A pilot randomised controlled trial to evaluate the efficacy and acceptability of the Baby Positive Parenting Programme compared with Treatment as Usual in women with Postnatal Depression

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## Table of Contents

Lists of Figures .................................................................................................................. 9
List of Tables ......................................................................................................................... 10
Abstract ............................................................................................................................... 12
DECLARATION ..................................................................................................................... 13
COPYRIGHT STATEMENT .................................................................................................... 14
Acknowledgements .............................................................................................................. 15
The Author .......................................................................................................................... 16
Overview ............................................................................................................................ 17
Chapter 1 ............................................................................................................................. 19
  Abstract ............................................................................................................................ 20
  1.0 Introduction .................................................................................................................. 21
    1.1.1 Definition of postnatal depression ................................................................. 21
    1.1.2 Clinical presentation of PND ...................................................................... 22
  1.2 A biopsychosocial model of PND ............................................................................. 23
    1.2.1 Prevalence of PND ...................................................................................... 25
    1.2.2 The experience of PND .............................................................................. 25
  1.3 Impact of PND on infant development ................................................................... 26
    1.3.1 The impact of PND on infant development .................................................... 26
    1.3.2 A model for the impact of PND on infant development ............................... 27
    1.3.3 Impact of PND on the mother-infant relationship ..................................... 27
  1.4 Overview of treatments for PND ............................................................................. 28
    1.4.1 Anti-depressant medication treatment for PND ............................................ 28
    1.4.2 Interventions in the antenatal period ............................................................ 33
    1.4.3 Psychoeducation groups ............................................................................ 36
    1.4.4 Cognitive behaviour therapy (CBT) for PND ............................................. 39
2.4.1 Sample ............................................................................. 82
2.4.2 Allocation ........................................................................ 82
2.4.3 Assessment ...................................................................... 82
2.4.4 Control groups ................................................................. 83
2.4.5 Analysis ........................................................................... 83
2.4.6 Active treatment ............................................................... 83
2.5 Maternal mood, dyadic relationship and developmental outcomes ........................................... 83
  2.5.1 Outcome measures .......................................................... 83
  2.5.2 Maternal mood ................................................................. 83
  2.5.3 Mother-infant relationship ................................................. 88
  2.5.4 Child development ........................................................... 89
2.6 Discussion ........................................................................... 91
References .................................................................................. 97
Chapter 3 .................................................................................. 101
  3.1 Introduction ....................................................................... 102
  3.2 The application of Baby Triple P to PND ............................ 102
  3.3 An overview of the Triple P Positive Parenting Programme .............................................. 103
  3.4 Possible mechanisms involved in Triple P .............................................. 105
  3.5 The Triple P evidence base ................................................... 105
  3.5 Parenting programmes with variants for new parents ................................................ 107
  3.7 An overview of Baby Triple P ................................................. 108
    3.7.1 Promoting self-regulation using the self-evaluation framework ............................ 109
    3.7.2 Possible mechanisms involved ............................................. 112
  3.8 Summary ........................................................................... 113
References .................................................................................. 114
Chapter 4 .................................................................................. 118
  4.0 Overview ........................................................................... 119
  4.1 Methodology for validation of Parenting Beliefs Scale for Parents- baby version .. 119
4.1.1 Design ........................................................................................................119
4.1.2 Measures .....................................................................................................119
4.1.3 Participant characteristics .........................................................................120
4.1.4 Sampling procedures .................................................................................120
4.1.5 Procedure .....................................................................................................121
4.1.6 Ethical considerations ..................................................................................121
4.2. Methodology for pilot trial of Baby Triple P in women with PND .............121
  4.2.1 Design .........................................................................................................121
  4.2.2 Measures .....................................................................................................122
  4.2.3 Mother-infant interaction .........................................................................124
  4.2.4 Parenting competence, cognitions, attitudes and emotional responses ....124
  4.2.5 Acceptability of Baby Triple P ..................................................................125
  4.2.6 Symptomatology across treatment sessions ............................................125
4.3 Participant characteristics ..............................................................................126
  4.3.1 Inclusion and exclusion criteria .................................................................126
4.4 Sampling procedures .....................................................................................126
  4.4.1 Sampling method and recruitment ..............................................................126
  4.4.2 Power calculation .......................................................................................127
  4.4.3 Randomisation Method .............................................................................127
4.5 Ethical considerations .....................................................................................128
References ............................................................................................................130

Chapter 5 .............................................................................................................132

