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## Protocol for economic evaluation alongside a cluster-randomised controlled trial of a psycho-educational intervention for the primary prevention of postnatal mental health problems in first-time mothers

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**Title:** Protocol for economic evaluation alongside a cluster-randomised controlled trial of a psycho-educational intervention for the primary prevention of postnatal mental health problems in first-time mothers

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## **Abstract**

### **Introduction**

Postnatal mental health problems, which are an international public health priority, are a suitable target for preventive approaches. The financial burden of these disorders is borne across sectors in society, including health, early childhood, education, justice and the workforce. This paper describes the planned economic evaluation of *What Were We Thinking*, a psycho-educational intervention for the prevention of postnatal mental health problems in first-time mothers.

### **Methods and analysis**

The evaluation will be conducted alongside a cluster-randomised controlled trial of its clinical effectiveness. Cost-effectiveness and costs-utility analyses will be conducted, resulting in estimates of cost per percentage point reduction in combined 30-day prevalence of depression, anxiety and adjustment disorders and cost per quality-adjusted life year gained. Uncertainty surrounding these estimates will be addressed using non-parametric bootstrapping and represented using cost-effectiveness acceptability curves. Additional cost analyses relevant for implementation will also be conducted. Modelling will be employed to estimate longer-term cost-effectiveness if the intervention is found to be clinically effective during the period of the trial.

### **Ethics and dissemination:**

Approval to conduct the study was granted by Southern Health (now Monash Health) Human Research Ethics Committee (24 April 2013; 11388B). The study was registered with Monash University Human Research Ethics Committee (30 April 2013; CF12/1022 – 2012000474). The Education and Policy Research Committee, Victorian Government Department of Education and Early Childhood Development approved the study (22 March 2012; 2012\_001472). Use of the EuroQol was registered with the EuroQol Group; 16 August 2012.

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3 The trial was registered with the Australian New Zealand Clinical Trials Registry on 7 May  
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5 2012 (registration number ACTRN12613000506796).  
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9 **Strengths and limitations:**

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  - 12 • Prospectively planned data collection for the purposes of economic evaluation  
13 alongside the clinical trial of effectiveness.
  - 14 • Will provide decision-makers with valuable evidence when considering any potential  
15 implementation of *What Were We Thinking*, a novel psycho-educational intervention  
16 for the prevention of postnatal mental health problems
  - 17 • Limited duration of data collection in the trial
  - 18 • Lack of data on willingness-to-pay for prevention of postnatal mental health problems

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28 **Keywords**

29 Economic evaluation; cost-effectiveness; cost-utility; postnatal mental health; postnatal  
30 depression; primary prevention; maternal and child health  
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39 **Background**

40 Postnatal depression (PND) is an international public health priority, being the most common  
41 cause of postnatal morbidity with a prevalence in high-income countries of approximately  
42 13%, and presenting a challenging target for prevention [1-4]. In the short term, PND is  
43 associated with the woman's own health, quality of life and interactions with her baby, plus  
44 practical caregiving factors such as breastfeeding and sleep management [5-9]. In the longer  
45 term, women who experience PND are more likely to experience recurrent or chronic mental  
46 health problems (including but not limited to postnatal mental health problems with  
47 subsequent pregnancies) and difficulties in the maternal-infant and intimate partner  
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3 relationships, including intimate partner violence [10,11]. Their children are more likely to  
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5 have psychological, behavioural, cognitive and health problems [12].  
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9 As a result, the burden of postnatal mental health problems and their consequences are  
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11 borne not only by families and the health care system, but also by other sectors in society  
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13 including early childhood, education, justice and the workforce. As with depression at other  
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15 life phases, women with postnatal depression use more health services than non-depressed  
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17 women, not limited to mental health services [13-16]. In general, depression is associated  
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19 with reduced work time and productivity [17]. Women's absence from the workforce may be  
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21 prolonged by postnatal mental health problems, which may also affect the work productivity  
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23 of her partner and extended family as they care for her and/or the baby.  
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27 A major focus in this field is non-psychotic depression, however a range of mental health  
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29 problems manifest in the postnatal period, including adjustment disorders, anxiety, bipolar  
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31 affective disorder, and disorders of maternal-infant bonding [7,18]. Postnatal anxiety has  
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33 similar prevalence to and is often comorbid with depression [19]. When considering  
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35 postnatal mental health problems it is important not to overlook these other disorders and  
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37 their associated burden.  
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41 Postnatal mental health problems are recognised as a suitable target for preventive  
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43 approaches, with the potential to avert the burden to women, their children and families, as  
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45 well as the social and economic costs [20]. Despite these incentives, the search for  
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47 successful preventive interventions has met with limited success. A recent systematic review  
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49 found promise in certain programs, such as professional home visits, telephone-based peer  
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51 support, and individual psychotherapy [21]. However, these interventions may be better  
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53 suited as targeted approaches for women at increased risk, rather than for primary  
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55 prevention.  
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3 *What Were We Thinking* (WWWT) is a psycho-educational intervention that may be suitable  
4 for primary prevention of postnatal mental health problems. In a before and after controlled  
5 study (n=364) WWWT was found to reduce the prevalence of postpartum mental health  
6 problems in women without a history of psychiatric disorder [22]. It involves group-based  
7 delivery of the program in one six-hour session, where both parents along with the infant are  
8 encouraged to attend.  
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17 The Sleep, Parenting and Relationships in a Community Setting (SPARCS) trial is a cluster-  
18 randomised controlled trial examining the effectiveness of WWWT, as delivered by Maternal  
19 and Child Health (MCH) nurses to groups of first time parents in preventing non-psychotic  
20 postnatal mental health problems. MCH centres in Victoria, Australia provide a free,  
21 universal service including ten visits between birth and school age, with a focus on parenting  
22 and the health and development of the child. They are jointly funded by the Victorian  
23 Department of Education and Early Childhood Development (DEECD) and Local  
24 Governments. MCH services see more than 90% of women who give birth in Victoria each  
25 year [23]. Many MCH centres facilitate First Time Parents' (FTP) groups, which provide an  
26 opportunity for education of new parents, as well as for social connections to form between  
27 parents in a local community [24]. WWWT may be suitable for integration into FTP groups.  
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41 This paper describes the protocol for the economic evaluation of WWWT, to be conducted  
42 alongside the SPARCS trial of its clinical effectiveness. The evaluation will address the  
43 question of whether WWWT provided by MCH nurses is a cost-effective intervention for the  
44 prevention of postnatal depression, anxiety and adjustment disorders in first-time mothers,  
45 compared with usual MCH care alone.  
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## 52 **Methods**

### 53 **Design**

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3 Full details of the trial protocol are provided in a separate paper [25]. The SPARCS trial is  
4 cluster-randomised, with the MCH centre as the unit of randomisation (due to the nature of  
5 the intervention it is not feasible to randomise by individuals). Six Local Government Areas  
6 (LGAs) (from a total of 31) in the greater metropolitan area of Melbourne, Australia will be  
7 selected to participate. The LGAs will be ranked by the Socio-Economic Indexes for Areas  
8 (SEIFA) Index of Relative Advantage and Disadvantage, and two will be included from each  
9 of low, middle and high tertiles of socioeconomic advantage [26]. Within these six LGAs 48  
10 MCH centres will be randomly allocated to intervention or control arms, with stratification by  
11 LGA. Although it is not possible to blind MCH staff to allocation, measures will be taken to  
12 minimise contamination across sites, and participants will be blinded to the intervention.  
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25 The economic evaluation will be conducted alongside the trial to examine the difference in  
26 costs and outcomes between the intervention and control arms. If the intervention is found to  
27 be both cost-saving and associated with equivalent or improved outcomes, then it is said to  
28 dominate the comparator. If (as is more likely) the intervention incurs additional costs, but  
29 provides additional health and/or utility gains, it is not immediately apparent whether the  
30 intervention would be preferred to the comparator. In these situations an economic  
31 evaluation comparing costs and outcomes can be informative for decision makers.  
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41 We will conduct both cost-effectiveness and cost-utility analyses (CEA and CUA) to explore  
42 and quantify the costs per health (or utility) gain. The difference between these two is the  
43 measure of effectiveness employed: CEA uses outcomes in natural units (such as cases  
44 prevented) while CUA uses Quality Adjusted Life Years (QALYs). QALYs weight periods of  
45 time spent in a particular state by the quality of life for that state.  
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54 Whether or not any gain achieved is *worth* the additional costs is in the domain of decision-  
55 makers, but the results of CEA and CUA provide a basis for understanding the opportunity  
56 costs of investing scarce health resources in one area relative to another [27]. The economic  
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3 evaluation will take a public sector perspective, considering costs and outcomes relevant to  
4 government departments of health, early childhood and human services (given the funding  
5 arrangements for maternal and child health in the Victorian setting), as well as out-of-pocket  
6 costs incurred by the participants.  
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### 10 11 12 13 Study population

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15 Trial participants will be first-time mothers who: reside in the same LGA and receive care  
16 from one of the 48 selected MCH centres, have given birth within two weeks prior to  
17 enrolment, and have sufficient English language proficiency to complete structured  
18 telephone interviews. Women who agree to participate, after being provided with details of  
19 what participation will entail, will provide their written consent.  
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### 25 Intervention and comparator

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27 The intervention consists of a single six-hour group session along with WWWT-informed  
28 postnatal care provided by trained MCH nurses throughout the study period. The session will  
29 provide information and training plus the opportunity for discussion and hands-on practice  
30 regarding managing infant behaviour, the intimate partner relationship and fatigue. MCH  
31 nurses at centres in the intervention arm of the trial will receive training on the principles of  
32 WWWT and its delivery. These trained nurses will deliver the session to participating women  
33 and their partners or other support people in group settings, within ten weeks of the baby's  
34 birth, in addition to any usual FTP group sessions. Unlike most FTP group sessions, WWWT  
35 will be delivered on a Saturday rather than a weekday to facilitate the attendance of the  
36 women's partners. The number of WWWT sessions run per centre will be tailored to the  
37 number of first-time mothers in the area.  
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50 Women in the comparator arm of the trial will receive usual care, including standard FTP  
51 groups, from MCH nurses who have not been trained in WWWT. Centres which share staff  
52 with other participating centres will be excluded to avoid cross-contamination with the  
53 intervention.  
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### Measures of outcome

The measures of outcome employed in the economic evaluation and the timing of their collection are presented in Table 1. Data for outcome assessment will be collected by means of computer-assisted telephone interviews (CATIs). The baseline CATI will be conducted before delivery of the WWWT session, and the follow-up CATI when the infant is six months of age.

