-P, cognitive behavioural approach postal group; EPDS, Edinburgh Postnatal Depression Scale; PCA-F, person-centred approach face-to-face group; PCA-P, person-centred approach postal group.*

Appendix 2
Economic analysis

At-risk women at 12 months

When the perspective was shifted to mother and baby costs up to 12 months no statistically significant differences were seen in the main components of resource use or cost (*Tables 70* and *71*). There appeared to be some anomalous results with the CG using fewer health service resources for the care of the baby but generating higher costs. This was due to a greater proportion of the contacts being hospitalisations, which at £516 per day have a big influence on the mean. The inclusion of these costs was also responsible for the increase in the size of the 95% confidence intervals around total costs.

All of this information was summarised in the form of a CEAC (*Figure 30*). This showed the probability that the intervention was cost-effective at various threshold values of a QALY. Even with no value placed on health gains, the intervention had a 65% chance of being cost-effective; this reflected the fact that 65% of observations were in the southeast quadrant. In the range of QALY values between £20,000 and £30,000 the probability of the intervention being cost-effective was just over 80%.

In summary, the 12-month analysis showed lower mean costs in the IG and higher mean QALYs gained (*Table 72*), and a greater than 90% chance of the intervention being cost-effective.

All women at 12 months

The 12-month data show a statistically significant increase in QALYs gained in the IG of 0.01 (95% CI 0.000 to 0.021) (*Table 73*). When combined with the almost identical costs in the two groups this produces a greater than 90% chance of the intervention being cost-effective in the £20,000–30,000 per QALY range (*Figure 31*).

TABLE 70 *Health service resource use for mother and baby for at-risk women at 12 months*

Item	Control mean ($n = 40$)	Intervention mean ($n = 83$)	Mean difference	95% CI of the difference
HV visits to 6 months	8.6	8.3	–0.3	–3.7 to 3.2
HV visits 6–12 months	2.9	3.6	+0.7	–0.4 to 1.8
Number of vaccinations to 6 months	8.4	8.2	–0.2	–1.0 to 0.7
Health service contacts for baby to 6 months	2.6	2.8	+0.2	–0.9 to 1.2
Health service contacts for baby 6–12 months	2.2	2.5	+0.3	–0.6 to 1.2

HV, health visitor.

TABLE 71 *Health service costs (£) for mother and baby for at-risk women at 12 months*

Item	Control mean ($n = 40$)	Intervention mean ($n = 83$)	Mean difference	95% CI of the difference
HV costs and other NHS costs for mother	442	493	+51	–142 to 243
NHS costs for baby up 12 months	486	352	–134	–408 to 140
Total mother and baby costs at 12 months	947	851	–96	–443 to 251

HV, health visitor.

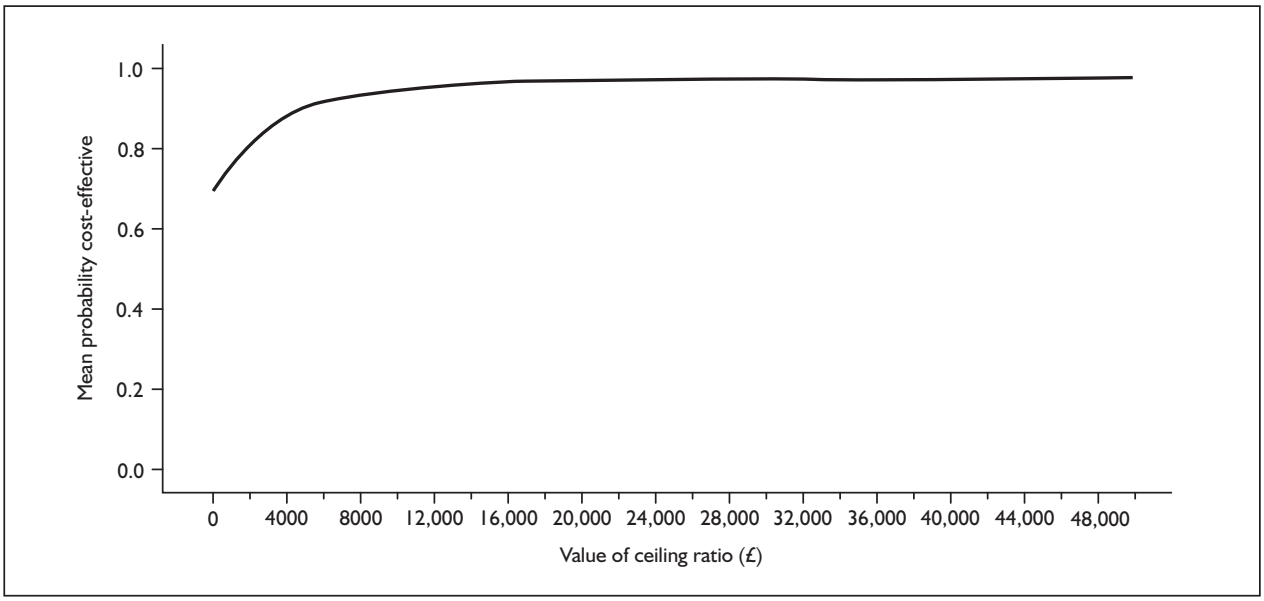

FIGURE 30 *Cost-effectiveness acceptability curve for at-risk women at 12 months.*

TABLE 72 *Mother and baby 12-month costs (£) and mother quality-adjusted life-years (QALYs) gained for at-risk women*

Item	Control mean ($n = 40$)	Intervention mean ($n = 83$)	Mean difference	95% CI of the difference
QALYs gained	0.087	0.112	+0.025	–0.008 to 0.059
Total costs	947	851	–96	–443 to 251

TABLE 73 *Mother and baby costs (£) and mother quality-adjusted life-years (QALYs) gained for all women at 12 months*

Item	Control mean ($n = 20$)	Intervention mean ($n = 83$)	Mean difference	95% CI of the difference
QALYs gained	0.107	0.117	+0.010	0.000 to 0.021
Total costs	772	763	–9	–177 to 159

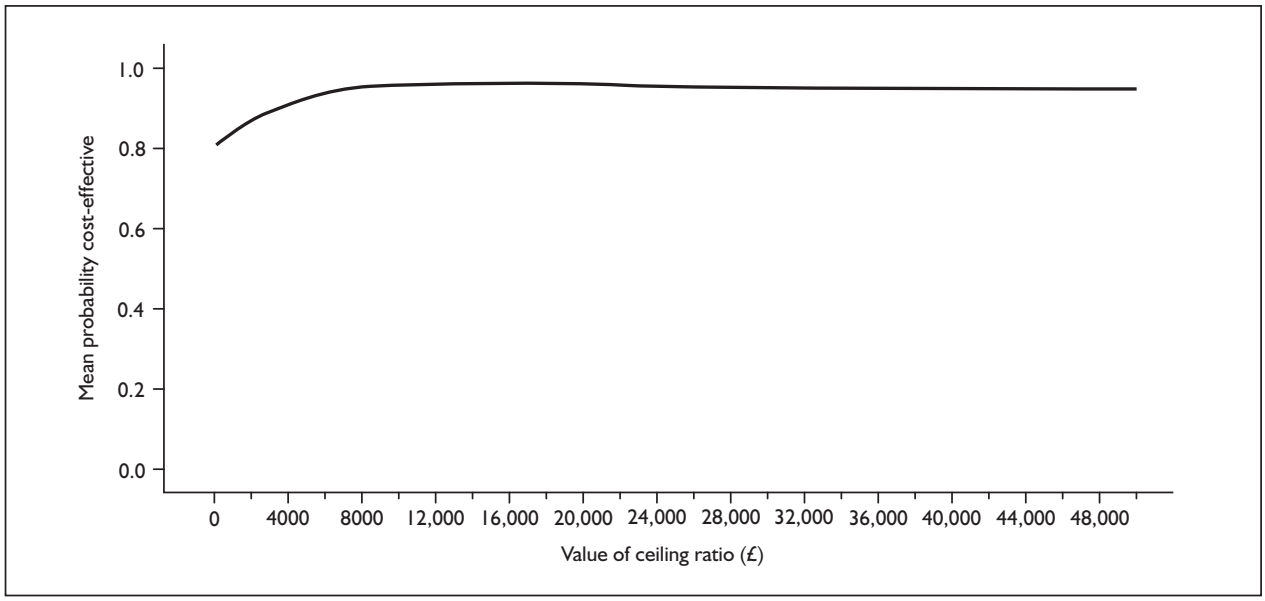

FIGURE 31 *Cost-effectiveness acceptability curve for all women at 12 months.*

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Systematic reviews of wound care management: (3) antimicrobial agents for chronic wounds; (4) diabetic foot ulceration.
By O'Meara S, Cullum N, Majid M, Sheldon T.

No. 22
Using routine data to complement and enhance the results of randomised controlled trials.
By Lewsey JD, Leyland AH, Murray GD, Boddy FA.

No. 23
Coronary artery stents in the treatment of ischaemic heart disease: a rapid and systematic review.
By Meads C, Cummins C, Jolly K, Stevens A, Burls A, Hyde C.

No. 24
Outcome measures for adult critical care: a systematic review.
By Hayes JA, Black NA, Jenkinson C, Young JD, Rowan KM, Daly K, *et al*.

No. 25
A systematic review to evaluate the effectiveness of interventions to promote the initiation of breastfeeding.
By Fairbank L, O'Meara S, Renfrew MJ, Woolridge M, Sowden AJ, Lister-Sharp D.

No. 26
Implantable cardioverter defibrillators: arrhythmias. A rapid and systematic review.
By Parkes J, Bryant J, Milne R.

No. 27
Treatments for fatigue in multiple sclerosis: a rapid and systematic review.
By Brañas P, Jordan R, Fry-Smith A, Burls A, Hyde C.

No. 28
Early asthma prophylaxis, natural history, skeletal development and economy (EASE): a pilot randomised controlled trial.
By Baxter-Jones ADG, Helms PJ, Russell G, Grant A, Ross S, Cairns JA, *et al*.

No. 29
Screening for hypercholesterolaemia versus case finding for familial hypercholesterolaemia: a systematic review and cost-effectiveness analysis.
By Marks D, Wonderling D, Thorogood M, Lambert H, Humphries SE, Neil HAW.

No. 30
A rapid and systematic review of the clinical effectiveness and cost-effectiveness of glycoprotein IIb/IIIa antagonists in the medical management of unstable angina.
By McDonagh MS, Bachmann LM, Golder S, Kleijnen J, ter Riet G.

No. 31
A randomised controlled trial of prehospital intravenous fluid replacement therapy in serious trauma.
By Turner J, Nicholl J, Webber L, Cox H, Dixon S, Yates D.

No. 32
Intrathecal pumps for giving opioids in chronic pain: a systematic review.
By Williams JE, Louw G, Towlerton G.

No. 33
Combination therapy (interferon alfa and ribavirin) in the treatment of chronic hepatitis C: a rapid and systematic review.
By Shepherd J, Waugh N, Hewitson P.

No. 34
A systematic review of comparisons of effect sizes derived from randomised and non-randomised studies.
By MacLehose RR, Reeves BC, Harvey IM, Sheldon TA, Russell IT, Black AMS.

No. 35
Intravascular ultrasound-guided interventions in coronary artery disease: a systematic literature review, with decision-analytic modelling, of outcomes and cost-effectiveness.
By Berry E, Kelly S, Hutton J, Lindsay HSJ, Blaxill JM, Evans JA, *et al*.

No. 36
A randomised controlled trial to evaluate the effectiveness and cost-effectiveness of counselling patients with chronic depression.
By Simpson S, Corney R, Fitzgerald P, Beecham J.

No. 37
Systematic review of treatments for atopic eczema.
By Hoare C, Li Wan Po A, Williams H.

No. 38
Bayesian methods in health technology assessment: a review.
By Spiegelhalter DJ, Myles JP, Jones DR, Abrams KR.

No. 39
The management of dyspepsia: a systematic review.
By Delaney B, Moayyedi P, Deeks J, Innes M, Soo S, Barton P, *et al*.