Abstract ................................................................................................................133
  5.1 Introduction ....................................................................................................134
  5.2 Method ............................................................................................................136
    5.2.1 Research design ........................................................................................136
    5.2.2 Participant characteristics .......................................................................136
    5.2.3 Procedure ..................................................................................................136
5.2.4 Measures ........................................................................................................... 137
5.2.5 Data analysis .................................................................................................... 138
5.3 Results .................................................................................................................. 138
  5.3.1 Participant characteristics ............................................................................. 138
  5.3.2 Exploratory factor analysis .......................................................................... 140
  5.3.3 Internal consistency ...................................................................................... 143
  5.3.4 Test-Retest reliability ................................................................................... 143
5.4 Discussion ............................................................................................................ 143
  5.4.1 Clinical implications .................................................................................... 144
  5.4.2 Limitations .................................................................................................... 144
  5.4.3 Future research ............................................................................................ 145
5.5 Conclusion ............................................................................................................ 145
References .................................................................................................................. 146

Chapter 6 ..................................................................................................................... 148
Abstract ..................................................................................................................... 149
  6.1 Introduction ....................................................................................................... 150
  6.2 Method ............................................................................................................... 152
    6.2.1 Research design ........................................................................................ 152
    6.2.2 Measures ................................................................................................... 153
    6.2.3 Participants ................................................................................................ 156
    6.2.4 Sampling procedures ................................................................................ 156
    6.2.5 Sample size and power ............................................................................. 157
    6.2.6 Planned analyses ....................................................................................... 157
  6.3 Results ............................................................................................................... 157
    6.3.1 Treatment as usual .................................................................................... 160
    6.3.2 Statistical analysis ..................................................................................... 160
    6.3.3 Maternal mood ........................................................................................... 160
    6.3.4 Self-regulation ........................................................................................... 162
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.3.5 Parenting attitudes</td>
<td>162</td>
</tr>
<tr>
<td>6.3.6 Subjective bonding</td>
<td>163</td>
</tr>
<tr>
<td>6.3.7 Dyad relationship</td>
<td>163</td>
</tr>
<tr>
<td>6.3.8 Reliable change index</td>
<td>166</td>
</tr>
<tr>
<td>6.3.9 Baby Triple P acceptability</td>
<td>166</td>
</tr>
<tr>
<td>6.4 Discussion</td>
<td>167</td>
</tr>
<tr>
<td>6.4.1 Implementation issues</td>
<td>168</td>
</tr>
<tr>
<td>6.4.2 Limitations</td>
<td>168</td>
</tr>
<tr>
<td>6.4.3 Recommendations for future research</td>
<td>169</td>
</tr>
<tr>
<td>6.5 Conclusion</td>
<td>170</td>
</tr>
<tr>
<td>References</td>
<td>172</td>
</tr>
<tr>
<td>Chapter 7</td>
<td>176</td>
</tr>
<tr>
<td>7.0 Overview of general discussion</td>
<td>177</td>
</tr>
<tr>
<td>7.1 Thesis summary</td>
<td>177</td>
</tr>
<tr>
<td>7.2 Review of Chapter 5</td>
<td>179</td>
</tr>
<tr>
<td>7.3 Review of Chapter 6</td>
<td>180</td>
</tr>
<tr>
<td>7.4 Exploration of the findings</td>
<td>180</td>
</tr>
<tr>
<td>7.5 Methodological limitations</td>
<td>183</td>
</tr>
<tr>
<td>7.6 Recruitment difficulties and barriers to access</td>
<td>185</td>
</tr>
<tr>
<td>7.7 Strengths of the study methodology</td>
<td>188</td>
</tr>
<tr>
<td>7.7.1 Sample size</td>
<td>188</td>
</tr>
<tr>
<td>7.7.2 Randomisation procedures</td>
<td>188</td>
</tr>
<tr>
<td>7.7.3 Study protocol development</td>
<td>189</td>
</tr>
<tr>
<td>7.7.4 Recruitment and consent</td>
<td>190</td>
</tr>
<tr>
<td>7.7.5 Acceptability of Baby Triple P</td>
<td>190</td>
</tr>
<tr>
<td>7.7.6 Measurement selection</td>
<td>191</td>
</tr>
<tr>
<td>7.7.7 Data collection procedures</td>
<td>192</td>
</tr>
<tr>
<td>7.7.8 Study design</td>
<td>192</td>
</tr>
</tbody>
</table>
Lists of Figures

Chapter 1
Figure 1. The biopsychosocial model of postnatal depression (Milgrom, Martin & Negri, 1999, p. 26) ..................................................................................................................24

