



PRISM: rationale and evolution of a community-randomised trial to reduce depression and physical ill-health after birth

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PRISM Program of Resources, Information and Support for Mothers www.latrobe.edu.au/csmch/prism

Introduction

This paper describes the evolution of a community-based and community-randomised trial – Program of Resources, Information and Support for Mothers, PRISM - to improve the mental and physical health of women in the first year after childbirth. It starts in 1989, placing the development of the project in the context of the accumulating evidence from population-based descriptive epidemiology in the local community, from strategies tried elsewhere, and from randomised trials to reduce maternal depression and improve physical health in the year after birth.

Background

In 1989 three of the authors participated in a committee set up by the Minister of Health in the State of Victoria, Australia to review and make recommendations about birthing services across the State, where there are 60,000 births each year. JL Chaired the Review, SB was the Consumer Advocate and RS was the Senior Research Officer. The terms of reference were broad, encompassing a review of current service provision, new models of service delivery, professional and support services at home and in the community before and after birth, and the implications for education and training of all the health practitioners involved. The Review's consultative process included seeking broad public comment through public advertising calling for submissions, public meetings, discussion groups; the establishment of a Consultative Body of provider associations and consumer organizations with formal constituencies; a series of small projects to consult with women who might not have access through other processes, and a state-wide Survey of Recent Mothers (Lumley, Small & Yelland, 1990). During the Review a women's support group drew the attention of the review group to the extent of unmet need around postnatal depression, reporting as evidence that they received 5000 telephone calls from women each year. While discussing this submission the Review Group discovered that there were as many different strongly held views within the group about the aetiology, detection and prevention of depression after birth as there were group members, and the Interim Report of the Ministerial Review Committee went on to call for more input on the topic of postnatal depression.

Subsequent submissions called for better education on depression for those working in primary care services relevant to mothers and babies (general practitioners (GPs) and maternal and child health nurses (MCHNs))¹, a public awareness campaign about postnatal depression, more linkages between GPs and other community services and agencies, and the development of identified referral networks and patterns of response at a local or regional level for crises. A few submissions emphasised the need of strategies

¹ Maternal and Child Health Nurses (MCHNs) are nurses with additional qualifications in midwifery and community health, within a state-wide, universal, community-based Program, funded by State and local government.

for primary prevention of postnatal depression with the overall goal of facilitating the transition into parenthood. The specific suggestions included ‘good antenatal education, positive birthing practices, postnatal support such as MCHNs, parent support groups, home help, occasional child care, and lowering the financial housing stresses experienced by families’ (Lumley et al, 1990, pp131-134). An appraisal of the contemporary reviews of research evidence found few consistent findings and little agreement on the relative importance of social adversity, cultural differences, aspects of maternity care, psychological, social and biological factors (Brockington & Kumar, 1988; Cox, 1989; Elliott, 1989; Kumar & Brockington, 1989; Romito, 1989). The Review Group’s contribution to informing further discussion was to call for further submissions on this topic, and summarise results on the prevalence of depression from the *1989 Survey of Recent Mothers* in the Review.

Methods

In order to describe the development of the project which came to be called PRISM (Program of Resources, Information and Support for Mothers) we reviewed publications, presentations, abstracts, posters, grant applications, correspondence, briefing notes, notes of meetings, and training manuals from the project.

The development of PRISM, 1989

Descriptive epidemiology in Victoria, 1989

A postal questionnaire was sent to all the women in Victoria who had given birth in one week, eight to nine months earlier, as part of the community consultation described above. The questionnaire was influenced by the work of Ann Cartwright (1986, 1988) who had published several key papers on methodological aspects of such surveys. Given the lack of local population data on depression after birth it was suggested by Dr Jill Astbury that this *1989 Survey of Recent Mothers* should incorporate a well-validated self-report measure, the Edinburgh Postnatal Depression Scale (EPDS) (Cox, Holden & Sagovsky, 1987; Murray & Carothers, 1990; Boyce, Stubbs & Todd, 1993). The response fraction to the postal questionnaire, adjusted for those returned to sender, was 71.4% (790/1107) and the inclusion of the EPDS, completed by 771/790 respondents, provided an estimate of the point prevalence of depression across the State as 15.4% or more than one in seven women. The 95% Confidence Interval (CI) was 12.9% to 18.0%. Multivariable analyses taking into account maternal age, parity, education, income and marital status, showed a lower prevalence of depression in women living outside the metropolitan area, and among those breastfeeding. The only common factors associated with an increased prevalence of depression were assisted delivery, and having been born overseas in a country where English is not the first language (NESB). More detailed measures of obstetric procedures were not retained as significant once assisted delivery was taken into account. Thus there was little support for the view that obstetric

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‘management’ made a major contribution to depression at a population level (Astbury, Brown, Lumley & Small 1994). There was no evidence that shorter postnatal hospital stay was a factor and this was important given local concerns about early discharge at that time and later (Small, Lumley & Brown 1992, Brown & Lumley 1998a). We could not confirm the reported association of depression with social adversity using a measure of family income (Astbury et al., 1994).