The primary measure of effectiveness for CEA will be combined prevalence of depression, anxiety and adjustment disorders in the previous 30 days. DSM-IV diagnoses of depression and anxiety will be measured by the Composite International Diagnostic Interview v3.0 (CIDI), while measurement of adjustment disorders will employ the Patient Health Questionnaire (see [25] for details). The CIDI is a standardised structured interview which can be administered, as in this trial, by telephone interview, and which yields diagnosis of psychiatric disorders according to the Diagnostic and Statistical Manual (DSM-IV) criteria. [28].

The EQ-5D-3L measure of health related quality of life will be used to calculate QALYs for the CUA [29]. The EQ-5D-3L is one of the most widely used multi-attribute utility measures and is regularly employed in health economic evaluations. Completion of the EQ-5D-3L involves responding to a series of questions across five dimensions of health-related quality of life: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is scored over three levels: no problems, some problems or extreme problems. The EQ-5D-3L has been shown to identify differences in quality of life between people with differing severity of depression and anxiety, and to detect changes over time in those conditions [30-33]. Responses to the EQ-5D-3L will be scored using preference weights developed for the Australian population, which convert the five responses into a single summary index, where a score of one reflects perfect health and zero is equivalent to dead

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3 [34]. QALYs will be estimated for each individual in the trial by estimating the area under the  
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5 quality of life curve [27].  
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#### 8 9 Measures of resource use and cost

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11 An overview of resource use and cost measures to be employed in the economic evaluation  
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13 is presented in Table 2. The included costs are those that are likely to differ across the  
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15 intervention and control groups, specifically the costs of: developing the intervention, training  
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17 of MCH staff, WWWT session delivery on a Saturday within the trial, materials used during  
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19 the sessions, and use of health and other services by participants during the follow up period.  
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21 The costs of developing WWWT will be obtained from the developers.  
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25 The costs of delivering a WWWT session will be affected by whether it would be additional to  
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27 existing FTP group sessions or if it would replace some elements of other services they offer.  
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29 This will be established by asking MCH coordinators about the feasibility of integrating  
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31 WWWT into existing FTP groups and how the inclusion of WWWT would affect the program  
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33 of sessions. The additional cost of making staff available to deliver WWWT on Saturdays will  
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35 be calculated based on the higher rate of pay applicable to MCH nurses on Saturdays  
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37 compared with their usual working hours.  
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41 Data on service use by mother and infant will be collected from participants in both  
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43 intervention and control arms during the follow-up CATIs (see table 3). After the baseline  
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45 interviews participants will be provided with a record card, on which they will be asked to  
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47 record all instances of health or other service use, including out-of-pocket costs. Parents will  
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49 be advised to keep the record card with the baby's usual health records book, which is  
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51 generally carried to all health-related appointments. During the follow-up CATI they will be  
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53 asked to refer to this card, and to report any other service use not listed on the card.  
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3 Unit costs for health service use will be estimated using data from the Medicare Benefits  
4 Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS), plus any additional out-of-  
5 pocket (OOP) costs reported by participants [35,36]. Services not covered in MBS or PBS  
6 data will be valued at market prices, and where necessary will reflect any OOP costs  
7 incurred by participants. Each participant's aggregate service use cost will be calculated  
8 from the total of instances of service use multiplied by the unit cost for that service.  
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17 All resources will be valued in 2013/14 Australian dollars, and the 6-month trial follow-up  
18 means there is no requirement to apply discounting. The expense of developing WWWT  
19 was incurred earlier over a period of some years prior to this trial, and will be inflated based  
20 on the Consumer Price Index (CPI) to reflect 2013/2014 prices.  
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### 27 Sample size

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29 For sample size calculations we assumed that the prevalence of the primary outcome would  
30 be 25% in the control group, based on results from the earlier before and after study of  
31 WWWT, which used the same measure (incorporating adjustment disorders along with  
32 postnatal depression and anxiety). We calculate that the minimum sample size required to  
33 detect as statistically significant a difference of 12.5 percentage points in the primary  
34 outcome measure (25% prevalence in the control group and 12.5% in the intervention group)  
35 is 184 participants per group, with type 1 error of 5%, 80% power and allowing for 10%  
36 attrition between baseline and follow up.  
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48 Notably the sample size is that prescribed by the trial effect size, rather than the economic  
49 outcomes. Sample size estimation using economic endpoints is possible, but it is both time  
50 consuming, thus generally infeasible prior to obtaining funding, and will more likely produce  
51 a sample size that is larger than that required for the clinical effect, so increases the cost of a  
52 trial, and thus decreases the likelihood of successfully receiving funding [37]. It was  
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3 necessary therefore to trade-off these issues, and as with many economic evaluations the  
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5 sample was powered by the clinical outcome of interest [38].  
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#### 8 9 Cost-effectiveness and cost-utility analyses

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11 We will calculate the total costs for intervention and control groups, as well as the average  
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13 cost per participant, incorporating the cost of development, training and delivery of WWWT  
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15 for the intervention group. Using regression analysis, we will control for differences in  
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17 characteristics of participants (such as age, socio-economic status, past history of mental  
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19 health problems, marital status), characteristics of MCH centres (such as SEIFA, rural/ urban,  
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21 size of service) and for baseline EQ-5D-3L scores. This will also allow us to better manage  
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23 skewed data, which is likely to be the case; we expect high proportions of participants to  
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25 have zero service use costs and QALYs of 1 (full health). From these regression analyses,  
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27 we will estimate the average cost per participant, the prevalence of postnatal mental health  
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29 problems, and the average QALY achieved per participant for intervention and control  
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31 groups.  
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35 Costs and outcomes will be combined into a single measure, the incremental cost-  
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37 effectiveness ratio (ICER), which is the difference between intervention and control groups in  
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39 costs divided by difference in outcomes. Results of the CEA will be expressed as cost per  
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41 percentage point reduction in combined 30-day prevalence of depression, anxiety and  
42  
43 adjustment disorders. Results of the CUA will be expressed as cost per QALY gained. The  
44  
45 ICER from the CEA will be comparable with other interventions using the same outcome  
46  
47 measure (prevention of postnatal depression, anxiety and adjustment disorders), whilst that  
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49 from the CUA will be comparable more broadly, as QALYs are not specific to the clinical  
50  
51 condition. Information on cost per QALY allows decision-makers to consider efficient  
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53 allocation of funding across divergent clinical disciplines; in this case allowing comparison  
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55 between the cost-effectiveness of WWWT and that of prevention and treatment interventions  
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57 for mental health, other perinatal interventions as well as unrelated health interventions.  
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### Addressing uncertainty

As we will have individual-level data on costs and outcomes for the period of trial follow up, we will evaluate uncertainty of the cost-effectiveness and cost-utility estimates using non-parametric bootstrapping [39]. Although standard statistical methods can be used to estimate standard errors for the costs and outcomes, it is the combined uncertainty surrounding the ICER that is of most interest; in particular we cannot assume independence of costs and effects. Bootstrapping produces an estimate of the joint distribution of costs and effectiveness that does not rely on assumptions about the nature of this distribution.

To represent decision uncertainty surrounding cost-effectiveness we will employ cost-effectiveness acceptability curves (CEACs) [40]. These display the proportion of the estimates produced by bootstrapping that would be 'acceptable' (below a given willingness-to-pay (WTP) threshold), over a range of these WTP thresholds.

We will also perform scenario analysis, incorporating different extremes of uncertain values in order to estimate a base case, "best case" and "worst case" scenarios, and other policy-relevant scenarios, including different service provision arrangements in other Australian jurisdictions [27].

### Modelling

Our base case will have a time horizon of up to six months, the period of trial follow up. If the intervention demonstrates clinical effectiveness in that period, we will employ decision analytic modelling to estimate cost-effectiveness beyond the trial period, incorporating the effect of the intervention on long-term correlates of postnatal mental health problems. It is acknowledged that the uncertainty in these estimates is likely to be significant due to the limitations of data available on connections between maternal mental health and later

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3 outcomes, but none-the-less it is likely to be of interest to policy makers to extrapolate the  
4 results beyond the trial.  
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#### 8 9 Additional cost analysis to inform implementation

10 We will report on total costs of the intervention, as well as its components: development,  
11 training and delivery. The costs of developing the programme will be accounted over the  
12 projected lifetime of the programme, 5 years. We will consider how costs of the intervention  
13 might differ if WWWT were to be delivered in MCH services more broadly. This will include  
14 such factors as the need for refresher training, training of new staff members and the  
15 ongoing availability of staff on Saturdays.  
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25 To assist with understanding the policy implications of this intervention, costs (and cost  
26 savings) will be identified as accruing to the public sector (State and Commonwealth  
27 government departments of health, early childhood and human services), to private health  
28 insurers or to participants and their families.  
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#### 35 Approvals and registration

36 Approval to conduct the study was granted by Southern Health (now Monash Health) Human  
37 Research Ethics Committee (24 April 2013; 11388B). The study was registered with Monash  
38 University Human Research Ethics Committee (30 April 2013; CF12/1022 – 2012000474).  
39 The Education and Policy Research Committee, Victorian Government Department of  
40 Education and Early Childhood Development approved the study (22 March 2012;  
41 2012\_001472). Use of the EuroQol was registered with the EuroQol Group; 16 August 2012.  
42 The trial was registered with the Australian New Zealand Clinical Trials Registry on 7 May  
43 2012 (registration number ACTRN12613000506796).  
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#### 55 Discussion

