Journal of Public Health | Vol. 33, No. 2, pp. 292–301 | doi:10.1093/pubmed/fdq075 | Advance Access Publication 29 September 2010

Outcome of a postnatal depression screening programme using the Edinburgh Postnatal Depression Scale: a randomized controlled trial

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ABSTRACT

Background There is a lack of evidence on the effectiveness of postnatal depression (PND) screening programmes in reducing morbidity. The aim of this study was to evaluate the effectiveness of a PND screening programme using Edinburgh Postnatal Depression Scale (EPDS) in improving maternal mental health.

Methods The randomized controlled trial design was used. Participants were 462 Chinese mothers with 2-month-old babies visiting Maternal and Child Health Centres in Hong Kong. Participants in the intervention group were screened for PND using the EPDS, whereas those in the control group were screened by clinical assessment. In both groups, participants identified with PND were offered follow-up management according to protocol.

Results Participants in the intervention group had better maternal mental health outcome as assessed by EPDS at 6 months (risk ratio: 0.59; 95% confidence interval: 0.39–0.89). The number needed to screen was 25.

Conclusions A PND screening programme comprising the use of EPDS as the screening tool and the provision of follow-up care had resulted in an improvement in maternal mental health at 6 months.
Trial Registration: ClinicalTrials.gov (US NIH) (NCT00251342).

Keywords adult, mental health, screening

Introduction

Postnatal depression (PND) is an important public health issue. The prevalence of non-psychotic PND is around 13–15%.[1,2] A Hong Kong study revealed that about 11–12% of local women were affected at 6 weeks postnatal.[3,4] The clinical course of PND is not well-defined. Many women are still depressed at 1 year *postpartum* if untreated.[5] Evidence shows that PND not only affects the mother, but also the mental health of the partner, marital relationship and health and development of the children.[1,2,6–10] Known

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risk factors include history of depression, depression during pregnancy, poor marital relationship and poor in-law relationship.[11] Non-directive counselling by health visitors has been found to be effective in treating PND.[12]

The evidence on the effectiveness of primary prevention is limited and inconclusive[1,13,14] and such information is unavailable for the Chinese population. For secondary prevention, the Edinburgh Postnatal Depression Scale (EPDS) has been established as a valid screening tool.[1,2,13] The Chinese version was validated with Hong Kong women at 6 weeks postnatal, against the structured clinical interview for DSM-III-R (SCID). With 9/10 as the cut-off, the sensitivity and specificity were 82 and 86%, respectively, with a positive predictive value of 44%.[3,15] Despite the higher sensitivity of EPDS than clinical assessment in identifying the condition,[16,17] the National Screening Committee recommends that there should be evidence from quality randomized controlled trials (RCTs) to demonstrate that a screening programme could reduce mortality or morbidity to justify its implementation.[18] A screening programme refers not only to the screening test itself, but all activities from identification of those likely to have the condition to diagnosis and treatment. As systematic differences between people who participate in screening programmes and those who do not are likely, people should be randomized to a screening programme or usual care, and the respective outcomes compared.[19] There has been no RCT demonstrating the effectiveness of a screening programme using EPDS as a screening tool in improving outcome.[1] This study attempted to fill this research gap. We hypothesized that maternal mental health outcome under the EPDS screening programme would be better than that under usual care.

Methods

Settings

The study was carried out in Maternal and Child Health Centres (MCHCs) in Hong Kong, attended by about 90% of newborns. Staffed by doctors and nurses, MCHCs provide preventive services for mothers and children from birth to 5 years. Participants were recruited from the MCHCs of four selected communities (Sham Shui Po, Tin Shui Wai, Tseung Kwan O and Tuen Mun) during different periods from 2005 to 2006.

Participants

Participants were mothers of 2-month-old babies who visited the MCHCs for routine child health services. Non-local residents and those who did not use the Chinese language, had participated in other PND screening programmes, or were receiving psychiatric treatment were excluded.