No. 40
A systematic review of treatments for severe psoriasis.
By Griffiths CEM, Clark CM, Chalmers RJG, Li Wan Po A, Williams HC.

Volume 5, 2001

No. 1
Clinical and cost-effectiveness of donepezil, rivastigmine and galantamine for Alzheimer's disease: a rapid and systematic review.
By Clegg A, Bryant J, Nicholson T, McIntyre L, De Broe S, Gerard K, *et al*.

No. 2
The clinical effectiveness and cost-effectiveness of riluzole for motor neurone disease: a rapid and systematic review.
By Stewart A, Sandercock J, Bryan S, Hyde C, Barton PM, Fry-Smith A, *et al*.

No. 3
Equity and the economic evaluation of healthcare.
By Sassi F, Archard L, Le Grand J.

No. 4
Quality-of-life measures in chronic diseases of childhood.
By Eiser C, Morse R.

No. 5
Eliciting public preferences for healthcare: a systematic review of techniques.
By Ryan M, Scott DA, Reeves C, Bate A, van Teijlingen ER, Russell EM, *et al*.

No. 6
General health status measures for people with cognitive impairment: learning disability and acquired brain injury.
By Riemsma RP, Forbes CA, Glanville JM, Eastwood AJ, Kleijnen J.

No. 7
An assessment of screening strategies for fragile X syndrome in the UK.
By Pembrey ME, Barnicoat AJ, Carmichael B, Bobrow M, Turner G.

No. 8
Issues in methodological research: perspectives from researchers and commissioners.
By Lilford RJ, Richardson A, Stevens A, Fitzpatrick R, Edwards S, Rock F, *et al*.

No. 9
Systematic reviews of wound care management: (5) beds; (6) compression; (7) laser therapy, therapeutic ultrasound, electrotherapy and electromagnetic therapy.
By Cullum N, Nelson EA, Flemming K, Sheldon T.

No. 10
Effects of educational and psychosocial interventions for adolescents with diabetes mellitus: a systematic review.
By Hampson SE, Skinner TC, Hart J, Storey L, Gage H, Foxcroft D, *et al*.

No. 11
Effectiveness of autologous chondrocyte transplantation for hyaline cartilage defects in knees: a rapid and systematic review.
By Jobanputra P, Parry D, Fry-Smith A, Burls A.

No. 12
Statistical assessment of the learning curves of health technologies.
By Ramsay CR, Grant AM, Wallace SA, Garthwaite PH, Monk AF, Russell IT.

No. 13
The effectiveness and cost-effectiveness of temozolomide for the treatment of recurrent malignant glioma: a rapid and systematic review.
By Dinnes J, Cave C, Huang S, Major K, Milne R.

No. 14
A rapid and systematic review of the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention.
By Lewis R, Whiting P, ter Riet G, O'Meara S, Glanville J.

No. 15
Home treatment for mental health problems: a systematic review.
By Burns T, Knapp M, Catty J, Healey A, Henderson J, Watt H, *et al*.

No. 16
How to develop cost-conscious guidelines.
By Eccles M, Mason J.

No. 17
The role of specialist nurses in multiple sclerosis: a rapid and systematic review.
By De Broe S, Christopher F, Waugh N.

No. 18
A rapid and systematic review of the clinical effectiveness and cost-effectiveness of orlistat in the management of obesity.
By O'Meara S, Riemsma R, Shirran L, Mather L, ter Riet G.

No. 19
The clinical effectiveness and cost-effectiveness of pioglitazone for type 2 diabetes mellitus: a rapid and systematic review.
By Chilcott J, Wight J, Lloyd Jones M, Tappenden P.

No. 20
Extended scope of nursing practice: a multicentre randomised controlled trial of appropriately trained nurses and preregistration house officers in preoperative assessment in elective general surgery.
By Kinley H, Czoski-Murray C, George S, McCabe C, Primrose J, Reilly C, *et al*.

No. 21
Systematic reviews of the effectiveness of day care for people with severe mental disorders: (1) Acute day hospital versus admission; (2) Vocational rehabilitation; (3) Day hospital versus outpatient care.
By Marshall M, Crowther R, Almaraz- Serrano A, Creed F, Sledge W, Kluiter H, *et al*.

No. 22
The measurement and monitoring of surgical adverse events.
By Bruce J, Russell EM, Mollison J, Krukowski ZH.

No. 23
Action research: a systematic review and guidance for assessment.
By Waterman H, Tillen D, Dickson R, de Koning K.

No. 24
A rapid and systematic review of the clinical effectiveness and cost-effectiveness of gemcitabine for the treatment of pancreatic cancer.
By Ward S, Morris E, Bansback N, Calvert N, Crellin A, Forman D, *et al*.

No. 25
A rapid and systematic review of the evidence for the clinical effectiveness and cost-effectiveness of irinotecan, oxaliplatin and raltitrexed for the treatment of advanced colorectal cancer.
By Lloyd Jones M, Hummel S, Bansback N, Orr B, Seymour M.

No. 26
Comparison of the effectiveness of inhaler devices in asthma and chronic obstructive airways disease: a systematic review of the literature.
By Brocklebank D, Ram F, Wright J, Barry P, Cates C, Davies L, *et al*.

No. 27
The cost-effectiveness of magnetic resonance imaging for investigation of the knee joint.
By Bryan S, Weatherburn G, Bungay H, Hatrick C, Salas C, Parry D, *et al*.

No. 28
A rapid and systematic review of the clinical effectiveness and cost-effectiveness of topotecan for ovarian cancer.
By Forbes C, Shirran L, Bagnall A-M, Duffy S, ter Riet G.

No. 29
Superseded by a report published in a later volume.

No. 30
The role of radiography in primary care patients with low back pain of at least 6 weeks duration: a randomised (unblinded) controlled trial.
By Kendrick D, Fielding K, Bentley E, Miller P, Kerslake R, Pringle M.

No. 31
Design and use of questionnaires: a review of best practice applicable to surveys of health service staff and patients.
By McColl E, Jacoby A, Thomas L, Soutter J, Bamford C, Steen N, *et al*.

No. 32
A rapid and systematic review of the clinical effectiveness and cost-effectiveness of paclitaxel, docetaxel, gemcitabine and vinorelbine in non-small-cell lung cancer.
By Clegg A, Scott DA, Sidhu M, Hewitson P, Waugh N.

No. 33
Subgroup analyses in randomised controlled trials: quantifying the risks of false-positives and false-negatives.
By Brookes ST, Whitley E, Peters TJ, Mulheran PA, Egger M, Davey Smith G.

No. 34
Depot antipsychotic medication in the treatment of patients with schizophrenia: (1) Meta-review; (2) Patient and nurse attitudes.
By David AS, Adams C.

No. 35
A systematic review of controlled trials of the effectiveness and cost-effectiveness of brief psychological treatments for depression.
By Churchill R, Hunot V, Corney R, Knapp M, McGuire H, Tylee A, *et al*.

No. 36
Cost analysis of child health surveillance.
By Sanderson D, Wright D, Acton C, Duree D.

Volume 6, 2002

No. 1
A study of the methods used to select review criteria for clinical audit.
By Hearnshaw H, Harker R, Cheater F, Baker R, Grimshaw G.

No. 2
Fludarabine as second-line therapy for B cell chronic lymphocytic leukaemia: a technology assessment.
By Hyde C, Wake B, Bryan S, Barton P, Fry-Smith A, Davenport C, *et al*.

No. 3
Rituximab as third-line treatment for refractory or recurrent Stage III or IV follicular non-Hodgkin's lymphoma: a systematic review and economic evaluation.
By Wake B, Hyde C, Bryan S, Barton P, Song F, Fry-Smith A, *et al*.

No. 4
A systematic review of discharge arrangements for older people.
By Parker SG, Peet SM, McPherson A, Cannaby AM, Baker R, Wilson A, *et al*.

No. 5
The clinical effectiveness and cost-effectiveness of inhaler devices used in the routine management of chronic asthma in older children: a systematic review and economic evaluation.
By Peters J, Stevenson M, Beverley C, Lim J, Smith S.

No. 6
The clinical effectiveness and cost-effectiveness of sibutramine in the management of obesity: a technology assessment.
By O'Meara S, Riemsma R, Shirran L, Mather L, ter Riet G.

No. 7
The cost-effectiveness of magnetic resonance angiography for carotid artery stenosis and peripheral vascular disease: a systematic review.
By Berry E, Kelly S, Westwood ME, Davies LM, Gough MJ, Bamford JM, *et al*.

No. 8
Promoting physical activity in South Asian Muslim women through 'exercise on prescription'.
By Carroll B, Ali N, Azam N.

No. 9
Zanamivir for the treatment of influenza in adults: a systematic review and economic evaluation.
By Burls A, Clark W, Stewart T, Preston C, Bryan S, Jefferson T, *et al*.

No. 10
A review of the natural history and epidemiology of multiple sclerosis: implications for resource allocation and health economic models.
By Richards RG, Sampson FC, Beard SM, Tappenden P.

No. 11
Screening for gestational diabetes: a systematic review and economic evaluation.
By Scott DA, Loveman E, McIntyre L, Waugh N.

No. 12
The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation.
By Clegg AJ, Colquitt J, Sidhu MK, Royle P, Loveman E, Walker A.

No. 13
The clinical effectiveness of trastuzumab for breast cancer: a systematic review.
By Lewis R, Bagnall A-M, Forbes C, Shirran E, Duffy S, Kleijnen J, *et al*.

No. 14
The clinical effectiveness and cost-effectiveness of vinorelbine for breast cancer: a systematic review and economic evaluation.
By Lewis R, Bagnall A-M, King S, Woolacott N, Forbes C, Shirran L, *et al*.

No. 15
A systematic review of the effectiveness and cost-effectiveness of metal-on-metal hip resurfacing arthroplasty for treatment of hip disease.
By Vale L, Wyness L, McCormack K, McKenzie L, Brazzelli M, Stearns SC.

No. 16
The clinical effectiveness and cost-effectiveness of bupropion and nicotine replacement therapy for smoking cessation: a systematic review and economic evaluation.
By Woolacott NF, Jones L, Forbes CA, Mather LC, Sowden AJ, Song FJ, *et al*.

No. 17
A systematic review of effectiveness and economic evaluation of new drug treatments for juvenile idiopathic arthritis: etanercept.
By Cummins C, Connock M, Fry-Smith A, Burls A.

No. 18
Clinical effectiveness and cost-effectiveness of growth hormone in children: a systematic review and economic evaluation.
By Bryant J, Cave C, Mihaylova B, Chase D, McIntyre L, Gerard K, *et al*.

No. 19
Clinical effectiveness and cost-effectiveness of growth hormone in adults in relation to impact on quality of life: a systematic review and economic evaluation.
By Bryant J, Loveman E, Chase D, Mihaylova B, Cave C, Gerard K, *et al*.

No. 20
Clinical medication review by a pharmacist of patients on repeat prescriptions in general practice: a randomised controlled trial.
By Zermansky AG, Petty DR, Raynor DK, Lowe CJ, Freementle N, Vail A.

No. 21
The effectiveness of infliximab and etanercept for the treatment of rheumatoid arthritis: a systematic review and economic evaluation.
By Jobanputra P, Barton P, Bryan S, Burls A.

No. 22
A systematic review and economic evaluation of computerised cognitive behaviour therapy for depression and anxiety.
By Kaltenthaler E, Shackley P, Stevens K, Beverley C, Parry G, Chilcott J.

No. 23
A systematic review and economic evaluation of pegylated liposomal doxorubicin hydrochloride for ovarian cancer.
By Forbes C, Wilby J, Richardson G, Sculpher M, Mather L, Reimsma R.

No. 24
A systematic review of the effectiveness of interventions based on a stages-of-change approach to promote individual behaviour change.
By Riemsma RP, Pattenden J, Bridle C, Sowden AJ, Mather L, Watt IS, *et al*.

No. 25
A systematic review update of the clinical effectiveness and cost-effectiveness of glycoprotein IIb/IIIa antagonists.
By Robinson M, Ginnelly L, Sculpher M, Jones L, Riemsma R, Palmer S, *et al*.