At this time, 1990, only three trials aiming to reduce postnatal depression had been published. The first two of these trials, which were controlled but not randomised, offered group interventions. Gordon, Gordon & Englewood, 1959, Gordon, Kapostins & Gordon, 1965) and Gordon & Gordon (1960), within their own obstetric practice, offered two additional antenatal classes on social and psychological aspects of being a new mother with 12 key messages. Leverton and Elliott developed a screening instrument for use in pregnancy and offered to women who screened positive participation in one of two programs: *Preparation for Parenthood*, designed for first time mothers, and *Surviving Parenthood* designed for mothers having a second child. Each of these programs ran for 11 sessions across the antenatal and postnatal periods, with partners invited to the second session. The groups, led by a psychologist and a Health Visitor, had a focus on ‘normalising and empowering’ and the expectation that the group would make the transition into a continuing support group. Attrition was a problem in the latter study, particularly for women who already had a child. Both trials reported large reductions in adverse outcomes: these were assessed as emotional distress in the first trial and by the Present State Examination in the second, where the differences were of borderline statistical significance. Neither trial adjusted for group effects. The third trial which provided non-directive counselling (‘active listening’) by Health Visitors with additional training, to women diagnosed with depression six weeks after birth, found the intervention to be very effective in treating depression (Holden et al., 1989).

These three trials exemplify the three complementary approaches to reducing mental health problems described by Mrazek & Haggerty (1994). The ‘universal’ strategy is a preventive one applicable at the population level, in this case with all or any pregnant women (e.g Gordon et al., 1959, Gordon & Gordon, 1960, Gordon et al., 1965). A ‘selected’ intervention is one implemented within a subgroup defined by screening as being at increased risk of being depressed after birth, and as such has both an early intervention and a secondary prevention role (e.g. Elliott, 1989; Leverton & Elliott, 1989). An ‘indicated’ intervention is implemented where depression has been diagnosed (e.g. Holden, Sagovsky & Cox, 1989).

The development of PRISM, 1990-1994

Descriptive epidemiology in Victoria 1990-1994

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The *Experience of Motherhood* project was initiated after the Review of Birthing Services by SB, RS and JL who sought funding from the Victorian Health Promotion Foundation to follow up two groups of women from the *1989 Survey of Recent Mothers*, with a long interview at home 12 to 18 months later. The interviews took place across rural and metropolitan areas of the State. Although respondents to the survey over-represented older and better-educated women those interviewed did include younger women, single women and women on low incomes. Although the survey had been anonymous women had been asked to write their phone number on the questionnaire, when they returned it, if they were willing to take part in further research. Over half (51%) did so: among women scoring as probably depressed on the EPDS the proportion was 58%. The final study group was 45 women who had been probably depressed eight to nine months after birth (EPDS ≥ 13) and a group of 45 women randomly selected from all whose scores on the EPDS were < 9 , that is below any recommended screening cut-off. Prior to the interview women completed five standard tools: the EPDS, a social support measure (Sarason, Levine, Basham & Sarason, 1983), the Life Experiences Questionnaire (Sarason, Johnson & Siegal, 1978; Norbeck, 1984; the Toddler Temperament Scale (Sewell, Oberklaid, Prior, Sanson & Kyrios 1988), and the Experience of Motherhood Scale (Astbury, 1994). The interview schedule focused on the social context of motherhood, including measures of women's and partners' participation in housework, child care and parenting; social and emotional support; physical health issues of women and children; 'time out' from mothering; women's own family and childhood; the role of paid work, expectations and experiences of motherhood, and the experience of depression. Interviews were recorded with women's permission and fully transcribed. More details of the design and conduct of this study are published elsewhere (Brown, Lumley, Small & Astbury, 1994, pp 20-27).

One key finding was that depression was not transient or self-limiting: differences between the two groups were still marked 18 to 21 months postpartum with a mean difference in the EPDS scores of 6 (11.3 vs 5.4). Almost a third (30%) of those scoring as depressed eight to nine months after birth were still depressed, or depressed again, while almost half had borderline scores (EPDS 9-12). Only 4% of the control group scored as depressed and over 80% of them had EPDS scores below nine. A second key finding was that only two in every five of the women who had been depressed after birth had sought any professional help. When they did seek help it was from their GP or MCHN. Despite frequent contacts with their MCHN and despite the title of the service, some women saw the role of the MCHN in its old terms as 'infant welfare'. Some of those who sought help found the response they received from a GP or MCHN was totally unhelpful (Brown et al, 1994; pp 250-6). Only 15% of those who had been depressed had sought help from, or been referred to, any mental health professional.

Half of those who had been depressed sought help from partners, friends, mothers, other relatives or a support group. Friends were the most likely to have been perceived as helpful. When women who had been depressed were asked an open-ended question about what advice they would give to other mothers in a similar situation the most frequent responses were 'find someone to talk to' and 'find time for your self', followed by 'get

out among people' and 'seek counselling' (Small, Brown, Lumley & Astbury 1994b). It was notable that although almost all the women in the case group agreed that they had been depressed at the time of the 1989 survey a third of them did not want to describe this experience as 'postnatal depression', a finding reported also in the UK (Whitton, Warner & Appleby, 1996).