The intervention

The intervention arm was the screening programme where EPDS was used to identify participants with PND. Those with scores above the cut-off (9/10) or suicidal ideation (positive answer to question 10) were offered non-directive counselling by MCH nurses or management by the community psychiatric team as appropriate. The control arm was the usual practice where nurses carried out clinical assessment. Mothers deemed to require further management were offered non-directive counselling or psychiatric referral.

The MCH nurses who provided counselling to both intervention and control groups had undergone a 12 h training course (a 3 h lecture on PND and a 9 h workshop on non-directive counselling), in addition to their basic professional and in-service training. They also received ongoing support from doctors and the community psychiatric team.

Outcome measures

Maternal mental health was measured by a battery of scales. The primary outcome measure was the participants' EPDS scores at 6 months postnatal, as a binary variable with 9/10 as cut-off.[3] The EPDS is a 10-item self-report scale designed to identify women with substantial depressive symptoms during the postnatal period. The secondary outcome measures included the participants' EPDS scores at 18 months, General Health Questionnaire-12 (GHQ-12) scores, Parenting Stress Index (PSI) scores and Chinese Kansas Marital Satisfaction Scale (CKMSS) scores at 6 and 18 months. The GHQ-12 is a self-report questionnaire designed to identify a range of neurotic conditions.[15,20] The PSI is a measure of stressful parent–child relationship.[21] The CKMSS is a 3-item 7-point self-report questionnaire assessing satisfaction with spouse, marriage and marital relationship. The Chinese versions of these scales have been validated.[3,15,20–22] Other secondary outcome measures included the child's body weight at 6 and 18 months obtained from MCHC records, and the number of hospitalizations and visits to doctors within the first 6 and 18 months, as reported by mothers or caregivers.

Demographic information and known predictors of PND including history of psychiatric illness, depression during pregnancy, marital relationship (CKMSS) and relationship with mother-in-law were collected.[11] Relationship with mother-in-law was measured on a 5-point Likert scale from 1 (very poor) to 5 (very good).

Procedures

Simple randomization was used. Prior to recruitment, random numbers were generated by research officer A, who was not involved in the rest of the study, using a computerized random number generator. The numbers were placed in sequentially numbered, opaque and sealed envelopes. Eligible mothers who consented to participate were directed to research officer B, who assigned them randomly to either the intervention or control group.

To mask the group allocation, both groups went through the same procedures: (i) completion of questionnaires on demographics and known risk factors[11] and 'screening' questionnaires (EPDS for the intervention group and the General Self-Efficacy Scale for the control group, both being similar in item number and format) and (ii) clinical assessment by an MCH nurse (nurse A) blind to the participants' group status and scores, who also made treatment recommendations. The clinical assessment included observing participants' expression and behaviour, enquiring about feelings, appetite, sleep pattern, childcare and suicidal ideas. After clinical assessment, clinical files were sent to research officer B who directed participants to further management according to their EPDS scores and/or clinical assessment results. According to protocol, participants in the control group assessed as having probable PND and those in the intervention group with EPDS scores $\geq$10 or suicidal ideation were directed to MCH nurse B for further exploration of the condition and non-directive counselling. Moreover, participants in the intervention group not meeting the above EPDS criteria but assessed by nurse A as having probable PND were also directed to nurse B for counselling, due to ethical reasons. The rest continued with routine services.

At each clinic session, the same nurse (B) provided counselling to both intervention and control group participants, and was blind to their group allocation and EPDS scores. The counselling lasted about 30–45 min. After counselling, nurse B recorded her recommendation for subsequent management (MCH nurse counselling or community psychiatric team referral) in the clinic record. To safeguard participants' welfare, a doctor not involved in the study reviewed all clinical information (EPDS scores where available, clinical notes and recommendations of both nurses) and made the final management recommendation according to protocol (participants with EPDS scores $\geq$10, suicidal ideation or identified with probable PND by clinical assessment were to be offered further counselling). At any stage, participants might be referred to the psychiatric team if deemed necessary.