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3 The value society places on prevention of postnatal mental health problems is unknown, nor  
4 is there an explicit WTP threshold for cost per QALY in the Australian health system. Some  
5 guidance can be derived given past behaviours of decision-makers (that is, approvals and  
6 rejections for funding of interventions by government agencies). A review of decisions on  
7 reimbursement of drugs in Australia found that in the 1990s the decision-making agency  
8 generally did not recommend approval of drugs with a cost per life-year saved of higher than  
9 AU\$76,000 (1998/99 figures) [41]. Stated WTP from the general population may also be  
10 indicative; a more recent population-based study reported an Australian stated WTP for an  
11 additional QALY was AU\$64,000 [42]. The figure of US\$50,000 per QALY gained is often  
12 considered an approximation for a threshold, but this figure has been used for many years  
13 and any threshold that exists may vary with other factors (such as the value society places  
14 on the availability of treatments for particular conditions) [42,43].  
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29 Adding to the uncertainty surrounding decision-makers' WTP is that the duration of follow up  
30 in the trial, as with all in this field, precludes collection of data on of long-term correlates of  
31 the mental health outcomes. The perceived value of preventing a case of postnatal  
32 depression, anxiety or adjustment disorder may depend on decision-makers' acceptance of  
33 the posited causal association between postnatal mental health problems and long-term  
34 problems for mothers, their children and partners.  
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44 Despite these uncertainties, this economic evaluation will provide decision-makers with  
45 valuable data to inform any future implementation of this innovative intervention for primary  
46 prevention of postnatal mental health problems.  
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#### 52 **List of abbreviations used**

53 CATI	Computer-assisted telephone interview
54 CEA	Cost-effectiveness analysis
55 CEAC	Cost-effectiveness acceptability curves

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2		
3	CIDI	Composite International Diagnostic Interview
4		
5	CPI	Consumer Price Index
6		
7	CUA	Cost-utility analysis
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9	DEECD	Department of Education and Early Childhood Development
10		
11	DSM	Diagnostic and Statistical Manual
12		
13	FTP	First Time Parents' (group)
14		
15	ICER	Incremental cost-effectiveness ratio
16		
17	LGA	Local Government Areas
18		
19	MBS	Medicare Benefits Schedule
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21	MCH	Maternal and Child Health
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23	OOP	Out-of-pocket
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25	PBS	Pharmaceutical Benefits Scheme
26		
27	PND	Postnatal depression
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29	QALY	Quality Adjusted Life Years
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31	SEIFA	Socio-Economic Indexes for Areas
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33	SPARCS	Sleep, Parenting and Relationships in a Community Setting
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35	WTP	Willingness-to-pay
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37	WWWT	What Were We Thinking
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### **Competing interests**

The authors declare that they have no competing interests to disclose.

### **Authors' contributions**

JF and HR developed the *WWWT* program and conducted the preliminary efficacy study. JR and PL will undertake the economic evaluation of the trial. JR drafted the manuscript, under the supervision of PL, and all authors reviewed the manuscript for intellectual content and approved the final version.



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## Tables

Table 1. Overview of outcome measures

Measure	Means of collection	Timing of collection
Prevalence of depression, anxiety and adjustment disorder	CIDI conducted via telephone interview	Baseline: prior to WWWT session delivery Follow-up: 6 months postpartum
Quality of life	EQ-5D-3L conducted via telephone interview	Baseline: prior to WWWT session delivery Follow-up: 6 months postpartum

Table 2. Overview of cost measures

Cost component	Means of collection	Timing of collection	Source of data
Cost of WWWT	Interviews with	After completion of	Developers of WWWT

development	programme developers	development	
Cost of training MCH staff	Interviews with project team, administrative records	After completion of training	Trial team
Cost of delivering WWWT	Trial records	After completion of all WWWT sessions	Trial records
Health service use	Telephone interview	6 months postpartum for the period since baseline interview	Quantity – participant interview (including record card). Unit cost – see table 3.
Other service use	Telephone interview	6 months postpartum for the period since baseline	Quantity – participant interview (including record card). Unit cost – see table 3.

Table 3. Information to be gathered on self-reported service use and sources of cost data

Service type	Source of unit costs
MCH	MCH data
MCH home visit	MCH data
Attendance at MCH-run parents' group	MCH data
GP (other than immunisation)	MBS/ OOP
Clinic nurse (other than immunisation)	MBS/ OOP
Obstetrician/ gynaecologist	MBS/ OOP
Psychologist	MBS/ OOP
Counsellor	MBS/ OOP
Psychiatrist	MBS/ OOP
Lactation consultant	OOP
Home visit from a Mothercraft nurse or another person specialising in sleep and settling	OOP
Dietician/ nutritionist	OOP
Physiotherapist	MBS/OOP
Complementary Health Care Practitioner (e.g. chiropractor, naturopath, Traditional Chinese Medicine practitioner)	OOP
Paediatrician	MBS/ OOP
Residential Early Parenting Service	DHS/ OOP
Day-stay early parenting program	DHS/ OOP
Admission to a psychiatric mother-baby unit	WIES
Hospital Emergency Department attendance	WIES
Hospital outpatients clinic	MBS
Admission to hospital overnight	WIES
Social worker/ family support services	DHS
Support groups including the Post and Antenatal Depression Association (PANDA), Australian Breastfeeding Association	Relevant organisation
Telephone helplines including Maternal and Child Health Line, Nurse on Call, Australian Breastfeeding Association	Relevant organisation
Online therapy resources	OOP
Other healthcare practitioners or services	OOP
Prescribed medicines.	PBS
Over-the-counter medicines	PBS
Unmet need for any of the listed services and why not able to access the service.	N/A

OOP= self-reported out of pocket costs; MBS = Medicare Benefits Scheme; WIES = Weighted Inlier Equivalent Separation (weights for casemix funding calculation); PBS = Pharmaceutical Benefits Scheme; DHS = Department of Human Services.

# BMJ Open

## Protocol for economic evaluation alongside a cluster-randomised controlled trial of a psycho-educational intervention for the primary prevention of postnatal mental health problems in first-time mothers

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Keywords:	HEALTH ECONOMICS, MENTAL HEALTH, PUBLIC HEALTH, Depression & mood disorders < PSYCHIATRY

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Manuscripts

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3 **Title:** Protocol for economic evaluation alongside a cluster-randomised controlled trial of a  
4 psycho-educational intervention for the primary prevention of postnatal mental health  
5 problems in first-time mothers  
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38 **Keywords**

39 Economic evaluation; cost-effectiveness; cost-utility; postnatal mental health; postnatal  
40 depression; primary prevention; maternal and child health  
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## **Abstract**

### **Introduction**

Postnatal mental health problems, which are an international public health priority, are a suitable target for preventive approaches. The financial burden of these disorders is borne across sectors in society, including health, early childhood, education, justice and the workforce. This paper describes the planned economic evaluation of *What Were We Thinking*, a psycho-educational intervention for the prevention of postnatal mental health problems in first-time mothers.

### **Methods and analysis**

The evaluation will be conducted alongside a cluster-randomised controlled trial of its clinical effectiveness. Cost-effectiveness and costs-utility analyses will be conducted, resulting in estimates of cost per percentage point reduction in combined 30-day prevalence of depression, anxiety and adjustment disorders and cost per quality-adjusted life year gained. Uncertainty surrounding these estimates will be addressed using non-parametric bootstrapping and represented using cost-effectiveness acceptability curves. Additional cost analyses relevant for implementation will also be conducted. Modelling will be employed to estimate longer-term cost-effectiveness if the intervention is found to be clinically effective during the period of the trial.

### **Ethics and dissemination:**

Approval to conduct the study was granted by Southern Health (now Monash Health) Human Research Ethics Committee (24 April 2013; 11388B). The study was registered with Monash University Human Research Ethics Committee (30 April 2013; CF12/1022 – 2012000474). The Education and Policy Research Committee, Victorian Government Department of Education and Early Childhood Development approved the study (22 March 2012; 2012\_001472). Use of the EuroQol was registered with the EuroQol Group; 16 August 2012.



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3 The trial was registered with the Australian New Zealand Clinical Trials Registry on 7 May  
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5 2012 (registration number ACTRN12613000506796).  
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9 **Strengths and limitations:**

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- 12 • Prospectively planned data collection for the purposes of economic evaluation  
13 alongside the clinical trial of effectiveness.
  - 14 • Will provide decision-makers with valuable evidence when considering any potential  
15 implementation of *What Were We Thinking*, a novel psycho-educational intervention  
16 for the prevention of postnatal mental health problems  
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  - 18 • Limited duration of data collection in the trial  
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  - 20 • Lack of data on willingness-to-pay for prevention of postnatal mental health problems  
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53 **Background**