No. 26
A systematic review of the effectiveness, cost-effectiveness and barriers to implementation of thrombolytic and neuroprotective therapy for acute ischaemic stroke in the NHS.
By Sandercock P, Berge E, Dennis M, Forbes J, Hand P, Kwan J, *et al*.

No. 27
A randomised controlled crossover trial of nurse practitioner versus doctor-led outpatient care in a bronchiectasis clinic.
By Caine N, Sharples LD, Hollingworth W, French J, Keogan M, Exley A, *et al*.

No. 28
Clinical effectiveness and cost – consequences of selective serotonin reuptake inhibitors in the treatment of sex offenders.
By Adi Y, Ashcroft D, Browne K, Beech A, Fry-Smith A, Hyde C.

No. 29
Treatment of established osteoporosis: a systematic review and cost–utility analysis.
By Kanis JA, Brazier JE, Stevenson M, Calvert NW, Lloyd Jones M.

No. 30
Which anaesthetic agents are cost-effective in day surgery? Literature review, national survey of practice and randomised controlled trial.
By Elliott RA Payne K, Moore JK, Davies LM, Harper NJN, St Leger AS, *et al*.

No. 31
Screening for hepatitis C among injecting drug users and in genitourinary medicine clinics: systematic reviews of effectiveness, modelling study and national survey of current practice.
By Stein K, Dalziel K, Walker A, McIntyre L, Jenkins B, Horne J, *et al*.

No. 32
The measurement of satisfaction with healthcare: implications for practice from a systematic review of the literature.
By Crow R, Gage H, Hampson S, Hart J, Kimber A, Storey L, *et al*.

No. 33
The effectiveness and cost-effectiveness of imatinib in chronic myeloid leukaemia: a systematic review.
By Garside R, Round A, Dalziel K, Stein K, Royle R.

No. 34
A comparative study of hypertonic saline, daily and alternate-day rhDNase in children with cystic fibrosis.
By Suri R, Wallis C, Bush A, Thompson S, Normand C, Flather M, *et al*.

No. 35
A systematic review of the costs and effectiveness of different models of paediatric home care.
By Parker G, Bhakta P, Lovett CA, Paisley S, Olsen R, Turner D, *et al*.

Volume 7, 2003

No. 1
How important are comprehensive literature searches and the assessment of trial quality in systematic reviews? Empirical study.
By Egger M, Jüni P, Bartlett C, Holenstein F, Sterne J.

No. 2
Systematic review of the effectiveness and cost-effectiveness, and economic evaluation, of home versus hospital or satellite unit haemodialysis for people with end-stage renal failure.
By Mowatt G, Vale L, Perez J, Wyness L, Fraser C, MacLeod A, *et al*.

No. 3
Systematic review and economic evaluation of the effectiveness of infliximab for the treatment of Crohn's disease.
By Clark W, Raftery J, Barton P, Song F, Fry-Smith A, Burls A.

No. 4
A review of the clinical effectiveness and cost-effectiveness of routine anti-D prophylaxis for pregnant women who are rhesus negative.
By Chilcott J, Lloyd Jones M, Wight J, Forman K, Wray J, Beverley C, *et al*.

No. 5
Systematic review and evaluation of the use of tumour markers in paediatric oncology: Ewing's sarcoma and neuroblastoma.
By Riley RD, Burchill SA, Abrams KR, Heney D, Lambert PC, Jones DR, *et al*.

No. 6
The cost-effectiveness of screening for *Helicobacter pylori* to reduce mortality and morbidity from gastric cancer and peptic ulcer disease: a discrete-event simulation model.
By Roderick P, Davies R, Raftery J, Crabbe D, Pearce R, Bhandari P, *et al*.

No. 7
The clinical effectiveness and cost-effectiveness of routine dental checks: a systematic review and economic evaluation.
By Davenport C, Elley K, Salas C, Taylor-Weetman CL, Fry-Smith A, Bryan S, *et al*.

No. 8
A multicentre randomised controlled trial assessing the costs and benefits of using structured information and analysis of women's preferences in the management of menorrhagia.
By Kennedy ADM, Sculpher MJ, Coulter A, Dwyer N, Rees M, Horsley S, *et al*.

No. 9
Clinical effectiveness and cost–utility of photodynamic therapy for wet age-related macular degeneration: a systematic review and economic evaluation.
By Meads C, Salas C, Roberts T, Moore D, Fry-Smith A, Hyde C.

No. 10
Evaluation of molecular tests for prenatal diagnosis of chromosome abnormalities.
By Grimshaw GM, Szczepura A, Hultén M, MacDonald F, Nevin NC, Sutton F, *et al*.

No. 11
First and second trimester antenatal screening for Down's syndrome: the results of the Serum, Urine and Ultrasound Screening Study (SURUSS).
By Wald NJ, Rodeck C, Hackshaw AK, Walters J, Chitty L, Mackinson AM.

No. 12
The effectiveness and cost-effectiveness of ultrasound locating devices for central venous access: a systematic review and economic evaluation.
By Calvert N, Hind D, McWilliams RG, Thomas SM, Beverley C, Davidson A.

No. 13
A systematic review of atypical antipsychotics in schizophrenia.
By Bagnall A-M, Jones L, Lewis R, Ginnelly L, Glanville J, Torgerson D, *et al.*

No. 14
Prostate Testing for Cancer and Treatment (ProtecT) feasibility study.
By Donovan J, Hamdy F, Neal D, Peters T, Oliver S, Brindle L, *et al*.

No. 15
Early thrombolysis for the treatment of acute myocardial infarction: a systematic review and economic evaluation.
By Boland A, Dundar Y, Bagust A, Haycox A, Hill R, Mujica Mota R, *et al*.

No. 16
Screening for fragile X syndrome: a literature review and modelling.
By Song FJ, Barton P, Sleightholme V, Yao GL, Fry-Smith A.

No. 17
Systematic review of endoscopic sinus surgery for nasal polyps.
By Dalziel K, Stein K, Round A, Garside R, Royle P.

No. 18
Towards efficient guidelines: how to monitor guideline use in primary care.
By Hutchinson A, McIntosh A, Cox S, Gilbert C.

No. 19
Effectiveness and cost-effectiveness of acute hospital-based spinal cord injuries services: systematic review.
By Bagnall A-M, Jones L, Richardson G, Duffy S, Riemsma R.

No. 20
Prioritisation of health technology assessment. The PATHS model: methods and case studies.
By Townsend J, Buxton M, Harper G.

No. 21
Systematic review of the clinical effectiveness and cost-effectiveness of tension-free vaginal tape for treatment of urinary stress incontinence.
By Cody J, Wyness L, Wallace S, Glazener C, Kilonzo M, Stearns S, *et al*.

No. 22
The clinical and cost-effectiveness of patient education models for diabetes: a systematic review and economic evaluation.
By Loveman E, Cave C, Green C, Royle P, Dunn N, Waugh N.

No. 23
The role of modelling in prioritising and planning clinical trials.
By Chilcott J, Brennan A, Booth A, Karnon J, Tappenden P.

No. 24
Cost–benefit evaluation of routine influenza immunisation in people 65–74 years of age.
By Allsup S, Gosney M, Haycox A, Regan M.

No. 25
The clinical and cost-effectiveness of pulsatile machine perfusion versus cold storage of kidneys for transplantation retrieved from heart-beating and non-heart-beating donors.
By Wight J, Chilcott J, Holmes M, Brewer N.

No. 26
Can randomised trials rely on existing electronic data? A feasibility study to explore the value of routine data in health technology assessment.
By Williams JG, Cheung WY, Cohen DR, Hutchings HA, Longo MF, Russell IT.

No. 27
Evaluating non-randomised intervention studies.
By Deeks JJ, Dinnes J, D'Amico R, Sowden AJ, Sakarovitch C, Song F, *et al*.

No. 28
A randomised controlled trial to assess the impact of a package comprising a patient-orientated, evidence-based self-help guidebook and patient-centred consultations on disease management and satisfaction in inflammatory bowel disease.
By Kennedy A, Nelson E, Reeves D, Richardson G, Roberts C, Robinson A, *et al*.

No. 29
The effectiveness of diagnostic tests for the assessment of shoulder pain due to soft tissue disorders: a systematic review.
By Dinnes J, Loveman E, McIntyre L, Waugh N.

No. 30
The value of digital imaging in diabetic retinopathy.
By Sharp PF, Olson J, Strachan F, Hipwell J, Ludbrook A, O'Donnell M, *et al*.

No. 31
Lowering blood pressure to prevent myocardial infarction and stroke: a new preventive strategy.
By Law M, Wald N, Morris J.

No. 32
Clinical and cost-effectiveness of capecitabine and tegafur with uracil for the treatment of metastatic colorectal cancer: systematic review and economic evaluation.
By Ward S, Kaltenthaler E, Cowan J, Brewer N.

No. 33
Clinical and cost-effectiveness of new and emerging technologies for early localised prostate cancer: a systematic review.
By Hummel S, Paisley S, Morgan A, Currie E, Brewer N.

No. 34
Literature searching for clinical and cost-effectiveness studies used in health technology assessment reports carried out for the National Institute for Clinical Excellence appraisal system.
By Royle P, Waugh N.

No. 35
Systematic review and economic decision modelling for the prevention and treatment of influenza A and B.
By Turner D, Wailoo A, Nicholson K, Cooper N, Sutton A, Abrams K.

No. 36
A randomised controlled trial to evaluate the clinical and cost-effectiveness of Hickman line insertions in adult cancer patients by nurses.
By Boland A, Haycox A, Bagust A, Fitzsimmons L.

No. 37
Redesigning postnatal care: a randomised controlled trial of protocol-based midwifery-led care focused on individual women's physical and psychological health needs.
By MacArthur C, Winter HR, Bick DE, Lilford RJ, Lancashire RJ, Knowles H, *et al*.

No. 38
Estimating implied rates of discount in healthcare decision-making.
By West RR, McNabb R, Thompson AGH, Sheldon TA, Grimley Evans J.

No. 39
Systematic review of isolation policies in the hospital management of methicillin-resistant *Staphylococcus aureus*: a review of the literature with epidemiological and economic modelling.
By Cooper BS, Stone SP, Kibbler CC, Cookson BD, Roberts JA, Medley GF, *et al*.

No. 40
Treatments for spasticity and pain in multiple sclerosis: a systematic review.
By Beard S, Hunn A, Wight J.

No. 41
The inclusion of reports of randomised trials published in languages other than English in systematic reviews.
By Moher D, Pham B, Lawson ML, Klassen TP.

No. 42
The impact of screening on future health-promoting behaviours and health beliefs: a systematic review.
By Bankhead CR, Brett J, Bukach C, Webster P, Stewart-Brown S, Munafo M, *et al*.

Volume 8, 2004

No. 1
What is the best imaging strategy for acute stroke?
By Wardlaw JM, Keir SL, Seymour J, Lewis S, Sandercock PAG, Dennis MS, *et al*.

No. 2
Systematic review and modelling of the investigation of acute and chronic chest pain presenting in primary care.
By Mant J, McManus RJ, Oakes RAL, Delaney BC, Barton PM, Deeks JJ, *et al*.

No. 3
The effectiveness and cost-effectiveness of microwave and thermal balloon endometrial ablation for heavy menstrual bleeding: a systematic review and economic modelling.
By Garside R, Stein K, Wyatt K, Round A, Price A.

No. 4
A systematic review of the role of bisphosphonates in metastatic disease.
By Ross JR, Saunders Y, Edmonds PM, Patel S, Wonderling D, Normand C, *et al*.

No. 5
Systematic review of the clinical effectiveness and cost-effectiveness of capecitabine (Xeloda®) for locally advanced and/or metastatic breast cancer.
By Jones L, Hawkins N, Westwood M, Wright K, Richardson G, Riemsma R.

No. 6
Effectiveness and efficiency of guideline dissemination and implementation strategies.
By Grimshaw JM, Thomas RE, MacLennan G, Fraser C, Ramsay CR, Vale L, *et al*.