Chapter 2
Figure 1. An integrative model for the transmission of risk to children of mothers with PND.................................................................................................................................................68

Figure 2. Schematic diagram of literature search for studies on treatment for PND with outcomes assessing mother-infant interaction and/or child outcomes............................73

Chapter 3
Figure 1. The Positive Parenting Programme intervention system..................................104

Chapter 4
Figure 1. Baby Triple P study procedure flowchart.............................................................127

Chapter 6
Figure 1. CONSORT diagram of participant involvement through study progress........158
List of Tables

Chapter 1
Table 1. Studies of anti-depressant medication for PND..................................................31
Table 2. Studies of antenatal interventions for PND..........................................................35
Table 3. Studies of psychoeducation for PND.................................................................38
Table 4. Studies of cognitive behavioural therapy (CBT) for PND......................................41
Table 5. Studies of interpersonal therapy (IPT) for PND..................................................45
Table 6. Studies with a relational (dyadic) focus..............................................................49
Table 7. Studies of baby massage for PND.....................................................................52

Chapter 2
Table 1. Participant characteristics including: marital status, age of baby and mother and level of depression (at baseline) across all studies................................................75
Table 2. Type of treatment, session length and treatment duration, CTAM scores and domains of assessment.................................................................77
Table 3. Means, Standard deviations (SD), Cohen’s D and effect sizes on measures of maternal depression and dyad measures across studies..............................................86
Table 4. Means, Standard deviations, Cohen’s D and effect sizes on measures of child development across studies.................................................................90

Chapter 3
Table 1. Baby Triple P session content........................................................................110

Chapter 5
Table 1. Socio demographics and characteristics of mothers and their infants at baseline........................................................................................................139
Table 2. Loadings for fixed rotated three-factor solution for the PBS-B in a healthy non-depressed sample (n= 99).................................................................142

Chapter 6
Table 1. Socio demographics and characteristics of mothers and their infants in Baby Triple P and treatment as usual (TAU) at baseline (Time 1)........................................159
Table 2. Adjusted means and confidence intervals for all outcome measures at all time points

Table 3. Medians and ranges for Care index variables for Baby TP group and TAU at Baseline (Time 1), post treatment (Time 2) and 3 month follow-up (Time 3)

Table 4. Client satisfaction ratings for women allocated to Baby Triple P
Abstract
Postnatal depression (PND) is an episode of major depression which occurs within the postnatal period. It has major implications for maternal wellbeing, the mother-infant relationship and child development. Whilst there is considerable evidence demonstrating the impact of PND on parenting, there has been limited focus on parenting as an intervention target. Therefore, the foremost aim of this thesis was to assess the efficacy and acceptability of the Baby Positive Parenting Programme (Baby Triple P) in women with Postnatal Depression.

In Chapter 1 a broad overview of the PND treatment literature is undertaken. The treatments represent a range including anti-depressant medication, antenatal group interventions, psychoeducation, cognitive behaviour therapy (CBT), interpersonal psychotherapy (IPT), interventions which focus on the mother-infant relationship and baby massage. Chapter 1 highlights the poverty of interventions focusing on parenting as well as limited assessment of dyadic and child developmental outcomes. Therefore, a systematic review in Chapter 2 sought to evaluate the quality and efficacy of treatments which did include the aforementioned outcomes. Having identified the little attention to parenting within the context of PND, Chapter 3 outlines the rationale for targeting parenting in PND and introduces the Triple P Positive Parenting Programme, its evidence base and details Baby Triple P. Self-regulation is also introduced as a possible mechanism for explaining the improvements and maintenance associated with Triple P programmes. Since there is no measure to assess self-regulation, one was designed for the purpose of this study. Chapter 4 presents the methodology for the two aforementioned empirical papers. Chapter 5 presents a Factor Analysis (FA) and psychometric properties of the Brief Parenting Beliefs Scale-baby version, designed to measure self-regulation in new parents. The result was a three-factor, brief reliable measure of self-regulation.

Chapter 6 presents the findings from the pilot randomised controlled trial (RCT) of Baby Triple P, compared with treatment as usual (TAU) in a sample of women with PND. Twenty-seven women and their infants (under 12 months) from primary care services in Greater Manchester, UK, were randomised to either receive the eight-session Baby Triple P programme in addition to TAU or to TAU only. Participants were assessed prior to randomisation at Baseline (Time 1), post-treatment (eight weeks for TAU) (Time 2) and three-month follow-up (Time 3). Self-report measures were used to compare groups, including symptoms of depression, happiness, the parenting experience, subjective bonding and self-regulation. An assessor-rated observational measure of mother-infant interaction, the Care Index, and a measure of intervention acceptability were also included.