Other contextual differences between the case and control group were lower levels of social support (Sarason et al. 1983), and higher scores for the stress and anxiety associated with being a mother (Astbury, 1994). Women in the case group reported more negative life events since the birth, especially in the domains of health, intimate relationships, parenting, family and personal/social events, with more negative appraisal of changes but there were no differences between the case and the control group in positive events nor impact of positive events (Sarason et al., 1978; Norbeck, 1984). There was also a high proportion of two year-olds with a 'difficult' temperament rating though this finding was of borderline statistical significance (Small et al., 1994a). Partners of women in the case group had significantly lower scores for their participation in household tasks and childcare tasks. There were no differences between the groups in the time which partners spent away from home: 70% were away for 10 or more hours a day or worked more than five days a week (Small et al., 1994a).

Thus the evidence from standard instruments matched women's own accounts that factors contributing to depression were social and contextual ones: isolation, lack of support, health issues (theirs and their infants'), financial issues, problems within close relationships; all of these having a strong postnatal component, requiring postnatal strategies. We did not find depression to be associated with unrealistic expectations about motherhood. If it were then there should have been a strong association with being a mother for the first time, instead of no association. In addition to that result was the finding that almost all women found being a mother harder than expected, and almost all had concepts of 'a good mother' which would have been impossible for anyone to fulfil (Brown, Small & Lumley, 1997). The experience of interviewing women at home across Victoria, including rural and remote areas, seeing and hearing about the ways in which the experience of motherhood was coloured by their local community, social and family context emphasised the need for interventions at multiple levels (Brown et al., 1994, pp190-226).

While finding someone to listen who is supportive was often mentioned few women had found this by way of 'New Mothers' Groups' and women who had been depressed talked about how difficult it was when everyone else appeared to be coping. Provision of 'New Mothers' Groups' within the Maternal and Child Health Program, is a very significant component of the service (Scott, Brady & Glynn, 2001), but groups are not provided for women having a second or subsequent child. We were also made aware during the home interviews that 'groups' were not necessarily an effective vehicle for overcoming isolation for women without transport, those who had a child with a difficult temperament, or those with chronic health problems. We concluded that additional ways of increasing social contacts needed to be developed.

Evidence of the effectiveness of interventions 1990-94

Two trials of maternity care strategies, one in the US (Hoffman, 1992), the other in South Africa, (Wolman, Chalmers, Hofmeyer, Nikodem, 1993), both involving the provision of a lay companion ('doula') in labour to women having their first child, have been reported. In both cases, but particularly in South Africa, the women were relatively disadvantaged but there was no risk screening, and the intervention was a potentially universal one. In the US trial there was no evidence of any independent effect of the doula on 'postpartum psychological adaptation'. In South Africa there was a reduction in depression scores at six weeks.

One quasi-randomised trial, with a group intervention, offered to women diagnosed two weeks after birth with depression on at least two of three standard self-report measures, was reported from Canada (Fleming, Klein & Corter, 1992). The goal of the intervention was to bring the women into contact with other women having similar experiences, to share problems and conflicts and talk about solutions, within an unstructured format with a different theme for each of the eight weekly sessions. A mailed version of the intervention was also developed, adapted from verbatim transcripts of the session above, together with a set of questions for the participant to reflect on. There was no detectable intervention effect, and no interaction between mood and the intervention.

The evolution of PRISM 1990-1994

The first grant application submitted in March 1994 proposed a program of three trials to reduce the prevalence of depression in the year after birth. Two of the three were supportive early postnatal interventions subsequently completed as separate projects, and discussed below (Gunn, Lumley, Chondros & Young, 1998; Small, Lumley Donohue, Potter & Waldenström, 2000). The third, described as *A randomised trial of community-based strategies to reduce the prevalence and duration of depression after birth* became PRISM. One major influence on the design was the recognition of depression after birth as at least in part a 'disease of populations' rather than a 'disease of individuals' (Rose, 1985). This recognition and 'reframing' were prompted by the lack of identifiable risk factors which were both common and associated with a large relative risk, the prevalence and duration of depression after birth and the equally large population of women with depressive symptoms not quite meeting 'probable depression' criteria.

The contextual constraints on women's capacity to follow the advice they would give to other women who were depressed pointed to the need to make changes in the context and the environment, rather than focus on educating women, or only educating health professionals. Other local findings discussed above drew attention to the importance of postnatal factors, and to the need for information on physical and emotional problems,

especially information from the perspective of women themselves, to be provided to all women after birth.

This led to a change of philosophy from the trials already completed. The proposed trial would be based in communities, would have a very broad definition of community to include primary care, community agencies, local government and the business sector, and would be implemented at a community-wide level, necessitating community (cluster) randomisation. Involving, supporting and strengthening primary care within communities would be a key component, as would providing information based on women's accounts of health and recovery after birth, making environments mother and baby friendly, and increasing opportunities for social contacts and making friends. The strategies would be universal, not 'targeted', 'selective' or designed for women at 'high-risk', but applicable to all women.