At 6 and 18 months postnatal, all participants were requested to complete a set of questionnaires (see outcome measures). Those personally attended MCHCs completed the questionnaires on-site. Those not attending personally were given the questionnaires and stamped envelopes through the caregivers. Participants no longer using the MCH service were sent the questionnaires and stamped envelopes by post. Figure 1 shows the diagram flow of recruitment and follow-up in the study.

This study was approved by the ethics committees of the Hong Kong Department of Health and Hospital Authority.

Sample size

On the basis of informed clinical experience, it was estimated that about two-thirds of mothers with depression would remit by 6 months postnatal with intervention, compared with one-fifth of those without. With a prevalence of PND of about 12% and a positive predictive value of 44% for the EPDS,[3] about 22% of the control group and 9% of the intervention group would have scores above the EPDS cut-off, at 6 months postnatal. To detect such difference (power = 0.90, alpha = 0.05, two-sided),[23] 161 participants per group were needed. Allowing for 30% wastage, 460 participants (230 per group) were required.

Statistical methods

The outcome variable of EPDS as a binary measure between intervention and control groups was analysed and presented as risk ratio (RR) and 95% confidence interval (CI). Other outcome variables as continuous scale were calculated by unpaired *t*-test. The reliability of all questionnaires was tested using the Cronbach's alpha. The analysis was performed on the intention-to-treat basis using the Statistical Package for Social Sciences (Version 14). Possible confounding of the risk of outcomes was controlled by multiple (logistic) regression if needed.

Results

The flow of participants through eligibility assessment, consent and randomization is shown in Fig. 2. Of 552 eligible mothers, 462 (83.7%) consented to participate and were randomized to the intervention or control group (231 per group). Eligible clients who refused participation ($n = 90$) did not differ in socio-economic characteristics from those who consented. The baseline characteristics of the participants in both groups are largely the same. The details are in Table 1.

Assessment at 2 months

At 2 months postnatal, among the 231 intervention group participants, 58 scored $\geq$10 on the EPDS and another 9