54 Postnatal depression (PND) is an international public health priority, being the most common  
55 cause of postnatal morbidity with a prevalence in high-income countries of approximately  
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3 13%, and presenting a challenging target for prevention [1-4]. In the short term, PND is  
4 associated with the woman's own health, quality of life and interactions with her baby, plus  
5 practical caregiving factors such as breastfeeding and sleep management [5-9]. In the longer  
6 term, women who experience PND are more likely to experience recurrent or chronic mental  
7 health problems (including but not limited to postnatal mental health problems with  
8 subsequent pregnancies) and difficulties in the maternal-infant and intimate partner  
9 relationships, including intimate partner violence [10,11]. Their children are more likely to  
10 have psychological, behavioural, cognitive and health problems [12].  
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21 As a result, the burden of postnatal mental health problems and their consequences are  
22 borne not only by families and the health care system, but also by other sectors in society  
23 including early childhood, education, justice and the workforce. As with depression at other  
24 life phases, women with postnatal depression use more health services than non-depressed  
25 women, not limited to mental health services [13-16]. In general, depression is associated  
26 with reduced work time and productivity [17]. Women's absence from the workforce may be  
27 prolonged by postnatal mental health problems, which may also affect the work productivity  
28 of her partner and extended family as they care for her and/or the baby.  
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39 A major focus in this field is non-psychotic depression, however a range of mental health  
40 problems manifest in the postnatal period, including adjustment disorders, anxiety, bipolar  
41 affective disorder, and disorders of maternal-infant bonding [7,18]. Postnatal anxiety has  
42 similar prevalence to and is often comorbid with depression [19]. When considering  
43 postnatal mental health problems it is important not to overlook these other disorders and  
44 their associated burden.  
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53 Postnatal mental health problems are recognised as a suitable target for preventive  
54 approaches, with the potential to avert the burden to women, their children and families, as  
55 well as the social and economic costs [20]. Despite these incentives, the search for  
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3 successful preventive interventions has met with limited success. A recent systematic review  
4 found promise in certain programs, such as professional home visits, telephone-based peer  
5 support, and individual psychotherapy [21]. However, these interventions may be better  
6 suited as targeted approaches for women at increased risk, rather than for primary  
7 prevention.  
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15 *What Were We Thinking* (WWWT) is a psycho-educational intervention that may be suitable  
16 for primary prevention of postnatal mental health problems. In a before and after controlled  
17 study (n=364) WWWT was found to reduce the prevalence of postpartum mental health  
18 problems in women without a history of psychiatric disorder [22]. It involves group-based  
19 delivery of the program in one six-hour session, where both parents along with the infant are  
20 encouraged to attend.  
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29 The Sleep, Parenting and Relationships in a Community Setting (SPARCS) trial is a cluster-  
30 randomised controlled trial examining the effectiveness of WWWT, as delivered by Maternal  
31 and Child Health (MCH) nurses to groups of first time parents in preventing non-psychotic  
32 postnatal mental health problems [23]. MCH centres in Victoria, Australia provide a free,  
33 universal service including ten visits between birth and school age, with a focus on parenting  
34 and the health and development of the child. They are jointly funded by the Victorian  
35 Department of Education and Early Childhood Development (DEECD) and Local  
36 Governments. MCH services see more than 90% of women who give birth in Victoria each  
37 year [24]. Many MCH centres facilitate First Time Parents' (FTP) groups, which provide an  
38 opportunity for education of new parents, as well as for social connections to form between  
39 parents in a local community [25]. WWWT may be suitable for integration into FTP groups.  
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54 This paper describes the protocol for the economic evaluation of WWWT, to be conducted  
55 alongside the SPARCS trial of its clinical effectiveness. The evaluation will address the  
56 question of whether WWWT provided by MCH nurses is a cost-effective intervention for the  
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3 prevention of postnatal depression, anxiety and adjustment disorders in first-time mothers,  
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5 compared with usual MCH care alone.  
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## 8 9 **Methods**

### 10 Design

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12 Full details of the trial protocol are provided in a separate paper. The SPARCS trial is  
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14 cluster-randomised, with the MCH centre as the unit of randomisation (due to the nature of  
15  
16 the intervention it is not feasible to randomise by individuals). Six Local Government Areas  
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18 (LGAs) (from a total of 31) in the greater metropolitan area of Melbourne, Australia will be  
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20 selected to participate. The LGAs will be ranked by the Socio-Economic Indexes for Areas  
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22 (SEIFA) Index of Relative Advantage and Disadvantage, and two will be included from each  
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24 of low, middle and high tertiles of socioeconomic advantage [26]. Within these six LGAs 48  
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26 MCH centres will be randomly allocated to intervention or control arms, with stratification by  
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28 LGA. Although it is not possible to blind MCH staff to allocation, measures will be taken to  
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30 minimise contamination across sites, and participants will be blinded to the intervention.  
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35 The economic evaluation will be conducted alongside the trial to examine the difference in  
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37 costs and outcomes between the intervention and control arms. If the intervention is found to  
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39 be both cost-saving and associated with equivalent or improved outcomes, then it is said to  
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41 dominate the comparator. If (as is more likely) the intervention incurs additional costs, but  
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43 provides additional health and/or utility gains, it is not immediately apparent whether the  
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45 intervention would be preferred to the comparator. In these situations an economic  
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47 evaluation comparing costs and outcomes can be informative for decision makers.  
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51 We will conduct both cost-effectiveness and cost-utility analyses (CEA and CUA) to explore  
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53 and quantify the costs per health (or utility) gain. The difference between these two is the  
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55 measure of effectiveness employed: CEA uses outcomes in natural units (such as cases  
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3 prevented) while CUA uses Quality Adjusted Life Years (QALYs). QALYs weight periods of  
4 time spent in a particular state by the quality of life for that state.  
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9 Whether or not any gain achieved is *worth* the additional costs is in the domain of decision-  
10 makers, but the results of CEA and CUA provide a basis for understanding the opportunity  
11 costs of investing scarce health resources in one area relative to another [27]. The economic  
12 evaluation will take a public sector perspective, considering costs and outcomes relevant to  
13 government departments of health, early childhood and human services (given the funding  
14 arrangements for maternal and child health in the Victorian setting), as well as out-of-pocket  
15 costs incurred by the participants.  
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#### 24 25 Study population

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27 Trial participants will be first-time mothers who: reside in the same LGA and receive care  
28 from one of the 48 selected MCH centres, have given birth within two weeks prior to  
29 enrolment, and have sufficient English language proficiency to complete structured  
30 telephone interviews. Women who agree to participate, after being provided with details of  
31 what participation will entail, will provide their written consent.  
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#### 40 Intervention and comparator

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42 The intervention consists of a single six-hour group session along with WWWT-informed  
43 postnatal care provided by trained MCH nurses throughout the study period. The session will  
44 provide information and training plus the opportunity for discussion and hands-on practice  
45 regarding managing infant behaviour, the intimate partner relationship and fatigue. MCH  
46 nurses at centres in the intervention arm of the trial will receive training on the principles of  
47 WWWT and its delivery. These trained nurses will deliver the session to participating women  
48 and their partners or other support people in group settings, within ten weeks of the baby's  
49 birth, in addition to any usual FTP group sessions. Unlike most FTP group sessions, WWWT  
50 will be delivered on a Saturday rather than a weekday to facilitate the attendance of the  
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3 women's partners. The number of WWWT sessions run per centre will be tailored to the  
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5 number of first-time mothers in the area.  
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9 Women in the comparator arm of the trial will receive usual care, including standard FTP  
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11 groups, from MCH nurses who have not been trained in WWWT. Centres which share staff  
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13 with other participating centres will be excluded to avoid cross-contamination with the  
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15 intervention.  
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### 18 19 Measures of outcome

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21 The measures of outcome employed in the economic evaluation and the timing of their  
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23 collection are presented in Table 1. Data for outcome assessment will be collected by means  
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25 of computer-assisted telephone interviews (CATIs). The baseline CATI will be conducted  
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27 before delivery of the WWWT session, and the follow-up CATI when the infant is six months  
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29 of age.  
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33 The primary measure of effectiveness for CEA will be combined prevalence of depression,  
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35 anxiety and adjustment disorders in the previous 30 days. DSM-IV diagnoses of depression  
36  
37 and anxiety will be measured by the Composite International Diagnostic Interview v3.0  
38  
39 (CIDI), while measurement of adjustment disorders will employ the Patient Health  
40  
41 Questionnaire (see [25] for details). The CIDI is a standardised structured interview which  
42  
43 can be administered, as in this trial, by telephone interview, and which yields diagnosis of  
44  
45 psychiatric disorders according to the Diagnostic and Statistical Manual (DSM-IV) criteria.  
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47 [28].  
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51 The EQ-5D-3L measure of health related quality of life will be used to calculate QALYs for  
52  
53 the CUA [29]. The EQ-5D-3L is one of the most widely used multi-attribute utility measures  
54  
55 and is regularly employed in health economic evaluations. Completion of the EQ-5D-3L  
56  
57 involves responding to a series of questions across five dimensions of health-related quality  
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3 of life: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each  
4 dimension is scored over three levels: no problems, some problems or extreme problems.  
5  
6 The EQ-5D-3L has been shown to identify differences in quality of life between people with  
7 differing severity of depression and anxiety, and to detect changes over time in those  
8 conditions [30-33]. Responses to the EQ-5D-3L will be scored using preference weights  
9 developed for the Australian population, which convert the five responses into a single  
10 summary index, where a score of one reflects perfect health and zero is equivalent to dead  
11 [34]. QALYs will be estimated for each individual in the trial by estimating the area under the  
12 quality of life curve [27].  
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### 23 Measures of resource use and cost