The intervention plan had two components, one in primary care, the other with local government and community agencies, with a local steering committee to co-ordinate implementation.

The aims in **primary care** were:

- Increased recognition of depression in mothers of babies and children under 12 months of age at all primary care contacts;
- An active response to the recognition of depression, with explicit offers of time to talk by GPs and MCHNs;
- Increased recognition and treatment of common postnatal physical problems, using an evidence-based approach;

The strategies were:

- a training program for MCHNs and GPs, including new information on the prevalence, associated factors and implications, of depression after birth and health after childbirth; with skills training in non-directive counselling/active listening;
- the establishment of professional peer support Programs for MCHNs and GPs;
- with the assistance of the local steering committee, local government and the local GP Divisions², the development of networks between the different groups of primary care providers, with existing self-help groups, and with community psychiatric services, so that support in primary care could be offered in the context of ready access to consultation, liaison and referral.

Implementation of the professional training primary care component would be through existing professional bodies, local State and national bodies.

The aims in **local government and community agencies** were:

- to increase the availability of support and 'time out' for recent mothers.

² GP divisions are groupings of GPs within defined areas, with a local secretariat, to facilitate collaboration, participation in research and continuing education.

The strategies were:

- assessment of the availability and accessibility of services such as groups for mothers, occasional child care, recreational, library, information and counselling services, neighbourhood houses, community centres, community health centres, shopping centres, and the extent to which they were mother and baby friendly;
- an information kit for mothers with a listing of local services (see above), a brochure outlining some of the common difficulties of being a mother and some strategies which other women had found helpful, an information sheet for fathers, and a booklet of free service vouchers (Griepsma, Marcollo, Casey, Cherry, Vary & Walton, 1994) for recent mothers, the kit to be given to all mothers by MCHNs during the home visit made soon after hospital discharge;
- the establishment of a mother-to-mother support network based on the principle of non-professional befriending (Barnett & Parker, 1985; Cox, Pound, Mills, Puckering & Owen, 1991; Elliott, 1989; Johnson, Howell & Molloy, 1993), the format being likely to be different in each community.

Implementation of the local government and community agencies strategy would be carried out by a community development field researcher in each local government area to facilitate the establishment of the intervention in the initial 12 to 18 months, and the subsequent integration of the community service program, once established, within ongoing provision by local government or community agencies. Although the major elements of the intervention were defined it was explicit that local steering committees would be encouraged to tailor the intervention to suit the local community and to develop strategies beyond key elements outlined in our agreements with local Councils.

The intervention was planned to be implemented in communities, who would agree to participation prior to randomisation. The reasons for defining the communities in terms of local government areas was partly the important administrative role of local government and local councils but also because of their key roles and responsibilities with respect to the Maternal and Child Health service and other community agencies. The trial would be a cluster-randomised (community-randomised) trial. The minimum number of communities needed was estimated to be seven pairs. Our estimate of a realistic effect size for the intervention was a relative risk reduction of 20%, the alternative framing of this being that the intervention would prevent, or reduce the duration of, one experience of depression in every five.

The 1994 application was not funded.

The development of PRISM, 1995-1999

Descriptive epidemiology in Victoria 1995-1999

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We sought funding to repeat the *Survey of Recent Mothers* in 1994, incorporating the EPDS and including a series of questions about physical health problems, given the association between physical ill-health and depression found in *The Experience of Motherhood*. The prevalence of depression was very close to that found in 1989, being 16.9% (95% CI 14.9 to 18.9) (Brown & Lumley 1998b). One finding from 1989 was replicated in 1994: women who breastfed had a lower prevalence of depression than women who were bottle feeding. Women who had experienced an operative birth had a significantly higher prevalence of depression only if they had an elective caesarean birth: the higher proportion with depression was not significant for other forms of assisted delivery. In 1994, unlike 1989, depression was commoner among women in the lowest income group, and it was no longer less common in rural Victoria (Brown, 1998). The prevalence of physical problems such as incontinence, back pain, exhaustion, mastitis, haemorrhoids, and continuing perineal pain (Brown & Lumley, 1998b) confirmed a substantial body of work by MacArthur & Knox (1991) and Glazener, Abdella, Stroud, Naji, Templeton & Russell (1995) in the UK, drawing attention to the extent, persistence and severity of ill-health following childbirth.

The *1994 Survey* was followed by telephone interviews with 204 survey participants. A third were selected from those who had scored as depressed on the EPDS (≥ 13), a third from those who had borderline EPDS scores (10-12), a third from those whose scores suggested they were most unlikely to be depressed (<10). A research officer not directly involved in the study (Fiona Bruinsma) coded the EPDS as soon as the questionnaire was received, and also developed a register of names and phone numbers of women willing to take part in further research. The interviewers were given only the names and phone numbers: they were masked to the EPDS scores. A number of the physical health problems were found to have strong and significant associations with maternal depression (exhaustion, incontinence, back pain, bowel problems, repeated minor infections), though in all cases these physical health problems were also common in women who were not depressed. Relatively few women initiated discussion of the common health problems listed in the previous paragraph with their GP or MCHN, though almost half said they would have liked more help or advice about their own health problems (Brown & Lumley, 1998b; Brown & Lumley, 2000).