No. 7
Clinical effectiveness and costs of the Sugarbaker procedure for the treatment of pseudomyxoma peritonei.
By Bryant J, Clegg AJ, Sidhu MK, Brodin H, Royle P, Davidson P.

No. 8
Psychological treatment for insomnia in the regulation of long-term hypnotic drug use.
By Morgan K, Dixon S, Mathers N, Thompson J, Tomeny M.

No. 9
Improving the evaluation of therapeutic interventions in multiple sclerosis: development of a patient-based measure of outcome.
By Hobart JC, Riazi A, Lamping DL, Fitzpatrick R, Thompson AJ.

No. 10
A systematic review and economic evaluation of magnetic resonance cholangiopancreatography compared with diagnostic endoscopic retrograde cholangiopancreatography.
By Kaltenthaler E, Bravo Vergel Y, Chilcott J, Thomas S, Blakeborough T, Walters SJ, *et al*.

No. 11
The use of modelling to evaluate new drugs for patients with a chronic condition: the case of antibodies against tumour necrosis factor in rheumatoid arthritis.
By Barton P, Jobanputra P, Wilson J, Bryan S, Burls A.

No. 12
Clinical effectiveness and cost-effectiveness of neonatal screening for inborn errors of metabolism using tandem mass spectrometry: a systematic review.
By Pandor A, Eastham J, Beverley C, Chilcott J, Paisley S.

No. 13
Clinical effectiveness and cost-effectiveness of pioglitazone and rosiglitazone in the treatment of type 2 diabetes: a systematic review and economic evaluation.
By Czoski-Murray C, Warren E, Chilcott J, Beverley C, Psyllaki MA, Cowan J.

No. 14
Routine examination of the newborn: the EMREN study. Evaluation of an extension of the midwife role including a randomised controlled trial of appropriately trained midwives and paediatric senior house officers.
By Townsend J, Wolke D, Hayes J, Davé S, Rogers C, Bloomfield L, *et al*.

No. 15
Involving consumers in research and development agenda setting for the NHS: developing an evidence-based approach.
By Oliver S, Clarke-Jones L, Rees R, Milne R, Buchanan P, Gabbay J, *et al*.

No. 16
A multi-centre randomised controlled trial of minimally invasive direct coronary bypass grafting versus percutaneous transluminal coronary angioplasty with stenting for proximal stenosis of the left anterior descending coronary artery.
By Reeves BC, Angelini GD, Bryan AJ, Taylor FC, Cripps T, Spyt TJ, *et al*.

No. 17
Does early magnetic resonance imaging influence management or improve outcome in patients referred to secondary care with low back pain? A pragmatic randomised controlled trial.
By Gilbert FJ, Grant AM, Gillan MGC, Vale L, Scott NW, Campbell MK, *et al*.

No. 18
The clinical and cost-effectiveness of anakinra for the treatment of rheumatoid arthritis in adults: a systematic review and economic analysis.
By Clark W, Jobanputra P, Barton P, Burls A.

No. 19
A rapid and systematic review and economic evaluation of the clinical and cost-effectiveness of newer drugs for treatment of mania associated with bipolar affective disorder.
By Bridle C, Palmer S, Bagnall A-M, Darba J, Duffy S, Sculpher M, *et al*.

No. 20
Liquid-based cytology in cervical screening: an updated rapid and systematic review and economic analysis.
By Karnon J, Peters J, Platt J, Chilcott J, McGoogan E, Brewer N.

No. 21
Systematic review of the long-term effects and economic consequences of treatments for obesity and implications for health improvement.
By Avenell A, Broom J, Brown TJ, Poobalan A, Aucott L, Stearns SC, *et al*.

No. 22
Autoantibody testing in children with newly diagnosed type 1 diabetes mellitus.
By Dretzke J, Cummins C, Sandercock J, Fry-Smith A, Barrett T, Burls A.

No. 23
Clinical effectiveness and cost-effectiveness of prehospital intravenous fluids in trauma patients.
By Dretzke J, Sandercock J, Bayliss S, Burls A.

No. 24
Newer hypnotic drugs for the short-term management of insomnia: a systematic review and economic evaluation.
By Dündar Y, Boland A, Strobl J, Dodd S, Haycox A, Bagust A, *et al*.

No. 25
Development and validation of methods for assessing the quality of diagnostic accuracy studies.
By Whiting P, Rutjes AWS, Dinnes J, Reitsma JB, Bossuyt PMM, Kleijnen J.

No. 26
EVALUATE hysterectomy trial: a multicentre randomised trial comparing abdominal, vaginal and laparoscopic methods of hysterectomy.
By Garry R, Fountain J, Brown J, Manca A, Mason S, Sculpher M, *et al*.

No. 27
Methods for expected value of information analysis in complex health economic models: developments on the health economics of interferon-β and glatiramer acetate for multiple sclerosis.
By Tappenden P, Chilcott JB, Eggington S, Oakley J, McCabe C.

No. 28
Effectiveness and cost-effectiveness of imatinib for first-line treatment of chronic myeloid leukaemia in chronic phase: a systematic review and economic analysis.
By Dalziel K, Round A, Stein K, Garside R, Price A.

No. 29
VenUS I: a randomised controlled trial of two types of bandage for treating venous leg ulcers.
By Iglesias C, Nelson EA, Cullum NA, Torgerson DJ, on behalf of the VenUS Team.

No. 30
Systematic review of the effectiveness and cost-effectiveness, and economic evaluation, of myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction.
By Mowatt G, Vale L, Brazzelli M, Hernandez R, Murray A, Scott N, *et al*.

No. 31
A pilot study on the use of decision theory and value of information analysis as part of the NHS Health Technology Assessment programme.
By Claxton K, Ginnelly L, Sculpher M, Philips Z, Palmer S.

No. 32
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.
By Wiggins M, Oakley A, Roberts I, Turner H, Rajan L, Austerberry H, *et al*.

No. 33
Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review.
By Green JM, Hewison J, Bekker HL, Bryant, Cuckle HS.

No. 34
Evaluation of abnormal uterine bleeding: comparison of three outpatient procedures within cohorts defined by age and menopausal status.
By Critchley HOD, Warner P, Lee AJ, Brechin S, Guise J, Graham B.

No. 35
Coronary artery stents: a rapid systematic review and economic evaluation.
By Hill R, Bagust A, Bakhai A, Dickson R, Dündar Y, Haycox A, *et al*.

No. 36
Review of guidelines for good practice in decision-analytic modelling in health technology assessment.
By Philips Z, Ginnelly L, Sculpher M, Claxton K, Golder S, Riemsma R, *et al*.

No. 37
Rituximab (MabThera®) for aggressive non-Hodgkin's lymphoma: systematic review and economic evaluation.
By Knight C, Hind D, Brewer N, Abbott V.

No. 38
Clinical effectiveness and cost-effectiveness of clopidogrel and modified-release dipyridamole in the secondary prevention of occlusive vascular events: a systematic review and economic evaluation.
By Jones L, Griffin S, Palmer S, Main C, Orton V, Sculpher M, *et al.*

No. 39
Pegylated interferon α-2a and -2b in combination with ribavirin in the treatment of chronic hepatitis C: a systematic review and economic evaluation.
By Shepherd J, Brodin H, Cave C, Waugh N, Price A, Gabbay J.

No. 40
Clopidogrel used in combination with aspirin compared with aspirin alone in the treatment of non-ST-segment-elevation acute coronary syndromes: a systematic review and economic evaluation.
By Main C, Palmer S, Griffin S, Jones L, Orton V, Sculpher M, *et al.*

No. 41
Provision, uptake and cost of cardiac rehabilitation programmes: improving services to under-represented groups.
By Beswick AD, Rees K, Griebsch I, Taylor FC, Burke M, West RR, *et al.*

No. 42
Involving South Asian patients in clinical trials.
By Hussain-Gambles M, Leese B, Atkin K, Brown J, Mason S, Tovey P.

No. 43
Clinical and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes.
By Colquitt JL, Green C, Sidhu MK, Hartwell D, Waugh N.

No. 44
Identification and assessment of ongoing trials in health technology assessment reviews.
By Song FJ, Fry-Smith A, Davenport C, Bayliss S, Adi Y, Wilson JS, *et al*.

No. 45
Systematic review and economic evaluation of a long-acting insulin analogue, insulin glargine
By Warren E, Weatherley-Jones E, Chilcott J, Beverley C.

No. 46
Supplementation of a home-based exercise programme with a class-based programme for people with osteoarthritis of the knees: a randomised controlled trial and health economic analysis.
By McCarthy CJ, Mills PM, Pullen R, Richardson G, Hawkins N, Roberts CR, *et al*.

No. 47
Clinical and cost-effectiveness of once-daily versus more frequent use of same potency topical corticosteroids for atopic eczema: a systematic review and economic evaluation.
By Green C, Colquitt JL, Kirby J, Davidson P, Payne E.

No. 48
Acupuncture of chronic headache disorders in primary care: randomised controlled trial and economic analysis.
By Vickers AJ, Rees RW, Zollman CE, McCarney R, Smith CM, Ellis N, *et al*.

No. 49
Generalisability in economic evaluation studies in healthcare: a review and case studies.
By Sculpher MJ, Pang FS, Manca A, Drummond MF, Golder S, Urdahl H, *et al*.

No. 50
Virtual outreach: a randomised controlled trial and economic evaluation of joint teleconferenced medical consultations.
By Wallace P, Barber J, Clayton W, Currell R, Fleming K, Garner P, *et al*.

Volume 9, 2005

No. 1
Randomised controlled multiple treatment comparison to provide a cost-effectiveness rationale for the selection of antimicrobial therapy in acne.
By Ozolins M, Eady EA, Avery A, Cunliffe WJ, O'Neill C, Simpson NB, *et al*.

No. 2
Do the findings of case series studies vary significantly according to methodological characteristics?
By Dalziel K, Round A, Stein K, Garside R, Castelnuovo E, Payne L.

No. 3
Improving the referral process for familial breast cancer genetic counselling: findings of three randomised controlled trials of two interventions.
By Wilson BJ, Torrance N, Mollison J, Wordsworth S, Gray JR, Haites NE, *et al*.

No. 4
Randomised evaluation of alternative electrosurgical modalities to treat bladder outflow obstruction in men with benign prostatic hyperplasia.
By Fowler C, McAllister W, Plail R, Karim O, Yang Q.

No. 5
A pragmatic randomised controlled trial of the cost-effectiveness of palliative therapies for patients with inoperable oesophageal cancer.
By Shenfine J, McNamee P, Steen N, Bond J, Griffin SM.

No. 6
Impact of computer-aided detection prompts on the sensitivity and specificity of screening mammography.
By Taylor P, Champness J, Given-Wilson R, Johnston K, Potts H.

No. 7
Issues in data monitoring and interim analysis of trials.
By Grant AM, Altman DG, Babiker AB, Campbell MK, Clemens FJ, Darbyshire JH, *et al*.

No. 8
Lay public's understanding of equipoise and randomisation in randomised controlled trials.
By Robinson EJ, Kerr CEP, Stevens AJ, Lilford RJ, Braunholtz DA, Edwards SJ, *et al*.

No. 9
Clinical and cost-effectiveness of electroconvulsive therapy for depressive illness, schizophrenia, catatonia and mania: systematic reviews and economic modelling studies.
By Greenhalgh J, Knight C, Hind D, Beverley C, Walters S.

No. 10
Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology.
By Smith SC, Lamping DL, Banerjee S, Harwood R, Foley B, Smith P, *et al*.

No. 11
Clinical effectiveness and cost-effectiveness of drotrecogin alfa (activated) (Xigris®) for the treatment of severe sepsis in adults: a systematic review and economic evaluation.
By Green C, Dinnes J, Takeda A, Shepherd J, Hartwell D, Cave C, *et al*.

No. 12
A methodological review of how heterogeneity has been examined in systematic reviews of diagnostic test accuracy.
By Dinnes J, Deeks J, Kirby J, Roderick P.

No. 13
Cervical screening programmes: can automation help? Evidence from systematic reviews, an economic analysis and a simulation modelling exercise applied to the UK.
By Willis BH, Barton P, Pearmain P, Bryan S, Hyde C.