24  
25 An overview of resource use and cost measures to be employed in the economic evaluation  
26 is presented in Table 2. The included costs are those that are likely to differ across the  
27 intervention and control groups, specifically the costs of: developing the intervention, training  
28 of MCH staff, WWWT session delivery on a Saturday within the trial, materials used during  
29 the sessions, and use of health and other services by participants during the follow up period.  
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31 The costs of developing WWWT will be obtained from the developers.  
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40 The costs of delivering a WWWT session will be affected by whether it would be additional to  
41 existing FTP group sessions or if it would replace some elements of other services they offer.  
42 This will be established by asking MCH coordinators about the feasibility of integrating  
43 WWWT into existing FTP groups and how the inclusion of WWWT would affect the program  
44 of sessions. The additional cost of making staff available to deliver WWWT on Saturdays will  
45 be calculated based on the higher rate of pay applicable to MCH nurses on Saturdays  
46 compared with their usual working hours.  
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55 Data on service use by mother and infant will be collected from participants in both  
56 intervention and control arms during the follow-up CATIs (see table 3). After the baseline  
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3 interviews participants will be provided with a record card, on which they will be asked to  
4 record all instances of health or other service use, including out-of-pocket costs. Parents will  
5 be advised to keep the record card with the baby's usual health records book, which is  
6 generally carried to all health-related appointments. During the follow-up CATI they will be  
7 asked to refer to this card, and to report any other service use not listed on the card.  
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15 Unit costs for health service use will be estimated using data from the Medicare Benefits  
16 Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS), plus any additional out-of-  
17 pocket (OOP) costs reported by participants [35,36]. Services not covered in MBS or PBS  
18 data will be valued at market prices, and where necessary will reflect any OOP costs  
19 incurred by participants. Each participant's aggregate service use cost will be calculated  
20 from the total of instances of service use multiplied by the unit cost for that service.  
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29 All resources will be valued in 2013/14 Australian dollars, and the 6-month trial follow-up  
30 means there is no requirement to apply discounting. The expense of developing WWWT  
31 was incurred earlier over a period of some years prior to this trial, and will be inflated based  
32 on the Consumer Price Index (CPI) to reflect 2013/2014 prices.  
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### 39 Sample size

40 For sample size calculations we assumed that the prevalence of the primary outcome would  
41 be 25% in the control group, based on results from the earlier before and after study of  
42 WWWT, which used the same measure (incorporating adjustment disorders along with  
43 postnatal depression and anxiety). We calculate that the minimum sample size required to  
44 detect as statistically significant a difference of 12.5 percentage points in the primary  
45 outcome measure (25% prevalence in the control group and 12.5% in the intervention group)  
46 is 184 participants per group, with type 1 error of 5%, 80% power and allowing for 10%  
47 attrition between baseline and follow up.  
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3 Notably the sample size is that prescribed by the trial effect size, rather than the economic  
4 outcomes. Sample size estimation using economic endpoints is possible, but it is both time  
5 consuming, thus generally infeasible prior to obtaining funding, and will more likely produce  
6 a sample size that is larger than that required for the clinical effect, so increases the cost of a  
7 trial, and thus decreases the likelihood of successfully receiving funding [37]. It was  
8 necessary therefore to trade-off these issues, and as with many economic evaluations the  
9 sample was powered by the clinical outcome of interest [38].  
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### 19 Cost-effectiveness and cost-utility analyses

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21 We will calculate the total costs for intervention and control groups, as well as the average  
22 cost per participant, incorporating the cost of development, training and delivery of WWWT  
23 for the intervention group. Using regression analysis, we will control for differences in  
24 characteristics of participants (such as age, socio-economic status, past history of mental  
25 health problems, marital status), characteristics of MCH centres (such as SEIFA, rural/ urban,  
26 size of service) and for baseline EQ-5D-3L scores. This will also allow us to better manage  
27 skewed data, which is likely to be the case; we expect high proportions of participants to  
28 have zero service use costs and QALYs of 1 (full health). From these regression analyses,  
29 we will estimate the average cost per participant, the prevalence of postnatal mental health  
30 problems, and the average QALY achieved per participant for intervention and control  
31 groups.  
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46 Costs and outcomes will be combined into a single measure, the incremental cost-  
47 effectiveness ratio (ICER), which is the difference between intervention and control groups in  
48 costs divided by difference in outcomes. Results of the CEA will be expressed as cost per  
49 percentage point reduction in combined 30-day prevalence of depression, anxiety and  
50 adjustment disorders. Results of the CUA will be expressed as cost per QALY gained. The  
51 ICER from the CEA will be comparable with other interventions using the same outcome  
52 measure (prevention of postnatal depression, anxiety and adjustment disorders), whilst that  
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3 from the CUA will be comparable more broadly, as QALYs are not specific to the clinical  
4 condition. Information on cost per QALY allows decision-makers to consider efficient  
5 allocation of funding across divergent clinical disciplines; in this case allowing comparison  
6 between the cost-effectiveness of WWWT and that of prevention and treatment interventions  
7 for mental health, other perinatal interventions as well as unrelated health interventions.  
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### 13 14 15 Addressing uncertainty

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17 As we will have individual-level data on costs and outcomes for the period of trial follow up,  
18 we will evaluate uncertainty of the cost-effectiveness and cost-utility estimates using non-  
19 parametric bootstrapping [39]. Although standard statistical methods can be used to  
20 estimate standard errors for the costs and outcomes, it is the combined uncertainty  
21 surrounding the ICER that is of most interest; in particular we cannot assume independence  
22 of costs and effects. Bootstrapping produces an estimate of the joint distribution of costs and  
23 effectiveness that does not rely on assumptions about the nature of this distribution.  
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33 To represent decision uncertainty surrounding cost-effectiveness we will employ cost-  
34 effectiveness acceptability curves (CEACs) [40]. These display the proportion of the  
35 estimates produced by bootstrapping that would be 'acceptable' (below a given willingness-  
36 to-pay (WTP) threshold), over a range of these WTP thresholds.  
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43 We will also perform scenario analysis, incorporating different extremes of uncertain values  
44 in order to estimate a base case, "best case" and "worst case" scenarios, and other policy-  
45 relevant scenarios, including different service provision arrangements in other Australian  
46 jurisdictions [27].  
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### 52 53 Modelling

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55 Our base case will have a time horizon of up to six months, the period of trial follow up. If the  
56 intervention demonstrates clinical effectiveness in that period, we will employ decision  
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3 analytic modelling to estimate cost-effectiveness beyond the trial period, incorporating the  
4 effect of the intervention on long-term correlates of postnatal mental health problems. It is  
5 acknowledged that the uncertainty in these estimates is likely to be significant due to the  
6 limitations of data available on connections between maternal mental health and later  
7 outcomes, but none-the-less it is likely to be of interest to policy makers to extrapolate the  
8 results beyond the trial.  
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#### 17 Additional cost analysis to inform implementation

18 We will report on total costs of the intervention, as well as its components: development,  
19 training and delivery. The costs of developing the programme will be accounted over the  
20 projected lifetime of the programme, 5 years. We will consider how costs of the intervention  
21 might differ if WWWT were to be delivered in MCH services more broadly. This will include  
22 such factors as the need for refresher training, training of new staff members and the  
23 ongoing availability of staff on Saturdays.  
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33 To assist with understanding the policy implications of this intervention, costs (and cost  
34 savings) will be identified as accruing to the public sector (State and Commonwealth  
35 government departments of health, early childhood and human services), to private health  
36 insurers or to participants and their families.  
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#### 43 Approvals and registration

44 Approval to conduct the study was granted by Southern Health (now Monash Health) Human  
45 Research Ethics Committee (24 April 2013; 11388B). The study was registered with Monash  
46 University Human Research Ethics Committee (30 April 2013; CF12/1022 – 2012000474).  
47 The Education and Policy Research Committee, Victorian Government Department of  
48 Education and Early Childhood Development approved the study (22 March 2012;  
49 2012\_001472). Use of the EuroQol was registered with the EuroQol Group; 16 August 2012.  
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3 The trial was registered with the Australian New Zealand Clinical Trials Registry on 7 May  
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5 2012 (registration number ACTRN12613000506796) [23].  
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## 8 **Discussion**

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10 The value society places on prevention of postnatal mental health problems is unknown, nor  
11  
12 is there an explicit WTP threshold for cost per QALY in the Australian health system. Some  
13  
14 guidance can be derived given past behaviours of decision-makers (that is, approvals and  
15  
16 rejections for funding of interventions by government agencies). A review of decisions on  
17  
18 reimbursement of drugs in Australia found that in the 1990s the decision-making agency  
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20 generally did not recommend approval of drugs with a cost per life-year saved of higher than  
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22 AU\$76,000 (1998/99 figures) [41]. Stated WTP from the general population may also be  
23  
24 indicative; a more recent population-based study reported an Australian stated WTP for an  
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26 additional QALY was AU\$64,000 [42]. The figure of US\$50,000 per QALY gained is often  
27  
28 considered an approximation for a threshold, but this figure has been used for many years  
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30 and any threshold that exists may vary with other factors (such as the value society places  
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32 on the availability of treatments for particular conditions) [42,43].  
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37 Adding to the uncertainty surrounding decision-makers' WTP is that the duration of follow up  
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39 in the trial, as with all in this field, precludes collection of data on long-term correlates of  
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41 the mental health outcomes. The perceived value of preventing a case of postnatal  
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43 depression, anxiety or adjustment disorder may depend on decision-makers' acceptance of  
44  
45 the posited causal association between postnatal mental health problems and long-term  
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47 problems for mothers, their children and partners.  
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51 Despite these uncertainties, this economic evaluation will provide decision-makers with  
52  
53 valuable data to inform any future implementation of this innovative intervention for primary  
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55 prevention of postnatal mental health problems.  
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**List of abbreviations used**

CATI	Computer-assisted telephone interview
CEA	Cost-effectiveness analysis
CEAC	Cost-effectiveness acceptability curves
CIDI	Composite International Diagnostic Interview
CPI	Consumer Price Index
CUA	Cost-utility analysis
DEECD	Department of Education and Early Childhood Development
DSM	Diagnostic and Statistical Manual
FTP	First Time Parents' (group)
ICER	Incremental cost-effectiveness ratio
LGA	Local Government Areas
MBS	Medicare Benefits Schedule
MCH	Maternal and Child Health
OOP	Out-of-pocket
PBS	Pharmaceutical Benefits Scheme
PND	Postnatal depression
QALY	Quality Adjusted Life Years
SEIFA	Socio-Economic Indexes for Areas
SPARCS	Sleep, Parenting and Relationships in a Community Setting
WTP	Willingness-to-pay
WWWT	What Were We Thinking

### **Competing interests**

The authors declare that they have no competing interests to disclose.