Significant improvements from baseline to post-treatment and baseline to three-month follow-up were found across both Baby Triple P and TAU conditions. However, the present study failed to demonstrate an additive effect of Baby Triple P. Despite the non-significant findings Baby Triple P was found to be highly acceptable to women with PND. Reasons for the non-significant findings are explored. The final Chapter (7) is a general discussion summarising the preceding chapters and provides a critical analysis of the pilot RCT of Baby Triple P.
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Overview

Postnatal depression (PND) or postpartum depression is a major depressive episode experienced by around 10-15% of new mothers following the birth of a baby. The pervasive effects of PND on the mother, baby and family functioning are evidenced by a large body of literature (Goodman & Gotlib, 2009; Letourneau et al., 2012; O’Hara, 2009). Whilst many women do spontaneously recover from PND, risks to the mother-infant relationship and child development may persist well beyond the first postnatal year. In particular, PND can grossly impact on a mother’s ability to parent in an adaptive and protective way. Although there is considerable research investigating various treatments for PND, few studies have targeted parenting and the majority of studies have not measured mother-infant dyad or child developmental outcomes.

The primary aim of this thesis was to examine the efficacy and acceptability of a new eight session parenting programme for new parents, the Baby Positive Parenting Programme (Baby Triple P; a newly developed variant of the Triple P Positive Parenting Programme) in a sample of women experiencing PND. The Triple P Programme is a system of parenting interventions with varying levels of intensity depending on family need. It is a strengths based intervention with a flexible delivery format largely underpinned by Bandura’s Social Learning Theory (1977).

It has been suggested that Triple P programmes (and parenting programmes more generally) function to improve self-regulatory skills involved in parenting. Self-regulation is proposed to be made up of four central concepts, including parental self-sufficiency, personal agency, parental self-efficacy and self-management. Increases in parental ability to self-regulate are proposed to be related to successful uptake and long-term maintenance of the strategies implicated in Triple P. So far, there has been no tool to measure self-regulation. Therefore, the secondary aim of this thesis was to investigate the factor structure and validate a measure of self-regulation for new mothers.

This thesis follows the alternative format and where indicated, some of the chapters have been prepared for submission to peer reviewed journals. Chapter 1 is a broad overview of the area and outlines the theoretical background, conceptualisation and treatment literature. Chapter 1 serves as an overview to put the present research into context of the broader literature.

---

1 Although the terms postnatal and postpartum depression are used interchangeably in the literature, the following thesis uses the term postnatal depression (PND).
Given the impact of PND on the mother-infant relationship and child developmental outcomes and the limitations highlighted in the broad overview, the author undertook a more focused review. Therefore, Chapter 2 is a systematic review of interventions for PND which assess maternal mood outcomes as well as mother-infant relationship and/or child developmental outcomes. Furthermore, the methodological quality of the studies included in the review was rigorously assessed using the Clinical Tool for Assessment of Methodology (CTAM; Tarrier & Wykes, 2003).

Chapter 3 focuses on parenting in the context of PND. Chapter 3 introduces and outlines the Triple framework; theoretical implications and the rationale for using Baby Triple P in the treatment of PND is also provided.

Chapter 4 will detail the methodology employed across the two empirical chapters. This chapter will be presented in two parts, and includes: section 1) the methods for the validation of a questionnaire designed to investigate self-regulation in parents of babies under 12 months and section 2) the methodology for the pilot randomised controlled trial (RCT) of Baby Triple P in PND.

Chapter 5 and 6 are empirical papers for two studies in the form of manuscripts prepared for publication. Chapter 5 will present the findings from a Factor Analysis (FA) of a brief measure designed to measure parental self-regulation.

Chapter 6 is the main research paper which will detail the primary and secondary outcomes (from baseline to three-month follow-up) from the pilot RCT comparing Baby Triple P with treatment as usual (TAU) in a sample of women experiencing PND. Methodological information is supplemented by Chapter 4.