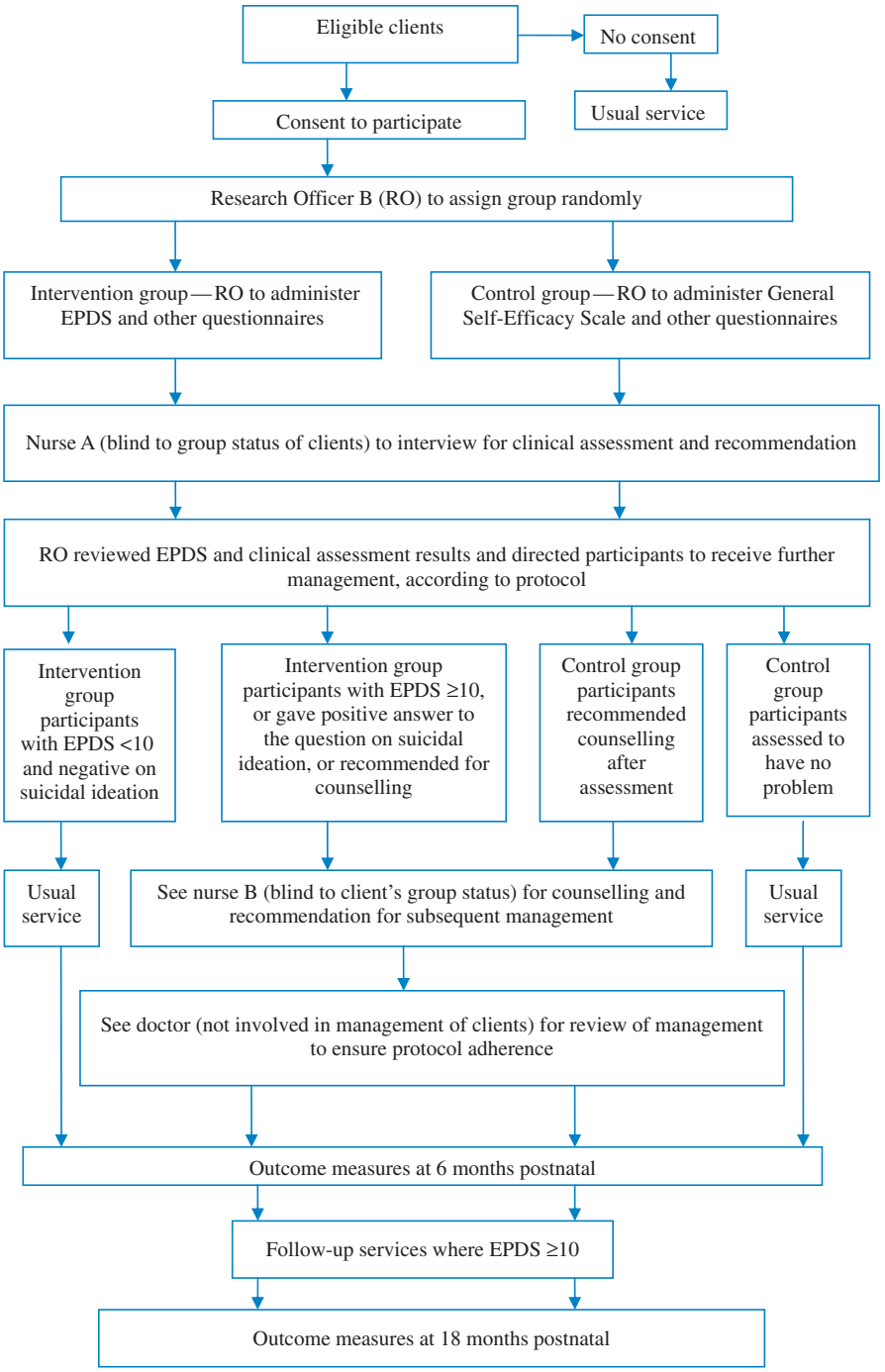

Fig. 1 Randomization procedures.

scored <10 but positive on suicidal ideation. According to the protocol, all 67 (29%) should have been offered follow-up counselling. However, 16 did not receive follow-up treatment (10 defaulted recommended treatment whereas 6 were inadvertently discharged). The remaining 51 received different combinations of treatments: (i) 42 received counselling by MCH nurses, of whom eight received additional psychiatric nurse counselling whereas 3 received psychiatric nurse counselling and treatment by a psychiatrist; (ii) another 8 received psychiatric nurse counselling initially, with one of them receiving further treatment by a psychiatrist; and (iii) 1 participant received treatment by a psychiatrist only. Among the 164 with EPDS scores <10 and without suicidal ideation, 6 were clinically assessed as having