A major limitation of postal questionnaires is the difficulty of making them accessible to women who are not fluent in reading and writing English yet in Victoria almost one in five women giving birth was born overseas in countries where English is not the first language. In order to assess the relevance of the *1989* and *1994 Survey* findings to women unlikely to take part in a postal survey we expanded the survey for use by bi-cultural interviewers at home, six months after birth, with three groups of women (Vietnamese, Turkish and Filipino), using both the EPDS and the SF-36 Health Survey as well as the problem checklist to assess their physical and emotional health. The findings of this project (*Mothers in a New Country (MINC)*) in relation to maternal depression and physical health were consistent with those of the broader community but with some additional adverse factors identified (Small, 2000).

A complementary series of projects examined maternal health after childbirth from the perspective of general practice. A State-wide survey of GPs showed that most GPs are involved in postnatal care (Gunn, Lumley & Young, 1998a). Health Insurance Commission data on general practice visits in the first six months after birth confirmed that non-disclosure of maternal health problems was not due to lack of contact with GPs. The average number of visits for a mother and baby in the first six months was 7.7 (Gunn, Lumley & Young, 1996). Despite these frequent contacts GPs described themselves as reluctant to initiate discussion of the troubling health problems identified in the *1994 Survey* and, even more tellingly, rated these health problems as topics where they were less confident than they were about other postnatal issues such as contraception and mastitis (Gunn, Lumley & Young 1998b).

The Maternal and Child Health Program Report 1995-6 reported that 94% of mothers received a home visit soon after hospital discharge, and that participation rates by mothers in the 'key visits' at 2, 4, and 8 weeks, and 4 to 8 months were 87 to 96% (Department of Human Services, 1997a). Thus the lack of identification of maternal health problems within the MCH program was not a matter of lack of contacts with the service. New mothers' groups were attended by 60% of new mothers. Later the same year a Consumer Survey indicated lower levels of satisfaction with the service in relation to maternal issues (support and reassurance on maternal health, counselling, referral and information) than with child issues (monitoring child development, support and reassurance on child health, feedback on progress). What mothers most enjoyed about new mothers' groups was informal discussion and meeting other mothers, preferences slightly at odds with the groups' relatively structured educational program (Department of Human Services, 1997b).

Evidence of the effectiveness of interventions 1995-99

These five years saw a marked increase in the number of published trials. Two Australian trials combined antenatal screening with a group intervention along the lines of that reported by Leverton & Elliott in 1989. Neither could identify a reduction in depression and both had problems with the screening instruments. Buist, Westley & Hill (1998) developed a new screening tool independently, reporting it to have much in common with other screening tools in the literature, but no women screened as 'at risk' developed depression. Stamp, Williams & Crowther (1995) replicated the Leverton & Elliott study but found that this screening tool, transferred to Australia, identified 58% of pregnant women as 'at risk' of depression. Neither intervention was effective in reducing postnatal depression and there were some problems with attrition, especially in the latter study which included women who already had children.

Three trials of strategies within maternity care were reported, all carried out with socially disadvantaged women. One was a longer follow-up of the 'lay companion' trial mentioned earlier carried out in South Africa, the follow-up showing the intervention effect had disappeared 16 weeks after birth (Nikodem, Nolte, Wolman, Gulmezoglu &

Hofmeyr, 1998). Another 'lay companion' trial was unable to detect any reduction in depression (Gordon, Walton, McAdam, Derman, Gallittero & Garrett, 1999). The third trial assessed the impact of a new model of maternity care which used midwifery teams to provide enhanced continuity of care. That trial did find a marked reduction in depression in the team midwifery arm, but the findings need to be interpreted with some caution as midwives providing care in the 'team' arm were more experienced than those providing standard care, and there was a higher response rate to the final postal questionnaire in the 'team' arm as well (Shields, Reid, Cheyne, Homes, McGinley, Turnbull & Smith, 1997).

There were seven new postnatal trials, three of them offering a 'universal' intervention potentially applicable to all women. A trial of changing the timing of the 'postnatal check' with the GP from six weeks after birth (the standard timing in Australia) to seven to ten days after leaving hospital could not detect any benefits on mothers' emotional or physical health at three or six months after birth (Gunn, Lumley, Chondros & Young, 1998). One trial of midwifery-led 'debriefing' offered to all women before postnatal hospital discharge in the UK showed a very large difference in anxiety and depression scores three weeks later (Lavender & Walkinshaw, 1998), though the timing of the follow-up suggests it may be more relevant to 'maternity blues' than to depression. Another, much larger trial of the same intervention in Australia was unable to identify any reduction in depression with postnatal 'debriefing' (Hagan, Priest, Evans, Malmgren, St Jack, Henderson & Sharp, 1999).