No. 14
Laparoscopic surgery for inguinal hernia repair: systematic review of effectiveness and economic evaluation.
By McCormack K, Wake B, Perez J, Fraser C, Cook J, McIntosh E, *et al*.

No. 15
Clinical effectiveness, tolerability and cost-effectiveness of newer drugs for epilepsy in adults: a systematic review and economic evaluation.
By Wilby J, Kainth A, Hawkins N, Epstein D, McIntosh H, McDaid C, *et al*.

No. 16
A randomised controlled trial to compare the cost-effectiveness of tricyclic antidepressants, selective serotonin reuptake inhibitors and lofepramine.
By Peveler R, Kendrick T, Buxton M, Longworth L, Baldwin D, Moore M, *et al*.

No. 17
Clinical effectiveness and cost-effectiveness of immediate angioplasty for acute myocardial infarction: systematic review and economic evaluation.
By Hartwell D, Colquitt J, Loveman E, Clegg AJ, Brodin H, Waugh N, *et al*.

No. 18
A randomised controlled comparison of alternative strategies in stroke care.
By Kalra L, Evans A, Perez I, Knapp M, Swift C, Donaldson N.

No. 19
The investigation and analysis of critical incidents and adverse events in healthcare.
By Woloshynowych M, Rogers S, Taylor-Adams S, Vincent C.

No. 20
Potential use of routine databases in health technology assessment.
By Raftery J, Roderick P, Stevens A.

No. 21
Clinical and cost-effectiveness of newer immunosuppressive regimens in renal transplantation: a systematic review and modelling study.
By Woodroffe R, Yao GL, Meads C, Bayliss S, Ready A, Raftery J, *et al*.

No. 22
A systematic review and economic evaluation of alendronate, etidronate, risedronate, raloxifene and teriparatide for the prevention and treatment of postmenopausal osteoporosis.
By Stevenson M, Lloyd Jones M, De Nigris E, Brewer N, Davis S, Oakley J.

No. 23
A systematic review to examine the impact of psycho-educational interventions on health outcomes and costs in adults and children with difficult asthma.
By Smith JR, Mugford M, Holland R, Candy B, Noble MJ, Harrison BDW, *et al*.

No. 24
An evaluation of the costs, effectiveness and quality of renal replacement therapy provision in renal satellite units in England and Wales.
By Roderick P, Nicholson T, Armitage A, Mehta R, Mullee M, Gerard K, *et al*.

No. 25
Imatinib for the treatment of patients with unresectable and/or metastatic gastrointestinal stromal tumours: systematic review and economic evaluation.
By Wilson J, Connock M, Song F, Yao G, Fry-Smith A, Raftery J, *et al*.

No. 26
Indirect comparisons of competing interventions.
By Glenny AM, Altman DG, Song F, Sakarovitch C, Deeks JJ, D'Amico R, *et al*.

No. 27
Cost-effectiveness of alternative strategies for the initial medical management of non-ST elevation acute coronary syndrome: systematic review and decision-analytical modelling.
By Robinson M, Palmer S, Sculpher M, Philips Z, Ginnelly L, Bowens A, *et al*.

No. 28
Outcomes of electrically stimulated gracilis neosphincter surgery.
By Tillin T, Chambers M, Feldman R.

No. 29
The effectiveness and cost-effectiveness of pimecrolimus and tacrolimus for atopic eczema: a systematic review and economic evaluation.
By Garside R, Stein K, Castelnuovo E, Pitt M, Ashcroft D, Dimmock P, *et al*.

No. 30
Systematic review on urine albumin testing for early detection of diabetic complications.
By Newman DJ, Mattock MB, Dawnay ABS, Kerry S, McGuire A, Yaqoob M, *et al*.

No. 31
Randomised controlled trial of the cost-effectiveness of water-based therapy for lower limb osteoarthritis.
By Cochrane T, Davey RC, Matthes Edwards SM.

No. 32
Longer term clinical and economic benefits of offering acupuncture care to patients with chronic low back pain.
By Thomas KJ, MacPherson H, Ratcliffe J, Thorpe L, Brazier J, Campbell M, *et al*.

No. 33
Cost-effectiveness and safety of epidural steroids in the management of sciatica.
By Price C, Arden N, Coglan L, Rogers P.

No. 34
The British Rheumatoid Outcome Study Group (BROSG) randomised controlled trial to compare the effectiveness and cost-effectiveness of aggressive versus symptomatic therapy in established rheumatoid arthritis.
By Symmons D, Tricker K, Roberts C, Davies L, Dawes P, Scott DL.

No. 35
Conceptual framework and systematic review of the effects of participants' and professionals' preferences in randomised controlled trials.
By King M, Nazareth I, Lampe F, Bower P, Chandler M, Morou M, *et al*.

No. 36
The clinical and cost-effectiveness of implantable cardioverter defibrillators: a systematic review.
By Bryant J, Brodin H, Loveman E, Payne E, Clegg A.

No. 37
A trial of problem-solving by community mental health nurses for anxiety, depression and life difficulties among general practice patients. The CPN-GP study.
By Kendrick T, Simons L, Mynors-Wallis L, Gray A, Lathlean J, Pickering R, *et al*.

No. 38
The causes and effects of socio-demographic exclusions from clinical trials.
By Bartlett C, Doyal L, Ebrahim S, Davey P, Bachmann M, Egger M, *et al*.

No. 39
Is hydrotherapy cost-effective? A randomised controlled trial of combined hydrotherapy programmes compared with physiotherapy land techniques in children with juvenile idiopathic arthritis.
By Epps H, Ginnelly L, Utley M, Southwood T, Gallivan S, Sculpher M, *et al*.

No. 40
A randomised controlled trial and cost-effectiveness study of systematic screening (targeted and total population screening) versus routine practice for the detection of atrial fibrillation in people aged 65 and over. The SAFE study.
By Hobbs FDR, Fitzmaurice DA, Mant J, Murray E, Jowett S, Bryan S, *et al*.

No. 41
Displaced intracapsular hip fractures in fit, older people: a randomised comparison of reduction and fixation, bipolar hemiarthroplasty and total hip arthroplasty.
By Keating JF, Grant A, Masson M, Scott NW, Forbes JF.

No. 42
Long-term outcome of cognitive behaviour therapy clinical trials in central Scotland.
By Durham RC, Chambers JA, Power KG, Sharp DM, Macdonald RR, Major KA, *et al*.

No. 43
The effectiveness and cost-effectiveness of dual-chamber pacemakers compared with single-chamber pacemakers for bradycardia due to atrioventricular block or sick sinus syndrome: systematic review and economic evaluation.
By Castelnuovo E, Stein K, Pitt M, Garside R, Payne E.

No. 44
Newborn screening for congenital heart defects: a systematic review and cost-effectiveness analysis.
By Knowles R, Griebsch I, Dezateux C, Brown J, Bull C, Wren C.

No. 45
The clinical and cost-effectiveness of left ventricular assist devices for end-stage heart failure: a systematic review and economic evaluation.
By Clegg AJ, Scott DA, Loveman E, Colquitt J, Hutchinson J, Royle P, *et al*.

No. 46
The effectiveness of the Heidelberg Retina Tomograph and laser diagnostic glaucoma scanning system (GDx) in detecting and monitoring glaucoma.
By Kwartz AJ, Henson DB, Harper RA, Spencer AF, McLeod D.

No. 47
Clinical and cost-effectiveness of autologous chondrocyte implantation for cartilage defects in knee joints: systematic review and economic evaluation.
By Clar C, Cummins E, McIntyre L, Thomas S, Lamb J, Bain L, *et al*.

No. 48
Systematic review of effectiveness of different treatments for childhood retinoblastoma.
By McDaid C, Hartley S, Bagnall A-M, Ritchie G, Light K, Riemsma R.

No. 49
Towards evidence-based guidelines for the prevention of venous thromboembolism: systematic reviews of mechanical methods, oral anticoagulation, dextran and regional anaesthesia as thromboprophylaxis.
By Roderick P, Ferris G, Wilson K, Halls H, Jackson D, Collins R, *et al*.

No. 50
The effectiveness and cost-effectiveness of parent training/education programmes for the treatment of conduct disorder, including oppositional defiant disorder, in children.
By Dretzke J, Frew E, Davenport C, Barlow J, Stewart-Brown S, Sandercock J, *et al*.

Volume 10, 2006

No. 1
The clinical and cost-effectiveness of donepezil, rivastigmine, galantamine and memantine for Alzheimer's disease.
By Loveman E, Green C, Kirby J, Takeda A, Picot J, Payne E, *et al*.

No. 2
FOOD: a multicentre randomised trial evaluating feeding policies in patients admitted to hospital with a recent stroke.
By Dennis M, Lewis S, Cranswick G, Forbes J.

No. 3
The clinical effectiveness and cost-effectiveness of computed tomography screening for lung cancer: systematic reviews.
By Black C, Bagust A, Boland A, Walker S, McLeod C, De Verteuil R, *et al*.

No. 4
A systematic review of the effectiveness and cost-effectiveness of neuroimaging assessments used to visualise the seizure focus in people with refractory epilepsy being considered for surgery.
By Whiting P, Gupta R, Burch J, Mujica Mota RE, Wright K, Marson A, *et al*.

No. 5
Comparison of conference abstracts and presentations with full-text articles in the health technology assessments of rapidly evolving technologies.
By Dundar Y, Dodd S, Dickson R, Walley T, Haycox A, Williamson PR.

No. 6
Systematic review and evaluation of methods of assessing urinary incontinence.
By Martin JL, Williams KS, Abrams KR, Turner DA, Sutton AJ, Chapple C, *et al*.

No. 7
The clinical effectiveness and cost-effectiveness of newer drugs for children with epilepsy. A systematic review.
By Connock M, Frew E, Evans B-W, Bryan S, Cummins C, Fry-Smith A, *et al*.

No. 8
Surveillance of Barrett's oesophagus: exploring the uncertainty through systematic review, expert workshop and economic modelling.
By Garside R, Pitt M, Somerville M, Stein K, Price A, Gilbert N.

No. 9
Topotecan, pegylated liposomal doxorubicin hydrochloride and paclitaxel for second-line or subsequent treatment of advanced ovarian cancer: a systematic review and economic evaluation.
By Main C, Bojke L, Griffin S, Norman G, Barbieri M, Mather L, *et al*.

No. 10
Evaluation of molecular techniques in prediction and diagnosis of cytomegalovirus disease in immunocompromised patients.
By Szczepura A, Westmoreland D, Vinogradova Y, Fox J, Clark M.

No. 11
Screening for thrombophilia in high-risk situations: systematic review and cost-effectiveness analysis. The Thrombosis: Risk and Economic Assessment of Thrombophilia Screening (TREATS) study.
By Wu O, Robertson L, Twaddle S, Lowe GDO, Clark P, Greaves M, *et al*.

No. 12
A series of systematic reviews to inform a decision analysis for sampling and treating infected diabetic foot ulcers.
By Nelson EA, O'Meara S, Craig D, Iglesias C, Golder S, Dalton J, *et al*.

No. 13
Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial).
By Michaels JA, Campbell WB, Brazier JE, MacIntyre JB, Palfreyman SJ, Ratcliffe J, *et al*.

No. 14
The cost-effectiveness of screening for oral cancer in primary care.
By Speight PM, Palmer S, Moles DR, Downer MC, Smith DH, Henriksson M, *et al*.

No. 15
Measurement of the clinical and cost-effectiveness of non-invasive diagnostic testing strategies for deep vein thrombosis.
By Goodacre S, Sampson F, Stevenson M, Wailoo A, Sutton A, Thomas S, *et al*.

No. 16
Systematic review of the effectiveness and cost-effectiveness of HealOzone® for the treatment of occlusal pit/fissure caries and root caries.
By Brazzelli M, McKenzie L, Fielding S, Fraser C, Clarkson J, Kilonzo M, *et al*.