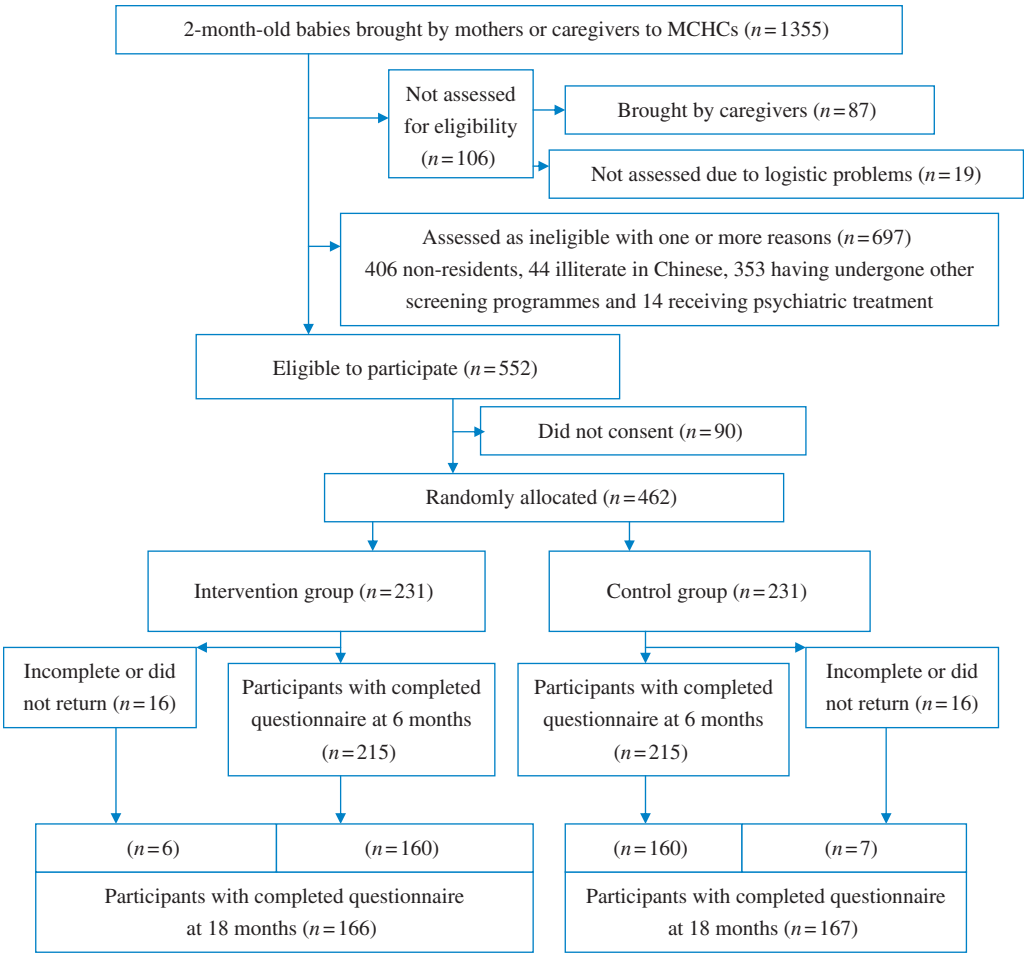

Fig. 2 Flow of participants through eligibility assessment, consent and randomization and completion of outcome measures.

probable PND and 4 received MCH nurse counselling. Two were inadvertently discharged. In total, 55 (23.8%) in the intervention arm received treatment.

In the control group, 14 (6.0%) of 231 were clinically assessed as having probable PND. Three were inadvertently discharged. Ten received MCH nurse counselling initially; four of whom received further psychiatric nurse counselling, with one of these having received additional psychiatric treatment. One participant received counselling by a psychiatric nurse only. In total, 11 (4.8%) in the control arm received treatment.

Findings at 6 and 18 months

At 6-month follow-up, 430 (93.1%) completed the questionnaires (215 per group). There were 32 with missing data (participants uncontactable, non-return or non-completion of the questionnaires). At 18 months, 166 (71.9%) from the intervention group and 167 (72.3%) from the control group completed the questionnaires. No adverse events were reported throughout the study. For those with incomplete data, a more conservative approach of substituting the missing values by the overall mean of participants in both groups was used.[24]

At 6 months, there were 30 in the intervention group with EPDS scores $\geq$10, of which 14 scored $<$10 and 16 scored $\geq$10 at 2 months (14 of these 16 received various treatment and two defaulted services). Subsequent to the 6 month assessment, 8 of these 30 received further MCH nurse counselling whereas 5 were seen by the community psychiatric team. Among those with EPDS scores $<$10 but assessed as probable PND cases clinically at 2 months, none of them had EPDS scores $\geq$10 at 6 months. In the control group, there were 51 with EPDS scores $\geq$10, of whom 45 were assessed as negative at 2 months and 6 were assessed as having probable PND (1 of these 6 was inadvertently discharged and 5 received treatment). Subsequent to the 6 month assessment, 17 of these 51 received further MCH nurse counselling and seven were seen by the community psychiatric team.