The other four postnatal trials used screening. One screened women for social risk factors and risk of depression, offering intensive home visiting as the intervention. This had a marked effect in the short term, including a significant reduction in probable depression at six weeks (EPDS score >12) (Armstrong et al, 1999). The other trials used screening and diagnostic tests for case identification of depression at about six weeks after birth. Wickberg & Hwang (1996), in a quasi-randomised trial, compared standard care with counselling by Child Health Nurses given additional training, finding it to be effective in reducing depression. Cooper & Murray (1997), in a randomised trial, compared standard postnatal care with three different counselling modalities provided at home: all three were more effective than standard care in reducing maternal depression. The remaining trial (Appleby, Warner, Whitton & Faragher, 1997) had a complex factorial design involving either one or six sessions of cognitive behavioural counselling, and fluoxetine or placebo. Both fluoxetine and cognitive-behavioural counselling were effective, and after one session of counselling additional benefit was found from either fluoxetine or additional counselling. There was no additional benefit of receiving both.

The evolution of PRISM 1995-99

The new grant application in 1996 included the improvement of maternal physical health as a specific aim, and as a primary outcome. The rationale for this was both the link

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between depression and poorer physical health, and reducing the potential stigma for women of focusing on depression. This also strengthened the universal nature of the intervention. The application was able to include stronger evidence about the extent and severity of maternal physical health problems both in their own right, and as contributing to depression. The literature review provided a more detailed discussion and justification for the importance of the ‘active listening’/non-directive counselling component in primary care, supported at this stage by all four of the secondary prevention trials where counselling intervention had been provided after additional training by Health Visitors and Child Health Nurses, whose background has strong similarities to that of maternal and child health nurses, as well as by psychologists (Holden et al., 1989; Wickberg & Hwang, 1996; Appleby et al., 1997; Cooper & Murray, 1997).

The application had an explicit aim that the intervention would have a secondary prevention effect, and added to the original aim of reducing depression six to nine months after birth in intervention communities, a later follow-up of women who had been depressed at that earlier time. It drew attention to the possibility that changes in the community might contribute to primary prevention as well as secondary prevention. The grant application included a more realistic budget, restricted to the research component only, with an explicit plan to seek funding for the implementation from the Victorian Department of Health and Community Services [now Department of Human Services], the Commonwealth Department of Health and Family Services under the National Mental Health Plan and from the Victorian Health Promotion Foundation.

This application was partly successful in that pilot funding was provided for two years in order to increase the links of the research team with social scientists with expertise in social ecological and social network theory, to be able to report on aspects of feasibility in the early development stage, and to develop an economic evaluation with the capacity to measure broader impacts of the intervention and flow-on effects. We developed a collaboration with a research team from the University of Sydney, including a social scientist with a particular interest in community interventions and their evaluation (P. Hawe), and a health economist whose particular interests included the measurement of benefits at a community level (A. Shiell). As well as contributing to the development of *PRISM* they developed a ‘sister’ research project (*EcoPRISM*) which is an ecological and economic evaluation of *PRISM*, detecting broader intervention effects, reflecting an ecological systems theory/social ecological view of the intervention. This meant seeing *PRISM*’s potential in a community sense at multiple, complex, interacting levels; individual, inter-personal, group, organization and policy. An overview of the *EcoPRISM* evaluation has been submitted for publication (Hawe, Shiell, Riley, Gold: *unpublished data*).

Our experience at the grant interview suggested that we would also be wise to re-examine our plans for the GP professional education training and development. We built on existing links with Dr Jane Gunn at the University of Melbourne in the development of her planned project *Guidelines for Assessing Postnatal Problems (GAPP)*, which had been designed using current evidence about the most effective ways to improve

physicians' behaviour. Its key features included the recruitment of local GP advisors to the project team, use of multiple strategies in the educational Program (interactive workshops, role-play, simulated patient visits with confidential feedback, peer discussion groups, evidence-based guidelines, interviewing prompts, clinical audit and Program newsletter), use of adult social learning theories in the delivery of the Program, and the health planning model to implement and sustain the Program. The original design was that *GAPP* would be implemented in *PRISM* intervention areas as a randomised trial with half the intervention areas 'waitlisted' to receive the intervention. A more detailed account of the implementation and outcomes of *GAPP* has been submitted for publication (Gunn, Southern, Chondros *unpublished data*).

In 1997 two applications were submitted to the National Health and Medical Research Council. An application was made for the full five years of funding for *PRISM*, given the development of collaborations to establish *EcoPRISM* and *GAPP*, in order to facilitate the approach to potential local government partners for participation, and to increase the probability of getting the implementation funded by State and Commonwealth agencies. A separate application to the National Health and Medical Research Council was made for *EcoPRISM*. Funding for *GAPP* was sought from the General Practice Evaluation Program.

Changes to the 1997 *PRISM* application involved describing the new collaborations with reference to their separate applications. The revised application also set out a framework for the intervention as a whole in social ecological network theory, and social network theory (Bracht & Kinsbury, 1990; Goodman, Wandersman, Chinman, Imm & Morrissey, 1996; Hawe, Noort, King & Jordens, 1997). There was a new section about the theoretical basis for, and the complexities of, the development of support networks. However, the Regional Grant Interview Committee 'was concerned that the applicants provided no new evidence of further development of the model and pilot work on the intervention' and no further funding for *PRISM* was recommended at that stage. The application for *GAPP* was seen as too expensive to be funded. *EcoPRISM* was funded, for the first two years only.