No. 17
Randomised controlled trials of conventional antipsychotic versus new atypical drugs, and new atypical drugs versus clozapine, in people with schizophrenia responding poorly to, or intolerant of, current drug treatment.
By Lewis SW, Davies L, Jones PB, Barnes TRE, Murray RM, Kerwin R, *et al*.

No. 18
Diagnostic tests and algorithms used in the investigation of haematuria: systematic reviews and economic evaluation.
By Rodgers M, Nixon J, Hempel S, Aho T, Kelly J, Neal D, *et al*.

No. 19
Cognitive behavioural therapy in addition to antispasmodic therapy for irritable bowel syndrome in primary care: randomised controlled trial.
By Kennedy TM, Chalder T, McCrone P, Darnley S, Knapp M, Jones RH, *et al*.

No. 20
A systematic review of the clinical effectiveness and cost-effectiveness of enzyme replacement therapies for Fabry's disease and mucopolysaccharidosis type 1.
By Connock M, Juarez-Garcia A, Frew E, Mans A, Dretzke J, Fry-Smith A, *et al*.

No. 21
Health benefits of antiviral therapy for mild chronic hepatitis C: randomised controlled trial and economic evaluation.
By Wright M, Grieve R, Roberts J, Main J, Thomas HC, on behalf of the UK Mild Hepatitis C Trial Investigators.

No. 22
Pressure relieving support surfaces: a randomised evaluation.
By Nixon J, Nelson EA, Cranny G, Iglesias CP, Hawkins K, Cullum NA, *et al*.

No. 23
A systematic review and economic model of the effectiveness and cost-effectiveness of methylphenidate, dexamfetamine and atomoxetine for the treatment of attention deficit hyperactivity disorder in children and adolescents.
By King S, Griffin S, Hodges Z, Weatherly H, Asseburg C, Richardson G, *et al.*

No. 24
The clinical effectiveness and cost-effectiveness of enzyme replacement therapy for Gaucher's disease: a systematic review.
By Connock M, Burls A, Frew E, Fry-Smith A, Juarez-Garcia A, McCabe C, *et al*.

No. 25
Effectiveness and cost-effectiveness of salicylic acid and cryotherapy for cutaneous warts. An economic decision model.
By Thomas KS, Keogh-Brown MR, Chalmers JR, Fordham RJ, Holland RC, Armstrong SJ, *et al*.

No. 26
A systematic literature review of the effectiveness of non-pharmacological interventions to prevent wandering in dementia and evaluation of the ethical implications and acceptability of their use.
By Robinson L, Hutchings D, Corner L, Beyer F, Dickinson H, Vanoli A, *et al*.

No. 27
A review of the evidence on the effects and costs of implantable cardioverter defibrillator therapy in different patient groups, and modelling of cost-effectiveness and cost–utility for these groups in a UK context.
By Buxton M, Caine N, Chase D, Connelly D, Grace A, Jackson C, *et al*.

No. 28
Adefovir dipivoxil and pegylated interferon alfa-2a for the treatment of chronic hepatitis B: a systematic review and economic evaluation.
By Shepherd J, Jones J, Takeda A, Davidson P, Price A.

No. 29
An evaluation of the clinical and cost-effectiveness of pulmonary artery catheters in patient management in intensive care: a systematic review and a randomised controlled trial.
By Harvey S, Stevens K, Harrison D, Young D, Brampton W, McCabe C, *et al*.

No. 30
Accurate, practical and cost-effective assessment of carotid stenosis in the UK.
By Wardlaw JM, Chappell FM, Stevenson M, De Nigris E, Thomas S, Gillard J, *et al*.

No. 31
Etanercept and infliximab for the treatment of psoriatic arthritis: a systematic review and economic evaluation.
By Woolacott N, Bravo Vergel Y, Hawkins N, Kainth A, Khadjesari Z, Misso K, *et al*.

No. 32
The cost-effectiveness of testing for hepatitis C in former injecting drug users.
By Castelnuovo E, Thompson-Coon J, Pitt M, Cramp M, Siebert U, Price A, *et al*.

No. 33
Computerised cognitive behaviour therapy for depression and anxiety update: a systematic review and economic evaluation.
By Kaltenthaler E, Brazier J, De Nigris E, Tumur I, Ferriter M, Beverley C, *et al*.

No. 34
Cost-effectiveness of using prognostic information to select women with breast cancer for adjuvant systemic therapy.
By Williams C, Brunskill S, Altman D, Briggs A, Campbell H, Clarke M, *et al*.

No. 35
Psychological therapies including dialectical behaviour therapy for borderline personality disorder: a systematic review and preliminary economic evaluation.
By Brazier J, Tumur I, Holmes M, Ferriter M, Parry G, Dent-Brown K, *et al*.

No. 36
Clinical effectiveness and cost-effectiveness of tests for the diagnosis and investigation of urinary tract infection in children: a systematic review and economic model.
By Whiting P, Westwood M, Bojke L, Palmer S, Richardson G, Cooper J, *et al*.

No. 37
Cognitive behavioural therapy in chronic fatigue syndrome: a randomised controlled trial of an outpatient group programme.
By O'Dowd H, Gladwell P, Rogers CA, Hollinghurst S, Gregory A.

No. 38
A comparison of the cost-effectiveness of five strategies for the prevention of nonsteroidal anti-inflammatory drug-induced gastrointestinal toxicity: a systematic review with economic modelling.
By Brown TJ, Hooper L, Elliott RA, Payne K, Webb R, Roberts C, et al.

No. 39
The effectiveness and cost-effectiveness of computed tomography screening for coronary artery disease: systematic review.
By Waugh N, Black C, Walker S, McIntyre L, Cummins E, Hillis G.

No. 40
What are the clinical outcome and cost-effectiveness of endoscopy undertaken by nurses when compared with doctors? A Multi-Institution Nurse Endoscopy Trial (MINuET).
By Williams J, Russell I, Durai D, Cheung W-Y, Farrin A, Bloor K, *et al*.

No. 41
The clinical and cost-effectiveness of oxaliplatin and capecitabine for the adjuvant treatment of colon cancer: systematic review and economic evaluation.
By Pandor A, Eggington S, Paisley S, Tappenden P, Sutcliffe P.

No. 42
A systematic review of the effectiveness of adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis in adults and an economic evaluation of their cost-effectiveness.
By Chen Y-F, Jobanputra P, Barton P, Jowett S, Bryan S, Clark W, *et al*.

No. 43
Telemedicine in dermatology: a randomised controlled trial.
By Bowns IR, Collins K, Walters SJ, McDonagh AJG.

No. 44
Cost-effectiveness of cell salvage and alternative methods of minimising perioperative allogeneic blood transfusion: a systematic review and economic model.
By Davies L, Brown TJ, Haynes S, Payne K, Elliott RA, McCollum C.

No. 45
Clinical effectiveness and cost-effectiveness of laparoscopic surgery for colorectal cancer: systematic reviews and economic evaluation.
By Murray A, Lourenco T, de Verteuil R, Hernandez R, Fraser C, McKinley A, *et al*.

No. 46
Etanercept and efalizumab for the treatment of psoriasis: a systematic review.
By Woolacott N, Hawkins N, Mason A, Kainth A, Khadjesari Z, Bravo Vergel Y, *et al*.

No. 47
Systematic reviews of clinical decision tools for acute abdominal pain.
By Liu JLY, Wyatt JC, Deeks JJ, Clamp S, Keen J, Verde P, *et al*.

No. 48
Evaluation of the ventricular assist device programme in the UK.
By Sharples L, Buxton M, Caine N, Cafferty F, Demiris N, Dyer M, *et al*.

No. 49
A systematic review and economic model of the clinical and cost-effectiveness of immunosuppressive therapy for renal transplantation in children.
By Yao G, Albon E, Adi Y, Milford D, Bayliss S, Ready A, *et al*.

No. 50
Amniocentesis results: investigation of anxiety. The ARIA trial.
By Hewison J, Nixon J, Fountain J, Cocks K, Jones C, Mason G, *et al*.

Volume 11, 2007

No. 1
Pemetrexed disodium for the treatment of malignant pleural mesothelioma: a systematic review and economic evaluation.
By Dundar Y, Bagust A, Dickson R, Dodd S, Green J, Haycox A, *et al*.

No. 2
A systematic review and economic model of the clinical effectiveness and cost-effectiveness of docetaxel in combination with prednisone or prednisolone for the treatment of hormone-refractory metastatic prostate cancer.
By Collins R, Fenwick E, Trowman R, Perard R, Norman G, Light K, *et al*.

No. 3
A systematic review of rapid diagnostic tests for the detection of tuberculosis infection.
By Dinnes J, Deeks J, Kunst H, Gibson A, Cummins E, Waugh N, *et al*.

No. 4
The clinical effectiveness and cost-effectiveness of strontium ranelate for the prevention of osteoporotic fragility fractures in postmenopausal women.
By Stevenson M, Davis S, Lloyd-Jones M, Beverley C.

No. 5
A systematic review of quantitative and qualitative research on the role and effectiveness of written information available to patients about individual medicines.
By Raynor DK, Blenkinsopp A, Knapp P, Grime J, Nicolson DJ, Pollock K, *et al*.

No. 6
Oral naltrexone as a treatment for relapse prevention in formerly opioid-dependent drug users: a systematic review and economic evaluation.
By Adi Y, Juarez-Garcia A, Wang D, Jowett S, Frew E, Day E, *et al*.

No. 7
Glucocorticoid-induced osteoporosis: a systematic review and cost–utility analysis.
By Kanis JA, Stevenson M, McCloskey EV, Davis S, Lloyd-Jones M.

No. 8
Epidemiological, social, diagnostic and economic evaluation of population screening for genital chlamydial infection.
By Low N, McCarthy A, Macleod J, Salisbury C, Campbell R, Roberts TE, *et al*.

No. 9
Methadone and buprenorphine for the management of opioid dependence: a systematic review and economic evaluation.
By Connock M, Juarez-Garcia A, Jowett S, Frew E, Liu Z, Taylor RJ, *et al*.

No. 10
Exercise Evaluation Randomised Trial (EXERT): a randomised trial comparing GP referral for leisure centre-based exercise, community-based walking and advice only.
By Isaacs AJ, Critchley JA, See Tai S, Buckingham K, Westley D, Harridge SDR, *et al*.

No. 11
Interferon alfa (pegylated and non-pegylated) and ribavirin for the treatment of mild chronic hepatitis C: a systematic review and economic evaluation.
By Shepherd J, Jones J, Hartwell D, Davidson P, Price A, Waugh N.

No. 12
Systematic review and economic evaluation of bevacizumab and cetuximab for the treatment of metastatic colorectal cancer.
By Tappenden P, Jones R, Paisley S, Carroll C.

No. 13
A systematic review and economic evaluation of epoetin alfa, epoetin beta and darbepoetin alfa in anaemia associated with cancer, especially that attributable to cancer treatment.
By Wilson J, Yao GL, Raftery J, Bohlius J, Brunskill S, Sandercock J, *et al*.

No. 14
A systematic review and economic evaluation of statins for the prevention of coronary events.
By Ward S, Lloyd Jones M, Pandor A, Holmes M, Ara R, Ryan A, *et al*.

No. 15
A systematic review of the effectiveness and cost-effectiveness of different models of community-based respite care for frail older people and their carers.
By Mason A, Weatherly H, Spilsbury K, Arksey H, Golder S, Adamson J, *et al*.

No. 16
Additional therapy for young children with spastic cerebral palsy: a randomised controlled trial.
By Weindling AM, Cunningham CC, Glenn SM, Edwards RT, Reeves DJ.

No. 17
Screening for type 2 diabetes: literature review and economic modelling.
By Waugh N, Scotland G, McNamee P, Gillett M, Brennan A, Goyder E, *et al*.

No. 18
The effectiveness and cost-effectiveness of cinacalcet for secondary hyperparathyroidism in end-stage renal disease patients on dialysis: a systematic review and economic evaluation.
By Garside R, Pitt M, Anderson R, Mealing S, Roome C, Snaith A, *et al*.

No. 19
The clinical effectiveness and cost-effectiveness of gemcitabine for metastatic breast cancer: a systematic review and economic evaluation.
By Takeda AL, Jones J, Loveman E, Tan SC, Clegg AJ.