Table 1 Comparison between intervention and control groups at baseline

	Intervention group (n = 231)	*Control group (n = 231)*
Family income		
HK$19 999 or below	107 (46.5%)	126 (55.0%)
HK$20 000 or above	123 (53.5%)	103 (45.0%)
Mother's educational attainment		
Form 5 or below	156 (67.5%)	168 (72.7%)
Form 6 or above	75 (32.5%)	63 (27.3%)
Mother's employment status		
Working	141 (61.0%)	124 (53.7%)
Not working	90 (39.0%)	107 (46.3%)
Father's educational attainment		
Form 5 or below	137 (59.3%)	141 (61.0%)
Form 6 or above	76 (32.9%)	67 (29.0%)
Missing	18 (7.8%)	23 (10.0%)
Father's employment status		
Working	222 (96.1%)	219 (94.8%)
Not working	9 (3.9%)	12 (5.2%)
Social security status		
On social security	7 (3.0%)	11 (4.8%)
Not on social security	224 (97.0%)	220 (95.2%)
Marital status		
Married/*de facto*	224 (97.0%)	217 (93.9%)
Separated/divorced/widowed/never married	7 (3.0%)	14 (6.1%)
Psychiatric illness during pregnancy		
Yes	1 (0.4%)	1 (0.4%)
No	230 (99.6%)	230 (99.6%)
Past history of psychiatric illness		
Yes	6 (2.6%)	1 (0.4%)
No	225 (97.4%)	230 (99.6%)
Living arrangement with child		
Lives with child all the time	223 (96.5%)	214 (92.6%)
Does not live with child all the time	8 (3.5%)	17 (7.4%)
Main child carer		
Parents	146 (63.2%)	151 (64.5%)
Others	85 (36.8%)	80 (34.6%)
Mothers' length of residence in HK (years), mean (SD)	23.98 (11.54)	23.65 (12.34)
In-law relationship, mean (SD)	3.98 (0.99)	4.01 (1.05)
Marital satisfaction, mean (SD)	17.37 (2.85)	17.32 (2.65)
EPDS score, mean (SD)	6.45 (4.26)	N/A

SD, standard deviation; N/A, not applicable.

Analysis based on intention to treat indicated that at 6 months, fewer participants in the intervention group ($n = 30$, 13%) had EPDS scores above the cut-off than the control group ($n = 51$, 22.1%; RR = 0.59, 95% CI: 0.39–0.89). After adjusting for known predictors of PND (marital relationship at 2 months, history of psychiatric illness, depression during pregnancy and relationship with mother-in-law) using multiple logistic regression, the effect remained significant (data not shown). The number needed to screen to prevent one PND case at 6 months postnatal was 11. However, as the EPDS (not a diagnostic tool) instead of a psychiatric assessment was used to ascertain the condition, the positive predictive value of the Chinese EPDS (44%) was used for adjustment. The adjusted number needed to screen was 25.[25]

At 18 months, there were 34 and 31 participants from the intervention and control groups, respectively, with

EPDS scores ≥10 (RR = 1.10, 95% CI: 0.70–1.73), with 18 (intervention group) and 13 (control group) assessed negative at both 2 and 6 months. Sixteen from the intervention group and 18 from the control group were assessed positive at 2 months and/or 6 months and remained positive (EPDS ≥10) at 18 months. There was no statistically significant difference between the intervention and control groups in all other outcome measures at 6 and 18 months, except the number of child visits to doctors, although the rest were all in the expected direction (Table 2). There was an increase in the number of child visits to doctors in the intervention group ($P = 0.039$) as reported at 6 months, but this difference must be interpreted with caution because of multiple comparisons. The Cronbach's alphas of PSI, GHQ-12 and CKMSS were above 0.8.