PRISM's pilot funding was used to begin the process of mapping local government in Victoria from June 1997, identifying potentially eligible communities, and collecting information from local communities and agencies. Development of the aspects of the trial relevant to its underlying design and analysis, including the justification for the chosen effect size, the sample size and the adjustments for cluster randomisation are discussed in more detail elsewhere, as is the process of briefing local governments and seeking their active participation (Watson, Small, Brown, Dawson, Mitchell, Lumley *unpublished data*).

In 1998 funding was sought from the same agencies as in 1997 for *PRISM* and *GAPP*. The *PRISM* application emphasised the innovative nature of the intervention, drawing attention to its combination of primary and secondary prevention strategies for a public health problem projected to be the second highest contributor to the global burden of

disease by the year 2020, to evidence of the effectiveness of the proposed interventions in small scale trials and to the potential for major population-benefits through bringing together the components in a concerted action, to evidence of its support by key relevant agencies within Victoria including initial funding for the implementation, and to the way in which the program was embedded with and within existing services and programs, facilitating wide dissemination and transfer, if it were effective, to other settings, and lending itself to being sustained when *PRISM* ended.

When the research team was interviewed by the Regional Grants Committee in June 1998 we were able to report that all 33 eligible local communities in Victoria had been sent an information package and offered a briefing about participating in *PRISM*, 26 had accepted the offer, 25 had received the briefing and 21 of them had signed a Memorandum of Understanding agreeing to take part in *PRISM*, including agreement to randomisation (intervention or comparison), and acceptance of the roles and responsibilities of the parties defined in the Memorandum. *PRISM* was officially launched earlier that month at a half-day workshop on ‘Evaluating social and community interventions’ planned for community representatives, primary care practitioners, and funding agencies. Randomisation of communities took place, in public, at the launch.

Both *PRISM* and *GAPP* were funded at the end of 1998, and *EcoPRISM* was fully funded after a further application in 1999.

Developments 2000-2001

How has the evidence on reducing depression and physical health problems changed since 1999?

Five trials of interventions starting in the antenatal period have been published since the application for *PRISM* was successful in 1999. The first was a potentially ‘universal’ psychoeducational intervention with a detailed manual, provided by a midwife to all women in their first pregnancy (Hayes, Muller & Bradley, 2001). This did not have a detectable effect on depression scores.

New antenatal trials of interventions with ‘selected’ groups included the full report of the influential trial of Leverton and Elliott discussed earlier (Elliott, 1989), with women screened as being ‘more vulnerable’ (Elliott, Leverton, Sanjack, Turner, Cowmeadow, Hopkins et al., 2000). Another was a larger trial of similar design, including 190 women, restricted to those having a first child. It involved six structured, 2 hour, weekly antenatal classes, fully documented and implemented with a manual, using cognitive and problem-solving approaches and enhancing social support. It was preceded by an initial introductory meeting including the woman’s partner and ended with a reunion class eight weeks after birth (Brugha, Wheatley, Taub, Culverwell, Friedman, Kirwan et al., 2000). This trial was unable to detect any benefits of the intervention. There was relatively poor attendance in the groups but no evidence that those who attended most sessions had better

outcomes. Follow-up was high. The fourth trial, including only 35 women, screened women in mid-pregnancy for risk of depression, excluded women with current major depression, and offered a four session group intervention based in interpersonal therapy principles, reporting this to be effective (Zlotnick, Johnson, Miller, Pearlstein, & Howard, 2001). None of the three group interventions adjusted for the increased variability of outcome measures likely between groups, thus their reported effects over-estimate the effectiveness of the intervention.

No new trials of enhanced maternity care strategies were published in full but one available as an abstract was unable to identify a reduction in postnatal depression among women with a previous episode of postnatal depression randomised to continuity of individual midwife care through the next pregnancy compared with standard maternity care (Marks, *unpublished data*).

One large postnatal trial of midwifery-led debriefing for women who had an operative birth was unable to detect any differences in depression or physical health six months after birth (Small et al, 2000). The trial of Armstrong, Fraser, Dodds & Morris (1999) providing additional support through postnatal home visiting published a later follow-up (Armstrong et al, 2000) showing the differences in maternal depression were no longer detectable 17 weeks after birth. Both of these were trials were carried out within a 'selected' group. A group intervention, very similar to that of Fleming et al (1992) discussed earlier, was offered to women screened as having depressive symptoms (EPDS >9) four weeks after birth and found to be effective (Chen, Tseng, Chou & Wang, 2000). No adjustments were made for group effects in this trial, either. The fourth trial involving screening assessed women's mental health with the EPDS in hospital two to five days after birth, then implemented a program integrating educational, support, cognitive-behavioural and psychodynamic components with women who scored > 8. This primary prevention program was effective in reducing depressive symptoms, defined as an EPDS score >10, at four to six weeks after birth. Those with depressive symptoms at this assessment, in both arms of the trial, were offered a diagnostic assessment, and if found to be depressed, offered a therapeutic counselling intervention of 5 to 8 home visits which was more likely to be effective in those who had experienced the primary prevention program (Chabrol, Teissedre, Saint-Jean, Teisseyre, Sistac, Michaud et al, 2002).