Finally, Chapter 7 will present a general discussion summarising the main results, strengths and limitations, issues related to the implementation of Baby Triple P in PND, recruitment difficulties and barriers to access, clinical implications, process issues in the application of Baby Triple P to PND and recommendations for future research.
Chapter 1

An introduction to postnatal depression and a broad overview of the treatment literature

A shorter version of this chapter was previously published as Tsivos, Wittkowski, Calam & Sanders (2011). Postnatal depression- the impact for women and children and interventions to enhance the mother-infant relationship. Perspectives, 11, 16-20.
Abstract
This aim of this overview was to provide an introduction to postnatal depression (PND), including a definition of PND, clinical presentation, prevalence, and experience of PND. Research on the effects of PND on the mother, infant and their relationship is also covered briefly. An overview of the treatment literature is also provided, including anti-depression medication, antenatal group interventions, psychoeducation, cognitive behaviour therapy (CBT), interpersonal psychotherapy (IPT), interventions which focus on the mother-infant relationship and baby massage. In addition, challenges to PND treatments and limitations to current research are also outlined and suggestions made to address limitations. Despite the difficulties women with PND experience in the domain of parenting, there exists a poverty of interventions focusing on parenting. The review indicates parenting is under-researched in the context of PND and may be a viable target.
1.0 Introduction

When [baby] Jodie cries it makes me angry, I don’t know why. Sometimes I feel like she does it just to get to me... I get so angry with her, then I cry because I feel so guilty... because I’m her mother and I can’t comfort her when she needs me... because I can’t stay calm within myself...looking back now...I spent a lot of time in tears, I wasn’t able to feel happy about anything. I felt inadequate- a failure as a mother and a partner...

(p. 6, Milgrom, Martin & Negri, 1999)

Motherhood can be both rewarding and fulfilling. However, the stress and daily pressures of raising children can impact on parental well-being. The transition to parenthood represents a period of significant adjustment for all parents. Although depression is common in women at different ages and life stages, and the overall prevalence may not vary greatly, women are particularly vulnerable to developing depressive feelings or clinical depression during the postnatal period (Cox, Murray, & Chapman, 1993).

It is widely evidenced that maternal mental illness, specifically PND, has profound and widespread effects on the mother (Reck, Noe, Gerstenlauer & Stehle, 2012), the mother-infant relationship (Moehler, Brunner, Wiebel, Reck, & Resch, 2006; Reck et al., 2011) and serious implications for subsequent infant development (Feldman et al., 2009; Hay, Pawlby, Angold, Harold & Sharp, 2003) and family well-being more generally (Letourneau et al., 2012; Tronick & Reck, 2009; Meany et al., 2001). Its treatment is, therefore, a major public health concern, spanning both adult and infant mental health.

The purpose of this chapter is to provide a context for the prospective study, a pilot RCT comparing Baby Triple P with treatment as usual (TAU). This chapter is an introduction to PND and overview of treatments for PND including anti-depression medication, antenatal group interventions, psychoeducation, cognitive behaviour therapy (CBT), interpersonal psychotherapy (IPT), interventions which focus on the mother-infant relationship and baby massage. For this reason, the intention is not to conduct a critical review of the literature, but to provide an orienting account of the literature. The present overview will also briefly consider the impact of PND on the mother, the infant’s development and the mother-infant relationship. A biopsychosocial model of PND is also presented.

1.1.1 Definition of postnatal depression

Postnatal depression (PND) is an episode of major depression defined by its onset following the birth of a baby. It is considered distinct in comparison with other perinatal mood disorders including postnatal blues and puerperal psychosis (Williamson & McCutcheon, 2004). Postnatal depression (PND) is more serious than postnatal blues,
which is transient and defined as a natural response to hormone change and stress following delivery. Postnatal depression (PND) is also more prevalent, with rates between 10 and 20%, compared with puerperal psychosis, which is a less prevalent (0.1-0.2%; Kendell, Chalmers, & Platz, 1987) psychotic episode following childbirth with increased risk of suicide and harm towards the infant (Lee & Chung, 2007a).

The National Institute of Clinical Excellence (NICE, 2007) guideline on Antenatal and Postnatal Mental Health (APMH) suggests that depressive illness in the postnatal period is not dissimilar to the prevalence of major depression at other times in a woman’s life. However, the incidence may be heightened. One study found a threefold increase in incidence in the first five weeks in the postnatal period (Cox, et al., 1993). The guideline authors note changes in mental state and general functioning (NICE, 2007).

1.1.2 Clinical presentation of PND
The Diagnostic and Statistical Manual of Mental Disorders (APA, 1994a) criteria list the following symptoms: significant weight gain or loss, loss of libido, insomnia or hypersomnia, fatigue or energy loss, a sense of hopelessness, a decreased ability to concentrate and make decisions, suicidal ideation and planning, feeling sad or empty with spontaneous crying, psychomotor agitation or retardation, and overwhelming feelings of guilt; all symptoms synonymous with a major depressive episode. Postnatal depression (PND) is characterized by heterogeneity with respect to onset, chronicity and severity (Brockington, 2004; Williamson & McCutcheon, 2004). This demonstrates one of the challenges in defining PND.