Discussion

Main findings

Our results indicated that mothers who went through a PND screening programme using EPDS had better mental health outcome than those under usual care. The essential difference between the two programmes was the method of identification. In a primary care setting with non-specialist nurses, a simple tool such as the EPDS can improve PND identification. Under the EPDS screening programme, a higher proportion of mothers with probable PND were identified (29.0% in the intervention group versus 6.0% in the control), with a 41% reduction in the proportion with EPDS scores ≥10 at 6 months (13% in the intervention group versus 22% in the control group). Twenty-five women would need to be screened (and appropriately managed) to prevent one having PND at 6 months postnatal.

There was no significant difference in EPDS scores between the intervention and control groups at 18 months. The ethical imperative to treat mothers with EPDS scores above the cut-off in both groups at the 6 month assessment had posed limitations on this study to detect a group difference at 18 months. There was also no significant difference with respect to the other secondary outcome measures (e.g. parenting stress, child health), which is inconsistent with previous findings.[1,2,6–10] This could be due to a lack of power as the sample size was calculated based on the primary outcome measure.

It was observed that a proportion of participants in each group (18 of 34 in the intervention group and 13 of 31 in the control group) had developed the condition between 6 and 18 months. This is consistent with the finding[26] that up to a third of postnatal women with no previous history developed depression within 3.5 years of follow-up from 18 months postnatal.

What is already known

In a study comparing a historical control group with an intervention group assessed with EPDS together with non-directive counselling for those who scored ≥12, there was a 42% reduction in the proportion with EPDS scores ≥12.[27]

Both the Canadian Task Force on Preventive Health Care and the US Preventive Service Task Force found good to fair evidence from RCTs that screening improved the accuracy of identifying adult patients with depression in primary care settings, and if coupled with a good system of treatment and follow-up, would improve patient outcome. Meta-analysis of six of these RCTs with sufficient data showed that persistent depression decreased with screening and intervention (RR = 0.90; 95% CI: 0.82–0.98)[28,29] which is consistent with our results at 6 months. However, these studies did not specifically address PND.

What this study adds

The UK National Screening Committee recommends that there should be evidence from high-quality RCT to show that a screening programme is effective in reducing mortality or morbidity of a condition.[30] This study contributes to the evidence on the effectiveness of a PND screening programme. This is a multi-site effectiveness study using EPDS as the screening tool together with follow-up management according to the protocol. In this study, clients were identified in a primary care setting, using a validated screening instrument. The management protocol did not require the referral of the screened positive participants (i.e. with elevated EPDS scores) for a formal psychiatric diagnosis of PND, obviating labelling of the participant and the generation of anxiety. Treatment was provided in the same setting, either by trained primary care professionals or the community psychiatric team, depending on severity of the condition. The completion rate for the measurement of primary outcome at 6 months was 93% (215 out of 231 in both the intervention and control groups).

Limitations of this study

There are several limitations in this study. First, while careful precautionary measures had been taken to ensure that both participants and nurses were unaware of the group allocation, no specific tests were conducted to test the success of blinding. Second, measurement of the primary outcome was only based on mother's self-completion of EPDS at 6 months. There was no psychiatric diagnosis to ascertain

Table 2 Mean scores (95% CIs) of outcome measures of participants at 6 and 18 months postnatal based on intention to treat