Two postnatal trials of interventions to reduce depression in women diagnosed with a major depressive episode were reported, one providing 12 one hour sessions of interpersonal psychotherapy (O'Hara, Stuart, Gorman and Wenzel, 2000). The other offered six sessions of treatment to all participants, but women's partners were asked to attend two of the sessions in the intervention arm (Misri, Kostaras, Fox & Kostaras, 2000). In both trials the intervention was effective.

A 'universal' postnatal intervention, implemented in a randomised trial, providing a substantial component of additional practical and emotional support to women in their own homes, was unable to detect any benefit of the intervention on either physical or

mental ill-health six months after birth (Morell, Spiby, Stewart, Walters & Morgan, 2000). Two other potentially universal interventions, the provision of an information package (developed by the British advocacy body Maternity Alliance), and groups for new mothers, were compared in a randomised trial with a complex factorial design so that women received either the information package, or an invitation to a group, or both, or neither. This trial was unable to detect any differences in women's mental or physical health at three and six months across the four intervention comparisons (Reid, Glazener, Murray & Taylor, 1999). In contrast to those trials the cluster-randomised postnatal care trial by MacArthur, Winter, Bick, Knowles, Lilford, Henderson et al. (2002) demonstrates that marked improvements in women's mental health, with a reduction in depression, can be achieved by a redesigned community midwifery program providing care at home, though there was no impact of the intervention on women's physical health. The model was tailored to individual needs, using symptom checklists and the EPDS to identify health needs, with guidelines for care and referral, and it was integrated into the existing service. It is difficult to see how it could be implemented anywhere else without the UK's statutory provision of community-based postnatal care by midwives.

Summary of key stages in the implementation of PRISM

The implementation of PRISM really began with the first approach to communities early in 1998 but other important first steps were the formal agreements with communities and the launch of the project in June 1998. Later that year, with local involvement in the selection process, and interviews carried out in each of the intervention areas, a Community Development Officer was appointed for each local government area. They were employed for two years from October/November 1998. Local steering committees were set up as soon as possible in early 1999. The components of the intervention including GP/MCHN training, development and distribution of a PRISM information kit to all women giving birth in intervention communities over an 18 month period, implementation of peer befriending strategies and changes to local physical environments to make them more mother – and baby – friendly, were developed and put in place over the next 12 to 15 months.

Forums bringing together key individuals from intervention communities were held in 1999, 2000 and 2001. The initial forum brought together GPs and MCHNs from across the eight communities. The latter two forums involved the full cross-section of local government (including councillors), community organizations, GP Divisions and GP representatives, MCHNs and local women taking part in implementing PRISM in their community. A newsletter *PRISM Points* was mailed out with information from communities at least twice a year, in separate versions for intervention and comparison communities. Process evaluation by multiple methods was carried out throughout the period of implementation.

Measurement of maternal health outcomes six months after birth began for births from early February 2000 in August 2000, and continued for births up to August 2001 in February 2002. The analysis will be completed by the end of 2002.

In 2001 the National Health and Medical Research Council funded a follow-up of women and their two-year old children in PRISM communities to begin early in 2002. All sixteen communities agreed to take part and the data collection began in February 2002.

Conclusion

The more than ten-fold increase since 1989 in the number of published trials of interventions to reduce maternal depression after birth, with almost half of them published in the last three years, confirms that there is substantial agreement about the importance of the issue, something which could not have been said in 1989. The trials provide no evidence to support the introduction of antenatal interventions, an earlier postnatal check, increased practical support at home, additional information and access to new mothers' groups. They provide very limited evidence to support intensive postnatal home visiting in women screened as having increased social and other risks, increased continuity of maternity care, or 'doula' care in labour. They provide strong evidence for a specific, evidence-based, redesigned, universal, postnatal care program.

There is now strong and consistent evidence to support a wide variety of 'counselling' interventions for women diagnosed as depressed in the postnatal period. We know very little about how to improve mothers' physical health in the six months after birth.

There are still many unresolved issues around depression after birth which have not been raised in this paper. The major ones are the classification and taxonomy of depression at this point in the life-cycle (Elliott, 1990; Elliott 2000), the continuities and discontinuities in disorders before pregnancy, during pregnancy and postpartum (e.g. Fergusson, Horwood & Thorpe, 1996), the frequent co-existence of anxiety with depression at this time, as at many other times (Stuart, Couser, Schilder, O'Hara & Gorman, 1998), and the full range of possible and probable aetiological factors (O'Hara & Swain, 1996), including biological factors and physical health problems (Brown & Lumley, 2000). Their exclusion is not a comment on their relative importance. It reflects the focus of *PRISM* on reducing the prevalence of depression after birth at a community level through a mixture of strategies hypothesised to have some impact across subtypes of depression, and across incident, recurrent and chronic depressive illness, and on reducing physical health problems at the same time.

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