No. 20
A systematic review of duplex ultrasound, magnetic resonance angiography and computed tomography angiography for the diagnosis and assessment of symptomatic, lower limb peripheral arterial disease.
By Collins R, Cranny G, Burch J, Aguiar-Ibáñez R, Craig D, Wright K, *et al*.

No. 21
The clinical effectiveness and cost-effectiveness of treatments for children with idiopathic steroid-resistant nephrotic syndrome: a systematic review.
By Colquitt JL, Kirby J, Green C, Cooper K, Trompeter RS.

No. 22
A systematic review of the routine monitoring of growth in children of primary school age to identify growth-related conditions.
By Fayter D, Nixon J, Hartley S, Rithalia A, Butler G, Rudolf M, *et al*.

No. 23
Systematic review of the effectiveness of preventing and treating *Staphylococcus aureus* carriage in reducing peritoneal catheter-related infections.
By McCormack K, Rabindranath K, Kilonzo M, Vale L, Fraser C, McIntyre L, *et al*.

No. 24
The clinical effectiveness and cost of repetitive transcranial magnetic stimulation versus electroconvulsive therapy in severe depression: a multicentre pragmatic randomised controlled trial and economic analysis.
By McLoughlin DM, Mogg A, Eranti S, Pluck G, Purvis R, Edwards D, *et al*.

No. 25
A randomised controlled trial and economic evaluation of direct versus indirect and individual versus group modes of speech and language therapy for children with primary language impairment.
By Boyle J, McCartney E, Forbes J, O'Hare A.

No. 26
Hormonal therapies for early breast cancer: systematic review and economic evaluation.
By Hind D, Ward S, De Nigris E, Simpson E, Carroll C, Wyld L.

No. 27
Cardioprotection against the toxic effects of anthracyclines given to children with cancer: a systematic review.
By Bryant J, Picot J, Levitt G, Sullivan I, Baxter L, Clegg A.

No. 28
Adalimumab, etanercept and infliximab for the treatment of ankylosing spondylitis: a systematic review and economic evaluation.
By McLeod C, Bagust A, Boland A, Dagenais P, Dickson R, Dundar Y, *et al*.

No. 29
Prenatal screening and treatment strategies to prevent group B streptococcal and other bacterial infections in early infancy: cost-effectiveness and expected value of information analyses.
By Colbourn T, Asseburg C, Bojke L, Philips Z, Claxton K, Ades AE, *et al*.

No. 30
Clinical effectiveness and cost-effectiveness of bone morphogenetic proteins in the non-healing of fractures and spinal fusion: a systematic review.
By Garrison KR, Donell S, Ryder J, Shemilt I, Mugford M, Harvey I, *et al*.

No. 31
A randomised controlled trial of postoperative radiotherapy following breast-conserving surgery in a minimum-risk older population. The PRIME trial.
By Prescott RJ, Kunkler IH, Williams LJ, King CC, Jack W, van der Pol M, *et al*.

No. 32
Current practice, accuracy, effectiveness and cost-effectiveness of the school entry hearing screen.
By Bamford J, Fortnum H, Bristow K, Smith J, Vamvakas G, Davies L, *et al*.

No. 33
The clinical effectiveness and cost-effectiveness of inhaled insulin in diabetes mellitus: a systematic review and economic evaluation.
By Black C, Cummins E, Royle P, Philip S, Waugh N.

No. 34
Surveillance of cirrhosis for hepatocellular carcinoma: systematic review and economic analysis.
By Thompson Coon J, Rogers G, Hewson P, Wright D, Anderson R, Cramp M, *et al*.

No. 35
The Birmingham Rehabilitation Uptake Maximisation Study (BRUM). Homebased compared with hospital-based cardiac rehabilitation in a multi-ethnic population: cost-effectiveness and patient adherence.
By Jolly K, Taylor R, Lip GYH, Greenfield S, Raftery J, Mant J, *et al*.

No. 36
A systematic review of the clinical, public health and cost-effectiveness of rapid diagnostic tests for the detection and identification of bacterial intestinal pathogens in faeces and food.
By Abubakar I, Irvine L, Aldus CF, Wyatt GM, Fordham R, Schelenz S, *et al*.

No. 37
A randomised controlled trial examining the longer-term outcomes of standard versus new antiepileptic drugs. The SANAD trial.
By Marson AG, Appleton R, Baker GA, Chadwick DW, Doughty J, Eaton B, *et al*.

No. 38
Clinical effectiveness and cost-effectiveness of different models of managing long-term oral anti-coagulation therapy: a systematic review and economic modelling.
By Connock M, Stevens C, Fry-Smith A, Jowett S, Fitzmaurice D, Moore D, *et al*.

No. 39
A systematic review and economic model of the clinical effectiveness and cost-effectiveness of interventions for preventing relapse in people with bipolar disorder.
By Soares-Weiser K, Bravo Vergel Y, Beynon S, Dunn G, Barbieri M, Duffy S, *et al*.

No. 40
Taxanes for the adjuvant treatment of early breast cancer: systematic review and economic evaluation.
By Ward S, Simpson E, Davis S, Hind D, Rees A, Wilkinson A.

No. 41
The clinical effectiveness and cost-effectiveness of screening for open angle glaucoma: a systematic review and economic evaluation.
By Burr JM, Mowatt G, Hernández R, Siddiqui MAR, Cook J, Lourenco T, *et al*.

No. 42
Acceptability, benefit and costs of early screening for hearing disability: a study of potential screening tests and models.
By Davis A, Smith P, Ferguson M, Stephens D, Gianopoulos I.

No. 43
Contamination in trials of educational interventions.
By Keogh-Brown MR, Bachmann MO, Shepstone L, Hewitt C, Howe A, Ramsay CR, *et al*.

No. 44
Overview of the clinical effectiveness of positron emission tomography imaging in selected cancers.
By Facey K, Bradbury I, Laking G, Payne E.

No. 45
The effectiveness and cost-effectiveness of carmustine implants and temozolomide for the treatment of newly diagnosed high-grade glioma: a systematic review and economic evaluation.
By Garside R, Pitt M, Anderson R, Rogers G, Dyer M, Mealing S, *et al*.

No. 46
Drug-eluting stents: a systematic review and economic evaluation.
By Hill RA, Boland A, Dickson R, Dündar Y, Haycox A, McLeod C, *et al*.

No. 47
The clinical effectiveness and cost-effectiveness of cardiac resynchronisation (biventricular pacing) for heart failure: systematic review and economic model.
By Fox M, Mealing S, Anderson R, Dean J, Stein K, Price A, *et al*.

No. 48
Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study.
By Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald AM, Knight R, *et al*.

No. 49
Cost-effectiveness of functional cardiac testing in the diagnosis and management of coronary artery disease: a randomised controlled trial. The CECaT trial.
By Sharples L, Hughes V, Crean A, Dyer M, Buxton M, Goldsmith K, *et al*.

No. 50
Evaluation of diagnostic tests when there is no gold standard. A review of methods.
By Rutjes AWS, Reitsma JB, Coomarasamy A, Khan KS, Bossuyt PMM.

No. 51
Systematic reviews of the clinical effectiveness and cost-effectiveness of proton pump inhibitors in acute upper gastrointestinal bleeding.
By Leontiadis GI, Sreedharan A, Dorward S, Barton P, Delaney B, Howden CW, *et al*.

No. 52
A review and critique of modelling in prioritising and designing screening programmes.
By Karnon J, Goyder E, Tappenden P, McPhie S, Towers I, Brazier J, *et al*.

No. 53
An assessment of the impact of the NHS Health Technology Assessment Programme.
By Hanney S, Buxton M, Green C, Coulson D, Raftery J.

Volume 12, 2008

No. 1
A systematic review and economic model of switching from nonglycopeptide to glycopeptide antibiotic prophylaxis for surgery.
By Cranny G, Elliott R, Weatherly H, Chambers D, Hawkins N, Myers L, *et al*.

No. 2
'Cut down to quit' with nicotine replacement therapies in smoking cessation: a systematic review of effectiveness and economic analysis.
By Wang D, Connock M, Barton P, Fry-Smith A, Aveyard P, Moore D.

No. 3
A systematic review of the effectiveness of strategies for reducing fracture risk in children with juvenile idiopathic arthritis with additional data on long-term risk of fracture and cost of disease management.
By Thornton J, Ashcroft D, O'Neill T, Elliott R, Adams J, Roberts C, *et al*.

No. 4
Does befriending by trained lay workers improve psychological well-being and quality of life for carers of people with dementia, and at what cost? A randomised controlled trial.
By Charlesworth G, Shepstone L, Wilson E, Thalanany M, Mugford M, Poland F.

No. 5
A multi-centre retrospective cohort study comparing the efficacy, safety and cost-effectiveness of hysterectomy and uterine artery embolisation for the treatment of symptomatic uterine fibroids. The HOPEFUL study.
By Hirst A, Dutton S, Wu O, Briggs A, Edwards C, Waldenmaier L, *et al*.

No. 6
Methods of prediction and prevention of pre-eclampsia: systematic reviews of accuracy and effectiveness literature with economic modelling.
By Meads CA, Cnossen JS, Meher S, Juarez-Garcia A, ter Riet G, Duley L, *et al*.

No. 7
The use of economic evaluations in NHS decision-making: a review and empirical investigation.
By Williams I, McIver S, Moore D, Bryan S.

No. 8
Stapled haemorrhoidectomy (haemorrhoidopexy) for the treatment of haemorrhoids: a systematic review and economic evaluation.
By Burch J, Epstein D, Baba-Akbari A, Weatherly H, Fox D, Golder S, *et al*.

No. 9
The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review.
By Loveman E, Frampton GK, Clegg AJ.

No. 10
Payment to healthcare professionals for patient recruitment to trials: systematic review and qualitative study.
By Raftery J, Bryant J, Powell J, Kerr C, Hawker S.

No. 11
Cyclooxygenase-2 selective non-steroidal anti-inflammatory drugs (etodolac, meloxicam, celecoxib, rofecoxib, etoricoxib, valdecoxib and lumiracoxib) for osteoarthritis and rheumatoid arthritis: a systematic review and economic evaluation.
By Chen Y-F, Jobanputra P, Barton P, Bryan S, Fry-Smith A, Harris G, *et al*.

No. 12
The clinical effectiveness and cost-effectiveness of central venous catheters treated with anti-infective agents in preventing bloodstream infections: a systematic review and economic evaluation.
By Hockenhull JC, Dwan K, Boland A, Smith G, Bagust A, Dundar Y, *et al*.

No. 13
Stepped treatment of older adults on laxatives. The STOOL trial.
By Mihaylov S, Stark C, McColl E, Steen N, Vanoli A, Rubin G, *et al*.

No. 14
A randomised controlled trial of cognitive behaviour therapy in adolescents with major depression treated by selective serotonin reuptake inhibitors. The ADAPT trial.
By Goodyer IM, Dubicka B, Wilkinson P, Kelvin R, Roberts C, Byford S, *et al*.

No. 15
The use of irinotecan, oxaliplatin and raltitrexed for the treatment of advanced colorectal cancer: systematic review and economic evaluation.
By Hind D, Tappenden P, Tumur I, Eggington E, Sutcliffe P, Ryan A.

No. 16
Ranibizumab and pegaptanib for the treatment of age-related macular degeneration: a systematic review and economic evaluation.
By Colquitt JL, Jones J, Tan SC, Takeda A, Clegg AJ, Price A.

No. 17
Systematic review of the clinical effectiveness and cost-effectiveness of 64-slice or higher computed tomography angiography as an alternative to invasive coronary angiography in the investigation of coronary artery disease.
By Mowatt G, Cummins E, Waugh N, Walker S, Cook J, Jia X, *et al*.

No. 18
Structural neuroimaging in psychosis: a systematic review and economic evaluation.
By Albon E, Tsourapas A, Frew E, Davenport C, Oyebode F, Bayliss S, *et al*.