Some women also present with anxieties about negative feelings toward their baby or may describe delayed bonding (Williamson & McCutcheon, 2004). The NICE guidelines for APMH (2007) recommend that health care professionals ask two questions to identify possible depression. (1) During the past month, have you often been bothered by feeling down, depressed or hopeless? (2) During the past month, have you often been bothered by having little interest or pleasure in doing things? A third question should be considered if the woman answers ‘yes’ to either of the initial questions. (3) Is this something you feel you need or want help with? (Guideline 45; NICE, 2007).

The Edinburgh Postnatal Depression Scale (EPDS) is used as a screening tool and outcome measure. The EPDS is a ten-item measure of depressive symptoms over the past seven days. The EPDS has been shown to be the most effective tool in assessing and identifying probable symptoms specific to PND and has been validated and used widely as an outcome measure in many randomised controlled trials (RCTs) (Hanusa, Scholle,
Haskett, Spadaro, & Wisner, 2008; Lee & Chung, 2007). In the UK, Women scoring over 12 on the EPDS are offered up to six non-structured listening visits by a health visitor (NICE, 2007). If clients continue to display symptoms, further treatments are recommended by NICE guided by the severity of symptoms.

The DSM-IV specifies that PND typically begins within the first four weeks postpartum, however others (Cooper, Campbell, Day, Kennerley, & Bond, 1988) have argued for a longer period of onset of between three and seven months in the postnatal period. Research on PND in fathers is also beginning to emerge; however, this is beyond the scope of this overview (see Cox, 2005; Pilyoung & Swain, 2007).

Although birth, labour, other aspects of the perinatal context and transition to parenthood may be relevant factors in the onset of PND, they are not considered in diagnostic criteria (Barnett & Fowler, 1995). These include extreme, unreasonable disappointment in labour, delivery, breast-feeding or other aspects of motherhood; decreased interest in social contact and lack of social confidence; decreased desire for sex with partner; feelings of inadequacy, failure, inability to cope; feelings of anger (especially aimed at the partner); experiencing anxiety ranging from mild agitation to extreme panic; fear for and sometimes of the infant; fear of being alone with or going out with the infant; distressing thoughts of wanting to run away; fear of being unattractive, rejected, unwanted by the partner; and fear of or harm to the partner (Barnett & Fowler, 1995). Depression in the postnatal context warrants special attention due the vulnerability of the infant and the role of the mother as a care-giver and role as regulating infant emotional states.

1.2 A biopsychosocial model of PND
Like many psychological disorders, the development and maintenance of PND is complex and involves multiple factors. Milgrom, Martin and Negri (1999) offer a biopsychosocial model detailing multiple factors implicated in the onset, maintenance and exacerbation of PND (see Figure 1). The model includes factors at biological, psychological and sociological levels. Furthermore, it accounts for the differences in vulnerability between women. It also details that treatment requires a holistic conceptualisation and favours an approach whereby cognitive maintenance, risk and vulnerability factors are the subject of the intervention and hence they are reduced.
**Figure 1. The biopsychosocial model of postnatal depression** (Milgrom, Martin & Negri, 1999, p. 26)

**SOCIOCULTURAL FACTORS**
- Factors that contribute to the psychosocial context of PND
  - Unrealistic beliefs & myths
  - E.g. motherhood a joyful event.
  - Lack of belief to support new parent in some societies.
  - Cultural expectations that do not match circumstances.

**POSTNATAL DEPRESSION (PND)**
- Feelings of sadness, tearfulness, hopelessness, guilt, worthlessness, irritability & anxiety.
- Thoughts about suicide & death.
- Difficulties in concentration & decision making.
- Slowed speech & movement or agitation & hyperactivity.
- Disturbances of sleep & appetite.
- Lack of interest & energy & feeling exhausted.

**VULNERABILITY FACTORS**
- Factors occurring prior to the pregnancy that determine susceptibility
  - Personality and cognitive style
    - E.g. external locus of control, perfectionism, low self-esteem.
  - Childhood family experiences
    - E.g. poor relationship with own mother, family history of depression.
  - History of
    - PND or major depression.
    - Premenstrual syndrome.
  - Negative life events
    - E.g. miscarriage, still-birth, death of parent.
  - Poor marital relationship.