### **Authors' contributions**

JF and HR developed the *WWWT* program and conducted the preliminary efficacy study. JR and PL will undertake the economic evaluation of the trial. JR drafted the manuscript, under the supervision of PL, and all authors reviewed the manuscript for intellectual content and approved the final version.

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1  
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4  
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**Tables**

Table 1. Overview of outcome measures

Measure	Means of collection	Timing of collection
Prevalence of depression, anxiety and adjustment disorder	CIDI conducted via telephone interview	Baseline: prior to WWWT session delivery Follow-up: 6 months postpartum
Quality of life	EQ-5D-3L conducted via telephone interview	Baseline: prior to WWWT session delivery Follow-up: 6 months postpartum

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Table 2. Overview of cost measures

Cost component	Means of collection	Timing of collection	Source of data
Cost of WWWT development	Interviews with programme developers	After completion of development	Developers of WWWT
Cost of training MCH staff	Interviews with project team, administrative records	After completion of training	Trial team
Cost of delivering WWWT	Trial records	After completion of all WWWT sessions	Trial records
Health service use	Telephone interview	6 months postpartum for the period since baseline interview	Quantity – participant interview (including record card). Unit cost – see table 3.
Other service use	Telephone interview	6 months postpartum for the period since baseline	Quantity – participant interview (including record card). Unit cost – see table 3.

Table 3. Information to be gathered on self-reported service use and sources of cost data

Service type	Source of unit costs
MCH	MCH data
MCH home visit	MCH data
Attendance at MCH-run parents' group	MCH data
GP (other than immunisation)	MBS/ OOP
Clinic nurse (other than immunisation)	MBS/ OOP
Obstetrician/ gynaecologist	MBS/ OOP
Psychologist	MBS/ OOP
Counsellor	MBS/ OOP
Psychiatrist	MBS/ OOP
Lactation consultant	OOP
Home visit from a Mothercraft nurse or another person specialising in sleep and settling	OOP
Dietician/ nutritionist	OOP
Physiotherapist	MBS/OOP
Complementary Health Care Practitioner (e.g. chiropractor, naturopath, Traditional Chinese Medicine practitioner)	OOP
Paediatrician	MBS/ OOP
Residential Early Parenting Service	DHS/ OOP
Day-stay early parenting program	DHS/ OOP
Admission to a psychiatric mother-baby unit	WIES
Hospital Emergency Department attendance	WIES
Hospital outpatients clinic	MBS
Admission to hospital overnight	WIES
Social worker/ family support services	DHS
Support groups including the Post and Antenatal Depression Association (PANDA), Australian Breastfeeding Association	Relevant organisation
Telephone helplines including Maternal and Child Health Line, Nurse on Call, Australian Breastfeeding Association	Relevant organisation
Online therapy resources	OOP
Other healthcare practitioners or services	OOP
Prescribed medicines.	PBS
Over-the-counter medicines	PBS
Unmet need for any of the listed services and why not able to access the service.	N/A

OOP= self-reported out of pocket costs; MBS = Medicare Benefits Scheme; WIES = Weighted Inlier Equivalent Separation (weights for casemix funding calculation); PBS = Pharmaceutical Benefits Scheme; DHS = Department of Human Services.

**Title:** Protocol for economic evaluation alongside a cluster-randomised controlled trial of a psycho-educational intervention for the primary prevention of postnatal mental health problems in first-time mothers

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## **Abstract**

### **Introduction**

Postnatal mental health problems, which are an international public health priority, are a suitable target for preventive approaches. The financial burden of these disorders is borne across sectors in society, including health, early childhood, education, justice and the workforce. This paper describes the planned economic evaluation of *What Were We Thinking*, a psycho-educational intervention for the prevention of postnatal mental health problems in first-time mothers.

### **Methods and analysis**

The evaluation will be conducted alongside a cluster-randomised controlled trial of its clinical effectiveness. Cost-effectiveness and costs-utility analyses will be conducted, resulting in estimates of cost per percentage point reduction in combined 30-day prevalence of depression, anxiety and adjustment disorders and cost per quality-adjusted life year gained. Uncertainty surrounding these estimates will be addressed using non-parametric bootstrapping and represented using cost-effectiveness acceptability curves. Additional cost analyses relevant for implementation will also be conducted. Modelling will be employed to estimate longer-term cost-effectiveness if the intervention is found to be clinically effective during the period of the trial.

### **Ethics and dissemination:**

Approval to conduct the study was granted by Southern Health (now Monash Health) Human Research Ethics Committee (24 April 2013; 11388B). The study was registered with Monash University Human Research Ethics Committee (30 April 2013; CF12/1022 – 2012000474). The Education and Policy Research Committee, Victorian Government Department of Education and Early Childhood Development approved the study (22 March 2012; 2012\_001472). Use of the EuroQol was registered with the EuroQol Group; 16 August 2012.

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3 The trial was registered with the Australian New Zealand Clinical Trials Registry on 7 May  
4  
5 2012 (registration number ACTRN12613000506796).<sup>[11]</sup>  
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### 8 9 **Strengths and limitations:**

- 10 • Prospectively planned data collection for the purposes of economic evaluation  
11 alongside the clinical trial of effectiveness.
- 12 • Will provide decision-makers with valuable evidence when considering any potential  
13 implementation of *What Were We Thinking*, a novel psycho-educational intervention  
14 for the prevention of postnatal mental health problems
- 15 • Limited duration of data collection in the trial
- 16 • Lack of data on willingness-to-pay for prevention of postnatal mental health problems  
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### 27 28 **Keywords**

29 Economic evaluation; cost-effectiveness; cost-utility; postnatal mental health; postnatal  
30 depression; primary prevention; maternal and child health  
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### 38 39 **Background**

40 Postnatal depression (PND) is an international public health priority, being the most common  
41 cause of postnatal morbidity with a prevalence in high-income countries of approximately  
42 13%, and presenting a challenging target for prevention [1-4][2-5]. In the short term, PND is  
43 associated with the woman's own health, quality of life and interactions with her baby, plus  
44 practical caregiving factors such as breastfeeding and sleep management [5-9][6-10]. In the  
45 longer term, women who experience PND are more likely to experience recurrent or chronic  
46 mental health problems (including but not limited to postnatal mental health problems with  
47 subsequent pregnancies) and difficulties in the maternal-infant and intimate partner  
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3 relationships, including intimate partner violence [\[10,11\]](#)[\[41,42\]](#). Their children are more  
4 likely to have psychological, behavioural, cognitive and health problems [\[12\]](#)[\[43\]](#).  
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9 As a result, the burden of postnatal mental health problems and their consequences are  
10 borne not only by families and the health care system, but also by other sectors in society  
11 including early childhood, education, justice and the workforce. As with depression at other  
12 life phases, women with postnatal depression use more health services than non-depressed  
13 women, not limited to mental health services [\[13-16\]](#)[\[44-47\]](#). In general, depression is  
14 associated with reduced work time and productivity [\[17\]](#)[\[48\]](#). Women's absence from the  
15 workforce may be prolonged by postnatal mental health problems, which may also affect the  
16 work productivity of her partner and extended family as they care for her and/or the baby.  
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27 A major focus in this field is non-psychotic depression, however a range of mental health  
28 problems manifest in the postnatal period, including adjustment disorders, anxiety, bipolar  
29 affective disorder, and disorders of maternal-infant bonding [\[7,18\]](#)[\[8,19\]](#). Postnatal anxiety  
30 has similar prevalence to and is often comorbid with depression [\[19\]](#)[\[20\]](#). When considering  
31 postnatal mental health problems it is important not to overlook these other disorders and  
32 their associated burden.  
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41 Postnatal mental health problems are recognised as a suitable target for preventive  
42 approaches, with the potential to avert the burden to women, their children and families, as  
43 well as the social and economic costs [\[20\]](#)[\[24\]](#). Despite these incentives, the search for  
44 successful preventive interventions has met with limited success. A recent systematic review  
45 found promise in certain programs, such as professional home visits, telephone-based peer  
46 support, and individual psychotherapy [\[21\]](#)[\[22\]](#). However, these interventions may be better  
47 suited as targeted approaches for women at increased risk, rather than for primary  
48 prevention.  
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3 *What Were We Thinking* (WWWT) is a psycho-educational intervention that may be suitable  
4 for primary prevention of postnatal mental health problems. In a before and after controlled  
5 study (n=364) WWWT was found to reduce the prevalence of postpartum mental health  
6  
7 problems in women without a history of psychiatric disorder [22][23]. It involves group-based  
8  
9 delivery of the program in one six-hour session, where both parents along with the infant are  
10  
11 encouraged to attend.  
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17 The Sleep, Parenting and Relationships in a Community Setting (SPARCS) trial is a cluster-  
18 randomised controlled trial examining the effectiveness of WWWT, as delivered by Maternal  
19 and Child Health (MCH) nurses to groups of first time parents in preventing non-psychotic  
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21 postnatal mental health problems [23]. MCH centres in Victoria, Australia provide a free,  
22  
23 universal service including ten visits between birth and school age, with a focus on parenting  
24  
25 and the health and development of the child. They are jointly funded by the Victorian  
26  
27 Department of Education and Early Childhood Development (DEECD) and Local  
28  
29 Governments. MCH services see more than 90% of women who give birth in Victoria each  
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31 year [24]. Many MCH centres facilitate First Time Parents' (FTP) groups, which provide an  
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33 opportunity for education of new parents, as well as for social connections to form between  
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35 parents in a local community [25]. WWWT may be suitable for integration into FTP groups.  
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41 This paper describes the protocol for the economic evaluation of WWWT, to be conducted  
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43 alongside the SPARCS trial of its clinical effectiveness. The evaluation will address the  
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45 question of whether WWWT provided by MCH nurses is a cost-effective intervention for the  
46  
47 prevention of postnatal depression, anxiety and adjustment disorders in first-time mothers,  
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49 compared with usual MCH care alone.  
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## 52 53 **Methods**