No. 19
Systematic review and economic analysis of the comparative effectiveness of different inhaled corticosteroids and their usage with long-acting beta$_2$ agonists for the treatment of chronic asthma in adults and children aged 12 years and over.
By Shepherd J, Rogers G, Anderson R, Main C, Thompson-Coon J, Hartwell D, *et al*.

No. 20
Systematic review and economic analysis of the comparative effectiveness of different inhaled corticosteroids and their usage with long-acting beta$_2$ agonists for the treatment of chronic asthma in children under the age of 12 years.
By Main C, Shepherd J, Anderson R, Rogers G, Thompson-Coon J, Liu Z, *et al*.

No. 21
Ezetimibe for the treatment of hypercholesterolaemia: a systematic review and economic evaluation.
By Ara R, Tumur I, Pandor A, Duenas A, Williams R, Wilkinson A, *et al*.

No. 22
Topical or oral ibuprofen for chronic knee pain in older people. The TOIB study.
By Underwood M, Ashby D, Carnes D, Castelnuovo E, Cross P, Harding G, *et al*.

No. 23
A prospective randomised comparison of minor surgery in primary and secondary care. The MiSTIC trial.
By George S, Pockney P, Primrose J, Smith H, Little P, Kinley H, *et al*.

No. 24
A review and critical appraisal of measures of therapist–patient interactions in mental health settings.
By Cahill J, Barkham M, Hardy G, Gilbody S, Richards D, Bower P, *et al*.

No. 25
The clinical effectiveness and cost-effectiveness of screening programmes for amblyopia and strabismus in children up to the age of 4–5 years: a systematic review and economic evaluation.
By Carlton J, Karnon J, Czoski-Murray C, Smith KJ, Marr J.

No. 26
A systematic review of the clinical effectiveness and cost-effectiveness and economic modelling of minimal incision total hip replacement approaches in the management of arthritic disease of the hip.
By de Verteuil R, Imamura M, Zhu S, Glazener C, Fraser C, Munro N, *et al*.

No. 27
A preliminary model-based assessment of the cost–utility of a screening programme for early age-related macular degeneration.
By Karnon J, Czoski-Murray C, Smith K, Brand C, Chakravarthy U, Davis S, *et al*.

No. 28
Intravenous magnesium sulphate and sotalol for prevention of atrial fibrillation after coronary artery bypass surgery: a systematic review and economic evaluation.
By Shepherd J, Jones J, Frampton GK, Tanajewski L, Turner D, Price A.

No. 29
Absorbent products for urinary/faecal incontinence: a comparative evaluation of key product categories.
By Fader M, Cottenden A, Getliffe K, Gage H, Clarke-O'Neill S, Jamieson K, *et al*.

No. 30
A systematic review of repetitive functional task practice with modelling of resource use, costs and effectiveness.
By French B, Leathley M, Sutton C, McAdam J, Thomas L, Forster A, *et al*.

No. 31
The effectiveness and cost-effectivness of minimal access surgery amongst people with gastro-oesophageal reflux disease – a UK collaborative study. The REFLUX trial.
By Grant A, Wileman S, Ramsay C, Bojke L, Epstein D, Sculpher M, *et al*.

No. 32
Time to full publication of studies of anti-cancer medicines for breast cancer and the potential for publication bias: a short systematic review.
By Takeda A, Loveman E, Harris P, Hartwell D, Welch K.

No. 33
Performance of screening tests for child physical abuse in accident and emergency departments.
By Woodman J, Pitt M, Wentz R, Taylor B, Hodes D, Gilbert RE.

No. 34
Curative catheter ablation in atrial fibrillation and typical atrial flutter: systematic review and economic evaluation.
By Rodgers M, McKenna C, Palmer S, Chambers D, Van Hout S, Golder S, *et al*.

No. 35
Systematic review and economic modelling of effectiveness and cost utility of surgical treatments for men with benign prostatic enlargement.
By Lourenco T, Armstrong N, N'Dow J, Nabi G, Deverill M, Pickard R, *et al*.

No. 36
Immunoprophylaxis against respiratory syncytial virus (RSV) with palivizumab in children: a systematic review and economic evaluation.
By Wang D, Cummins C, Bayliss S, Sandercock J, Burls A.

Volume 13, 2009

No. 1
Deferasirox for the treatment of iron overload associated with regular blood transfusions (transfusional haemosiderosis) in patients suffering with chronic anaemia: a systematic review and economic evaluation.
By McLeod C, Fleeman N, Kirkham J, Bagust A, Boland A, Chu P, *et al*.

No. 2
Thrombophilia testing in people with venous thromboembolism: systematic review and cost-effectiveness analysis.
By Simpson EL, Stevenson MD, Rawdin A, Papaioannou D.

No. 3
Surgical procedures and non-surgical devices for the management of non-apnoeic snoring: a systematic review of clinical effects and associated treatment costs.
By Main C, Liu Z, Welch K, Weiner G, Quentin Jones S, Stein K.

No. 4
Continuous positive airway pressure devices for the treatment of obstructive sleep apnoea–hypopnoea syndrome: a systematic review and economic analysis.
By McDaid C, Griffin S, Weatherly H, Durée K, van der Burgt M, van Hout S, Akers J, *et al*.

No. 5
Use of classical and novel biomarkers as prognostic risk factors for localised prostate cancer: a systematic review.
By Sutcliffe P, Hummel S, Simpson E, Young T, Rees A, Wilkinson A, *et al*.

No. 6
The harmful health effects of recreational ecstasy: a systematic review of observational evidence.
By Rogers G, Elston J, Garside R, Roome C, Taylor R, Younger P, *et al*.

No. 7
Systematic review of the clinical effectiveness and cost-effectiveness of oesophageal Doppler monitoring in critically ill and high-risk surgical patients.
By Mowatt G, Houston G, Hernández R, de Verteuil R, Fraser C, Cuthbertson B, *et al*.

No. 8
The use of surrogate outcomes in model-based cost-effectiveness analyses: a survey of UK Health Technology Assessment reports.
By Taylor RS, Elston J.

No. 9
Controlling Hypertension and Hypotension Immediately Post Stroke (CHHIPS) – a randomised controlled trial.
By Potter J, Mistri A, Brodie F, Chernova J, Wilson E, Jagger C, *et al*.

No. 10
Routine antenatal anti-D prophylaxis for RhD-negative women: a systematic review and economic evaluation.
By Pilgrim H, Lloyd-Jones M, Rees A.

No. 11
Amantadine, oseltamivir and zanamivir for the prophylaxis of influenza (including a review of existing guidance no. 67): a systematic review and economic evaluation.
By Tappenden P, Jackson R, Cooper K, Rees A, Simpson E, Read R, *et al.*

No. 12
Improving the evaluation of therapeutic interventions in multiple sclerosis: the role of new psychometric methods.
By Hobart J, Cano S.

No. 13
Treatment of severe ankle sprain: a pragmatic randomised controlled trial comparing the clinical effectiveness and cost-effectiveness of three types of mechanical ankle support with tubular bandage. The CAST trial.
By Cooke MW, Marsh JL, Clark M, Nakash R, Jarvis RM, Hutton JL, *et al.*, on behalf of the CAST trial group.

No. 14
Non-occupational postexposure prophylaxis for HIV: a systematic review.
By Bryant J, Baxter L, Hird S.

No. 15
Blood glucose self-monitoring in type 2 diabetes: a randomised controlled trial.
By Farmer AJ, Wade AN, French DP, Simon J, Yudkin P, Gray A, *et al.*

No. 16
How far does screening women for domestic (partner) violence in different health-care settings meet criteria for a screening programme? Systematic reviews of nine UK National Screening Committee criteria.
By Feder G, Ramsay J, Dunne D, Rose M, Arsene C, Norman R, *et al.*

No. 17
Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin: systematic review and economic evaluation.
By Simpson, EL, Duenas A, Holmes MW, Papaioannou D, Chilcott J.

No. 18
The role of magnetic resonance imaging in the identification of suspected acoustic neuroma: a systematic review of clinical and cost-effectiveness and natural history.
By Fortnum H, O'Neill C, Taylor R, Lenthall R, Nikolopoulos T, Lightfoot G, *et al.*

No. 19
Dipsticks and diagnostic algorithms in urinary tract infection: development and validation, randomised trial, economic analysis, observational cohort and qualitative study.
By Little P, Turner S, Rumsby K, Warner G, Moore M, Lowes JA, *et al.*

No. 20
Systematic review of respite care in the frail elderly.
By Shaw C, McNamara R, Abrams K, Cannings-John R, Hood K, Longo M, *et al.*

No. 21
Neuroleptics in the treatment of aggressive challenging behaviour for people with intellectual disabilities: a randomised controlled trial (NACHBID).
By Tyrer P, Oliver-Africano P, Romeo R, Knapp M, Dickens S, Bouras N, *et al.*

No. 22
Randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of selective serotonin reuptake inhibitors plus supportive care, versus supportive care alone, for mild to moderate depression with somatic symptoms in primary care: the THREAD (THREshold for AntiDepressant response) study.
By Kendrick T, Chatwin J, Dowrick C, Tylee A, Morriss R, Peveler R, *et al.*

No. 23
Diagnostic strategies using DNA testing for hereditary haemochromatosis in at-risk populations: a systematic review and economic evaluation.
By Bryant J, Cooper K, Picot J, Clegg A, Roderick P, Rosenberg W, *et al.*

No. 24
Enhanced external counterpulsation for the treatment of stable angina and heart failure: a systematic review and economic analysis.
By McKenna C, McDaid C, Suekarran S, Hawkins N, Claxton K, Light K, *et al.*

No. 25
Development of a decision support tool for primary care management of patients with abnormal liver function tests without clinically apparent liver disease: a record-linkage population cohort study and decision analysis (ALFIE).
By Donnan PT, McLernon D, Dillon JF, Ryder S, Roderick P, Sullivan F, *et al.*

No. 26
A systematic review of presumed consent systems for deceased organ donation.
By Rithalia A, McDaid C, Suekarran S, Norman G, Myers L, Sowden A.

No. 27
Paracetamol and ibuprofen for the treatment of fever in children: the PITCH randomised controlled trial.
By Hay AD, Redmond NM, Costelloe C, Montgomery AA, Fletcher M, Hollinghurst S, *et al.*

No. 28
A randomised controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE).
By Newman SP, Cooke D, Casbard A, Walker S, Meredith S, Nunn A, *et al.*

No. 29
Sensitivity analysis in economic evaluation: an audit of NICE current practice and a review of its use and value in decision-making.
By Andronis L, Barton P, Bryan S.

Suppl. 1
Trastuzumab for the treatment of primary breast cancer in HER2-positive women: a single technology appraisal.
By Ward S, Pilgrim H, Hind D.

Docetaxel for the adjuvant treatment of early node-positive breast cancer: a single technology appraisal.
By Chilcott J, Lloyd Jones M, Wilkinson A.

The use of paclitaxel in the management of early stage breast cancer.
By Griffin S, Dunn G, Palmer S, Macfarlane K, Brent S, Dyker A, *et al.*

Rituximab for the first-line treatment of stage III/IV follicular non-Hodgkin's lymphoma.
By Dundar Y, Bagust A, Hounsome J, McLeod C, Boland A, Davis H, *et al.*

Bortezomib for the treatment of multiple myeloma patients.
By Green C, Bryant J, Takeda A, Cooper K, Clegg A, Smith A, *et al.*

Fludarabine phosphate for the first-line treatment of chronic lymphocytic leukaemia.
By Walker S, Palmer S, Erhorn S, Brent S, Dyker A, Ferrie L, *et al.*

Erlotinib for the treatment of relapsed non-small cell lung cancer.
By McLeod C, Bagust A, Boland A, Hockenhull J, Dundar Y, Proudlove C, *et al.*

Cetuximab plus radiotherapy for the treatment of locally advanced squamous cell carcinoma of the head and neck.
By Griffin S, Walker S, Sculpher M, White S, Erhorn S, Brent S, *et al.*

Infliximab for the treatment of adults with psoriasis.
By Loveman E, Turner D, Hartwell D, Cooper K, Clegg A.

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The HTA programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (www.hta.ac.uk) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.

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