**PRECIPITATING FACTORS**
- Factors occurring around the time of the birth that trigger PND
  - Stressful events
    - Before birth
      - E.g. loss of woman’s employment
      - At birth
      - E.g. complications such as unexpected caesarean.
    - After birth
      - E.g. illness, infant demands, financial pressures.
  - Stress moderating variables
    - E.g. loss of woman’s employment
    - At birth
    - E.g. complications such as unexpected caesarean.
    - After birth
      - E.g. illness, infant demands, financial pressures.

**EXACERBATING AND MAINTAINING FACTORS**
- Maladaptive reactions by woman and significant others
  - Negative cognitive responses
    - E.g. thoughts about inadequacy as parent and as partner.
  - Negative affective responses
    - E.g. guilt, anger, anxiety, frustration.
  - Negative Behavioural responses
    - E.g. for woman
      - Poor parenting skills
      - Social withdrawal
    - E.g. for significant others
      - Marital conflict
      - Mother-infant difficulties

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1.2.1 Prevalence of PND

It is estimated that at least one in ten women suffer from PND (Milgrom, et al., 1999) with episodes lasting from two to six months and in some cases longer (Cooper & Murray, 1997; Lee & Chung, 2007a; Williamson & McCutcheon, 2004). Following an episode of PND women are predisposed to future risk of depressive episodes after subsequent deliveries. It has been suggested that antenatal depression is a strong predictor of PND (Beck, 1996, 2001). Indeed, the presence of psychosocial factors including poverty, marital discord and life stressors (bereavement) also indicate increased risk of PND compared with biological or hormonal causes (Lee & Chung, 2007a). However, antenatal depression and individual risk factors alone may not be sufficient to cause PND. Biopsychosocial models of PND highlight multiple contributing factors at the biological, psychological and social levels (Milgrom, et al., 1999).

1.2.2 The experience of PND

Seven dimensions of the PND experience have been identified, including sleeping and eating disturbances, anxiety and insecurity, emotional lability, mental confusion, loss of self, guilt and shame, and suicidal thoughts (Beck & Indman, 2005). Researchers who have taken a specifically woman-centered approach and carried out qualitative interviews continue to add to the dimensions of understanding of PND. For example, Nicolson (1990), who carried out one antenatal and three postnatal interviews with 24 previously depressed women, found that women experienced losses and concerns which can affect mood and sense of wellbeing but are not covered by diagnostic criteria for clinical depression. These related specifically to childbirth and aspects of motherhood including physical adjustment (related to body changes), insecurities about the health of their baby, and loss of former self, including a shift in sexual identity (Nicolson, 1990). Further research is needed on illness experiences and perceptions of women in the postnatal period in order to best understand how to treat PND. For example, there may be culturally specific views regarding PND. Recently some aspects of PND experiences have been found across cultural groups (Baines, Wittkowski, & Wieck, 2012; Patel, Wittkowski, Fox, & Wieck, 2012).

Like other episodes of depression, those occurring after childbirth affect the woman’s feelings about herself and her interpersonal relationships, and notably the mother-baby relationship, the couple relationship and relationships with older children and the wider family (Lee & Chung, 2007b). In the postnatal period, an additional challenge for the mother is coping with depression at a time when there is a strong societal
expectation that motherhood will be a joyful and rewarding experience (Hall, 2006; Hall & Wittkowski, 2006; Petch & Halford, 2008). Social expectations about motherhood may also contribute to women’s reluctance to disclose negative feelings (Patel, et al., 2012).

Despite routine screening for PND around six to eight weeks postpartum, many women resist disclosure of the full extent of their negative feelings, fearing the consequences, so there are challenges in identifying and engaging women who might benefit from interventions (Chew-Graham et al., 2008; Dennis & Chung-Lee, 2006; Hendrick, 2003; Patel, et al., 2012).

1.3 Impact of PND on infant development

1.3.1 The impact of PND on infant development

Early relationships are central in promoting healthy social and emotional child development (Thompson, 1998). There are many variables which contribute to healthy development, termed protective factors. Likewise, development can also be disrupted by a number of variables known as risk factors. Postnatal depression (PND) has been identified as one such risk factor.

There is a large body of literature evidencing the impact of PND on child development. Having a mother with PND has been associated with poorer cognitive and language development (Grace, Evindar, & Stewart, 2003; Hay, Pawlby, Angold, Harold, & Sharp, 2003). Given the dynamic nature of development, however, the effects tend to vary depending on several factors including characteristics of individual child, gender and familial environmental factors and time and course of PND in the mother.