### 54 55 **Design**

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3 Full details of the trial protocol are provided in a separate paper [14]. The SPARCS trial is  
4 cluster-randomised, with the MCH centre as the unit of randomisation (due to the nature of  
5 the intervention it is not feasible to randomise by individuals). Six Local Government Areas  
6 (LGAs) (from a total of 31) in the greater metropolitan area of Melbourne, Australia will be  
7 selected to participate. The LGAs will be ranked by the Socio-Economic Indexes for Areas  
8 (SEIFA) Index of Relative Advantage and Disadvantage, and two will be included from each  
9 of low, middle and high tertiles of socioeconomic advantage [26]. Within these six LGAs 48  
10 MCH centres will be randomly allocated to intervention or control arms, with stratification by  
11 LGA. Although it is not possible to blind MCH staff to allocation, measures will be taken to  
12 minimise contamination across sites, and participants will be blinded to the intervention.  
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25 The economic evaluation will be conducted alongside the trial to examine the difference in  
26 costs and outcomes between the intervention and control arms. If the intervention is found to  
27 be both cost-saving and associated with equivalent or improved outcomes, then it is said to  
28 dominate the comparator. If (as is more likely) the intervention incurs additional costs, but  
29 provides additional health and/or utility gains, it is not immediately apparent whether the  
30 intervention would be preferred to the comparator. In these situations an economic  
31 evaluation comparing costs and outcomes can be informative for decision makers.  
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41 We will conduct both cost-effectiveness and cost-utility analyses (CEA and CUA) to explore  
42 and quantify the costs per health (or utility) gain. The difference between these two is the  
43 measure of effectiveness employed: CEA uses outcomes in natural units (such as cases  
44 prevented) while CUA uses Quality Adjusted Life Years (QALYs). QALYs weight periods of  
45 time spent in a particular state by the quality of life for that state.  
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54 Whether or not any gain achieved is *worth* the additional costs is in the domain of decision-  
55 makers, but the results of CEA and CUA provide a basis for understanding the opportunity  
56 costs of investing scarce health resources in one area relative to another [27]. The economic  
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3 evaluation will take a public sector perspective, considering costs and outcomes relevant to  
4 government departments of health, early childhood and human services (given the funding  
5 arrangements for maternal and child health in the Victorian setting), as well as out-of-pocket  
6 costs incurred by the participants.  
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### 10 11 12 13 Study population

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15 Trial participants will be first-time mothers who: reside in the same LGA and receive care  
16 from one of the 48 selected MCH centres, have given birth within two weeks prior to  
17 enrolment, and have sufficient English language proficiency to complete structured  
18 telephone interviews. Women who agree to participate, after being provided with details of  
19 what participation will entail, will provide their written consent.  
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### 25 26 27 Intervention and comparator

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29 The intervention consists of a single six-hour group session along with WWWT-informed  
30 postnatal care provided by trained MCH nurses throughout the study period. The session will  
31 provide information and training plus the opportunity for discussion and hands-on practice  
32 regarding managing infant behaviour, the intimate partner relationship and fatigue. MCH  
33 nurses at centres in the intervention arm of the trial will receive training on the principles of  
34 WWWT and its delivery. These trained nurses will deliver the session to participating women  
35 and their partners or other support people in group settings, within ten weeks of the baby's  
36 birth, in addition to any usual FTP group sessions. Unlike most FTP group sessions, WWWT  
37 will be delivered on a Saturday rather than a weekday to facilitate the attendance of the  
38 women's partners. The number of WWWT sessions run per centre will be tailored to the  
39 number of first-time mothers in the area.  
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53 Women in the comparator arm of the trial will receive usual care, including standard FTP  
54 groups, from MCH nurses who have not been trained in WWWT. Centres which share staff  
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3 with other participating centres will be excluded to avoid cross-contamination with the  
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5 intervention.  
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### 8 9 Measures of outcome

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11 The measures of outcome employed in the economic evaluation and the timing of their  
12  
13 collection are presented in Table 1. Data for outcome assessment will be collected by means  
14  
15 of computer-assisted telephone interviews (CATIs). The baseline CATI will be conducted  
16  
17 before delivery of the WWWT session, and the follow-up CATI when the infant is six months  
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19 of age.  
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23 The primary measure of effectiveness for CEA will be combined prevalence of depression,  
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25 anxiety and adjustment disorders in the previous 30 days. DSM-IV diagnoses of depression  
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27 and anxiety will be measured by the Composite International Diagnostic Interview v3.0  
28  
29 (CIDI), while measurement of adjustment disorders will employ the Patient Health  
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31 Questionnaire (see [25] for details). The CIDI is a standardised structured interview which  
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33 can be administered, as in this trial, by telephone interview, and which yields diagnosis of  
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35 psychiatric disorders according to the Diagnostic and Statistical Manual (DSM-IV) criteria.  
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37 [28].  
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41 The EQ-5D-3L measure of health related quality of life will be used to calculate QALYs for  
42  
43 the CUA [29]. The EQ-5D-3L is one of the most widely used multi-attribute utility measures  
44  
45 and is regularly employed in health economic evaluations. Completion of the EQ-5D-3L  
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47 involves responding to a series of questions across five dimensions of health-related quality  
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49 of life: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each  
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51 dimension is scored over three levels: no problems, some problems or extreme problems.  
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53 The EQ-5D-3L has been shown to identify differences in quality of life between people with  
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55 differing severity of depression and anxiety, and to detect changes over time in those  
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57 conditions [30-33]. Responses to the EQ-5D-3L will be scored using preference weights  
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3 developed for the Australian population, which convert the five responses into a single  
4 summary index, where a score of one reflects perfect health and zero is equivalent to dead  
5 [34]. QALYs will be estimated for each individual in the trial by estimating the area under the  
6 quality of life curve [27].  
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### 10 11 12 13 Measures of resource use and cost

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15 An overview of resource use and cost measures to be employed in the economic evaluation  
16 is presented in Table 2. The included costs are those that are likely to differ across the  
17 intervention and control groups, specifically the costs of: developing the intervention, training  
18 of MCH staff, WWWT session delivery on a Saturday within the trial, materials used during  
19 the sessions, and use of health and other services by participants during the follow up period.  
20 The costs of developing WWWT will be obtained from the developers.  
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29 The costs of delivering a WWWT session will be affected by whether it would be additional to  
30 existing FTP group sessions or if it would replace some elements of other services they offer.  
31 This will be established by asking MCH coordinators about the feasibility of integrating  
32 WWWT into existing FTP groups and how the inclusion of WWWT would affect the program  
33 of sessions. The additional cost of making staff available to deliver WWWT on Saturdays will  
34 be calculated based on the higher rate of pay applicable to MCH nurses on Saturdays  
35 compared with their usual working hours.  
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45 Data on service use by mother and infant will be collected from participants in both  
46 intervention and control arms during the follow-up CATIs (see table 3). After the baseline  
47 interviews participants will be provided with a record card, on which they will be asked to  
48 record all instances of health or other service use, including out-of-pocket costs. Parents will  
49 be advised to keep the record card with the baby's usual health records book, which is  
50 generally carried to all health-related appointments. During the follow-up CATI they will be  
51 asked to refer to this card, and to report any other service use not listed on the card.  
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5 Unit costs for health service use will be estimated using data from the Medicare Benefits  
6 Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS), plus any additional out-of-  
7 pocket (OOP) costs reported by participants [35,36]. Services not covered in MBS or PBS  
8 data will be valued at market prices, and where necessary will reflect any OOP costs  
9 incurred by participants. Each participant's aggregate service use cost will be calculated  
10 from the total of instances of service use multiplied by the unit cost for that service.  
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15 All resources will be valued in 2013/14 Australian dollars, and the 6-month trial follow-up  
16 means there is no requirement to apply discounting. The expense of developing WWWT  
17 was incurred earlier over a period of some years prior to this trial, and will be inflated based  
18 on the Consumer Price Index (CPI) to reflect 2013/2014 prices.  
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### 29 Sample size

30 For sample size calculations we assumed that the prevalence of the primary outcome would  
31 be 25% in the control group, based on results from the earlier before and after study of  
32 WWWT, which used the same measure (incorporating adjustment disorders along with  
33 postnatal depression and anxiety). We calculate that the minimum sample size required to  
34 detect as statistically significant a difference of 12.5 percentage points in the primary  
35 outcome measure (25% prevalence in the control group and 12.5% in the intervention group)  
36 is 184 participants per group, with type 1 error of 5%, 80% power and allowing for 10%  
37 attrition between baseline and follow up.  
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49 Notably the sample size is that prescribed by the trial effect size, rather than the economic  
50 outcomes. Sample size estimation using economic endpoints is possible, but it is both time  
51 consuming, thus generally infeasible prior to obtaining funding, and will more likely produce  
52 a sample size that is larger than that required for the clinical effect, so increases the cost of a  
53 trial, and thus decreases the likelihood of successfully receiving funding [37]. It was  
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3 necessary therefore to trade-off these issues, and as with many economic evaluations the  
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5 sample was powered by the clinical outcome of interest [38].  
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#### 8 9 Cost-effectiveness and cost-utility analyses