	6 Months			*18 Months*		
	Intervention (n = 231)	*Control (n = 231)*	*Estimation of effect/significance*[a]	*Intervention (n = 231)*	*Control (n = 231)*	*Estimation of effect/significance*[a]
Maternal outcome						
Number with EPDS score ≥10 (%)	30 (13.0)	51 (22.1)	RR = 0.59 (0.39–0.89)	34 (14.7)	31 (13.4)	RR = 1.10 (0.70–1.73)
EPDS score (95% CI)	5.14 (4.67–5.60)	6.50 (5.94–7.07)	$P < 0.001$	5.77 (5.27–6.28)	5.85 (5.39–6.31)	$P = 0.819$
GHQ score (95% CI)	1.06 (0.83–1.30)	1.39 (1.10–1.67)	$P = 0.084$	1.75 (1.39–2.11)	1.84 (1.45–2.24)	$P = 0.727$
PSI total score (95% CI)	80.89 (78.80–82.97)	83.67 (81.56–85.77)	$P = 0.065$	87.13 (84.73–89.53)	89.33 (87.09–91.57)	$P = 0.187$
PSI-PD score (95% CI)	29.93 (29.03–30.84)	31.14 (30.24–32.03)	$P = 0.063$	31.58 (30.61–32.54)	32.11 (31.22–32.99)	$P = 0.426$
PSI-PCDI score (95% CI)	24.77 (24.03–25.51)	25.85 (25.05–26.65)	$P = 0.050$	26.60 (25.66–27.55)	27.65 (26.76–28.54)	$P = 0.112$
PSI-DC score (95% CI)	26.19 (25.37–27.01)	26.68 (25.88–27.48)	$P = 0.397$	29.45 (28.52–30.37)	29.74 (28.84–30.64)	$P = 0.654$
Marital satisfaction score (95% CI)	16.94 (16.59–17.30)	16.47 (16.03–16.90)	$P = 0.093$	16.35 (15.98–16.72)	16.22 (15.81–16.62)	$P = 0.636$
Child outcome						
Child body weight in kg (95% CI)	7.71 (7.60–7.82)	7.66 (7.56–7.76)	$P = 0.504$	10.76 (10.63–10.90)	10.72 (10.58–10.83)	$P = 0.563$
Child number of visits to doctors (95% CI)	2.39 (2.07–2.70)	1.97 (1.73–2.21)	$P = 0.039$	5.14 (4.57–5.71)	4.97 (4.58–5.36)	$P = 0.625$
Child number of hospitalization (95% CI)	0.37 (0.28–0.46)	0.33 (0.23–0.42)	$P = 0.518$	0.42 (0.35–0.50)	0.40 (0.31–0.50)	$P = 0.772$

PD, parental distress; PCDI, parent–child dysfunctional interaction; DC, difficult child.

[a]Unpaired *t*-test.

their mental health status. Third, although the use of EPDS at 6 months postnatal has been validated,[31] the local validation was only based on mothers at 2 months postnatal. Fourth, the intervention group had to complete the EPDS at 2 and 6 months, although the control group only completed the EPDS at 6 months. Hence, there was the possibility of a systematic difference due to practice effect. Fifth, whereas the management recommendations of some participants were inadvertently down-graded and some defaulted services, the proportion of such cases in both arms was similar (24% in the intervention versus 21% in the control arm). The four cases identified through clinical assessment and treated in the intervention arm should not have been treated according to the EPDS screening criteria. However, in the worst-case scenario where all four cases had an EPDS score $\geq$10 at 6 months, the result still remained valid (revised RR = 0.67, 95% CI: 0.45–0.99). Sixth, our results might not be applicable to ineligible clients, such as non-residents and mothers illiterate in Chinese. However, the latter group constituted only a small proportion of the target population.[32] Other limitations including the ethical imperative to treat participants in both groups at 6 months and the calculation of the sample size based on primary outcome measure have been discussed earlier.

Conclusion

This study shows that an EPDS screening programme can improve the mental health outcome of postnatal women. However, the acceptability of PND screening by health professionals and women would need to be examined in the Chinese population. More evidence from rigorously conducted studies for different populations in different settings is needed to build a stronger evidence base for the effectiveness of a PND screening programme. Furthermore, the cost effectiveness of the programme remains to be established.

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