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11 We will calculate the total costs for intervention and control groups, as well as the average  
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13 cost per participant, incorporating the cost of development, training and delivery of WWWT  
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15 for the intervention group. Using regression analysis, we will control for differences in  
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17 characteristics of participants (such as age, socio-economic status, past history of mental  
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19 health problems, marital status), characteristics of MCH centres (such as SEIFA, rural/ urban,  
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21 size of service) and for baseline EQ-5D-3L scores. This will also allow us to better manage  
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23 skewed data, which is likely to be the case; we expect high proportions of participants to  
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25 have zero service use costs and QALYs of 1 (full health). From these regression analyses,  
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27 we will estimate the average cost per participant, the prevalence of postnatal mental health  
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29 problems, and the average QALY achieved per participant for intervention and control  
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31 groups.  
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35 Costs and outcomes will be combined into a single measure, the incremental cost-  
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37 effectiveness ratio (ICER), which is the difference between intervention and control groups in  
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39 costs divided by difference in outcomes. Results of the CEA will be expressed as cost per  
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41 percentage point reduction in combined 30-day prevalence of depression, anxiety and  
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43 adjustment disorders. Results of the CUA will be expressed as cost per QALY gained. The  
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45 ICER from the CEA will be comparable with other interventions using the same outcome  
46  
47 measure (prevention of postnatal depression, anxiety and adjustment disorders), whilst that  
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49 from the CUA will be comparable more broadly, as QALYs are not specific to the clinical  
50  
51 condition. Information on cost per QALY allows decision-makers to consider efficient  
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53 allocation of funding across divergent clinical disciplines; in this case allowing comparison  
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55 between the cost-effectiveness of WWWT and that of prevention and treatment interventions  
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57 for mental health, other perinatal interventions as well as unrelated health interventions.  
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### Addressing uncertainty

As we will have individual-level data on costs and outcomes for the period of trial follow up, we will evaluate uncertainty of the cost-effectiveness and cost-utility estimates using non-parametric bootstrapping [39]. Although standard statistical methods can be used to estimate standard errors for the costs and outcomes, it is the combined uncertainty surrounding the ICER that is of most interest; in particular we cannot assume independence of costs and effects. Bootstrapping produces an estimate of the joint distribution of costs and effectiveness that does not rely on assumptions about the nature of this distribution.

To represent decision uncertainty surrounding cost-effectiveness we will employ cost-effectiveness acceptability curves (CEACs) [40]. These display the proportion of the estimates produced by bootstrapping that would be 'acceptable' (below a given willingness-to-pay (WTP) threshold), over a range of these WTP thresholds.

We will also perform scenario analysis, incorporating different extremes of uncertain values in order to estimate a base case, "best case" and "worst case" scenarios, and other policy-relevant scenarios, including different service provision arrangements in other Australian jurisdictions [27].

### Modelling

Our base case will have a time horizon of up to six months, the period of trial follow up. If the intervention demonstrates clinical effectiveness in that period, we will employ decision analytic modelling to estimate cost-effectiveness beyond the trial period, incorporating the effect of the intervention on long-term correlates of postnatal mental health problems. It is acknowledged that the uncertainty in these estimates is likely to be significant due to the limitations of data available on connections between maternal mental health and later



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3 outcomes, but none-the-less it is likely to be of interest to policy makers to extrapolate the  
4 results beyond the trial.  
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#### 8 9 Additional cost analysis to inform implementation

10 We will report on total costs of the intervention, as well as its components: development,  
11 training and delivery. The costs of developing the programme will be accounted over the  
12 projected lifetime of the programme, 5 years. We will consider how costs of the intervention  
13 might differ if WWWT were to be delivered in MCH services more broadly. This will include  
14 such factors as the need for refresher training, training of new staff members and the  
15 ongoing availability of staff on Saturdays.  
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25 To assist with understanding the policy implications of this intervention, costs (and cost  
26 savings) will be identified as accruing to the public sector (State and Commonwealth  
27 government departments of health, early childhood and human services), to private health  
28 insurers or to participants and their families.  
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#### 35 Approvals and registration

36 Approval to conduct the study was granted by Southern Health (now Monash Health) Human  
37 Research Ethics Committee (24 April 2013; 11388B). The study was registered with Monash  
38 University Human Research Ethics Committee (30 April 2013; CF12/1022 – 2012000474).  
39 The Education and Policy Research Committee, Victorian Government Department of  
40 Education and Early Childhood Development approved the study (22 March 2012;  
41 2012\_001472). Use of the EuroQol was registered with the EuroQol Group; 16 August 2012.  
42 The trial was registered with the Australian New Zealand Clinical Trials Registry on 7 May  
43 2012 (registration number ACTRN12613000506796) [23].  
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#### 55 Discussion

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3 The value society places on prevention of postnatal mental health problems is unknown, nor  
4 is there an explicit WTP threshold for cost per QALY in the Australian health system. Some  
5 guidance can be derived given past behaviours of decision-makers (that is, approvals and  
6 rejections for funding of interventions by government agencies). A review of decisions on  
7 reimbursement of drugs in Australia found that in the 1990s the decision-making agency  
8 generally did not recommend approval of drugs with a cost per life-year saved of higher than  
9 AU\$76,000 (1998/99 figures) [41]. Stated WTP from the general population may also be  
10 indicative; a more recent population-based study reported an Australian stated WTP for an  
11 additional QALY was AU\$64,000 [42]. The figure of US\$50,000 per QALY gained is often  
12 considered an approximation for a threshold, but this figure has been used for many years  
13 and any threshold that exists may vary with other factors (such as the value society places  
14 on the availability of treatments for particular conditions) [42,43].  
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29 Adding to the uncertainty surrounding decision-makers' WTP is that the duration of follow up  
30 in the trial, as with all in this field, precludes collection of data on of long-term correlates of  
31 the mental health outcomes. The perceived value of preventing a case of postnatal  
32 depression, anxiety or adjustment disorder may depend on decision-makers' acceptance of  
33 the posited causal association between postnatal mental health problems and long-term  
34 problems for mothers, their children and partners.  
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43 Despite these uncertainties, this economic evaluation will provide decision-makers with  
44 valuable data to inform any future implementation of this innovative intervention for primary  
45 prevention of postnatal mental health problems.  
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#### 51 **List of abbreviations used**

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53	
54	CATI Computer-assisted telephone interview
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56	CEA Cost-effectiveness analysis
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58	CEAC Cost-effectiveness acceptability curves
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3	CIDI	Composite International Diagnostic Interview
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5	CPI	Consumer Price Index
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7	CUA	Cost-utility analysis
8		
9	DEECD	Department of Education and Early Childhood Development
10		
11	DSM	Diagnostic and Statistical Manual
12		
13	FTP	First Time Parents' (group)
14		
15	ICER	Incremental cost-effectiveness ratio
16		
17	LGA	Local Government Areas
18		
19	MBS	Medicare Benefits Schedule
20		
21	MCH	Maternal and Child Health
22		
23	OOP	Out-of-pocket
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25	PBS	Pharmaceutical Benefits Scheme
26		
27	PND	Postnatal depression
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29	QALY	Quality Adjusted Life Years
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31	SEIFA	Socio-Economic Indexes for Areas
32		
33	SPARCS	Sleep, Parenting and Relationships in a Community Setting
34		
35	WTP	Willingness-to-pay
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37	WWWT	What Were We Thinking
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### **Competing interests**

The authors declare that they have no competing interests to disclose.

### **Authors' contributions**

JF and HR developed the *WWWT* program and conducted the preliminary efficacy study. JR and PL will undertake the economic evaluation of the trial. JR drafted the manuscript, under the supervision of PL, and all authors reviewed the manuscript for intellectual content and approved the final version.

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**Tables**

Table 1. Overview of outcome measures

Measure	Means of collection	Timing of collection
Prevalence of depression, anxiety and adjustment disorder	CIDI conducted via telephone interview	Baseline: prior to WWWT session delivery Follow-up: 6 months postpartum
Quality of life	EQ-5D-3L conducted via telephone interview	Baseline: prior to WWWT session delivery Follow-up: 6 months postpartum

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Table 2. Overview of cost measures

Cost component	Means of collection	Timing of collection	Source of data
Cost of WWWT development	Interviews with programme developers	After completion of development	Developers of WWWT
Cost of training MCH staff	Interviews with project team, administrative records	After completion of training	Trial team
Cost of delivering WWWT	Trial records	After completion of all WWWT sessions	Trial records
Health service use	Telephone interview	6 months postpartum for the period since baseline interview	Quantity – participant interview (including record card). Unit cost – see table 3.
Other service use	Telephone interview	6 months postpartum for the period since baseline	Quantity – participant interview (including record card). Unit cost – see table 3.

Table 3. Information to be gathered on self-reported service use and sources of cost data

Service type	Source of unit costs
MCH	MCH data
MCH home visit	MCH data
Attendance at MCH-run parents' group	MCH data
GP (other than immunisation)	MBS/ OOP
Clinic nurse (other than immunisation)	MBS/ OOP
Obstetrician/ gynaecologist	MBS/ OOP
Psychologist	MBS/ OOP
Counsellor	MBS/ OOP
Psychiatrist	MBS/ OOP
Lactation consultant	OOP
Home visit from a Mothercraft nurse or another person specialising in sleep and settling	OOP
Dietician/ nutritionist	OOP
Physiotherapist	MBS/OOP
Complementary Health Care Practitioner (e.g. chiropractor, naturopath, Traditional Chinese Medicine practitioner)	OOP
Paediatrician	MBS/ OOP
Residential Early Parenting Service	DHS/ OOP
Day-stay early parenting program	DHS/ OOP
Admission to a psychiatric mother-baby unit	WIES
Hospital Emergency Department attendance	WIES
Hospital outpatients clinic	MBS
Admission to hospital overnight	WIES
Social worker/ family support services	DHS
Support groups including the Post and Antenatal Depression Association (PANDA), Australian Breastfeeding Association	Relevant organisation
Telephone helplines including Maternal and Child Health Line, Nurse on Call, Australian Breastfeeding Association	Relevant organisation
Online therapy resources	OOP
Other healthcare practitioners or services	OOP
Prescribed medicines.	PBS
Over-the-counter medicines	PBS
Unmet need for any of the listed services and why not able to access the service.	N/A

OOP= self-reported out of pocket costs; MBS = Medicare Benefits Scheme; WIES = Weighted Inlier Equivalent Separation (weights for casemix funding calculation); PBS = Pharmaceutical Benefits Scheme; DHS = Department of Human Services.