There have also been notable differences in the interactive style between depressed dyads and non-depressed dyads. For example, mothers with PND have been observed to display more negative behaviours towards their babies and their babies are less positive than babies of non-depressed mothers (Cohn, Campbell, Matias, & Hopkins, 1990; Tronick & Reck, 2009). An Australian comparative observational study of 48 ‘depressed’ and 40 ‘non-depressed’ mother-baby pairs found an association between poor maternal responsiveness and poorer developmental patterns, specifically increased fussiness and lower IQ scores at 48 months in babies of women with PND at six months postpartum (Milgrom, Westley, & Gemmill, 2004). Several studies have shown that cognitive outcomes in infants are related to the quality of the early mother-baby relationship, which were not reversed by later remittance of depression (Milgrom, et al., 2004; Murray & Stein, 1991).
Longitudinal studies have also reported a predictive link between early PND and problems which manifest much later in development (Hay, et al., 2003). Murray and Cooper (1997) suggested that the effects of PND on development are mediated through negative cognitions relating to parental ability and baby and poorer parenting practices, for example, being withdrawn or over-intrusive during interactions with their baby. This assumption is supported by a number of studies which have now shown that a mother’s ability to regulate her baby’s state plays an important role in helping children develop strategies for managing their feelings and emotions (Crittenden, 2008; Gerhardt, 2004; Hay, 1997; Meaney, 2001; Tronick & Reck, 2009).

In her book, Why Love Matters, Gerhardt (2004) outlined that responding inappropriately to a baby’s needs may lead to prolonged increase of cortisol, which may affect how babies tolerate stress later in life. Indeed, Van den Boom (1994) noted that educating parents on how to respond appropriately to their unsettled babies was central to the formation of secure attachment. Research shows that responding appropriately most of the time is central to a parent’s ability to regulate and soothe their baby during periods of distress.

Despite these findings, it is important to interpret the research findings with caution. It would be over simplistic, and deterministic, to imply that maternal depression is exclusively responsible for developmental difficulties or that the effects are immutable. Every child comes into this world with a unique biology and temperament and development is a dynamic process; with support and treatment maternal mood can improve and developmental pathways in children can be repaired (Gerhardt, 2004; Teti & Towe-Goodman, 2008). Early effective treatment of PND is therefore paramount.

1.3.2 A model for the impact of PND on infant development
Not only does PND greatly impact on maternal wellbeing, but there is considerable research evidencing the profound and deleterious effects of PND on infant cognitive and emotional development and is associated with later psychopathology and atypical development (Cooper & Murray, 1997). Goodman and Gotlib (1999) highlighted that conventional models of PND do not facilitate the understanding of relatedness or the role of development in explicating the transference and manifestation of vulnerability in infants (this model is presented in Chapter 2).

1.3.3 Impact of PND on the mother-infant relationship
So far this review has described the way that developmental literature has underscored the importance of early influence at putting children on adaptive developmental pathways. It
has highlighted that the infant-caregiver relationship plays an important role in child development (Thompson, 1998). When the infant-caregiver relationship is perturbed, subsequent development has been shown to be atypical. For example, cognitive deficits in infants were significantly related to the quality of the early mother-infant relationship, despite later remission of maternal PND (Murray et al., 2011; Murray & Cooper, 1997; Murray & Stein, 1991). Given the impact of PND on mother and baby and their relationship, effective timely intervention is essential (Field, 1997). NICE recommends a range of psychological interventions in different circumstances, based on their review of the evidence. The guideline provides evidence on self-help approaches, listening visits, CBT, Interpersonal Psychotherapy (IPT) and antidepressant (AD) medication (where preferred) for treatment of mild to moderate PND (NICE, 2007; see also McLeish, 2007).

1.4 Overview of treatments for PND

Literature Search Method

The literature search for this overview included publications related to the topic of PND in the last ten years from 1999-2012, using databases including Psychinfo, Psyarticles, Medline and Pubmed. The search used the following key terms in the search specifications: psychological, psychologic, treatments, therapeutic procedure, therapeutic, postnatal depression, postpartum depression, post partum depression, post natal depression and parenting programs for new mothers. Reference sections were also hand searched from relevant articles and reviews. Library databases were also searched for relevant books and publications. The “related citations” function in Pubmed was also utilised. The studies included in the present are not exhaustive, but represent an explorative search of treatments viable for PND to give a general overview of the area before completing a systematic search of treatments, the focus of Chapter 2.

1.4.1 Anti-depressant medication treatment for PND

While major depression and other mood disorders have often been treated with the use of anti-depressant medication, acceptability in the context of PND is a contentious issue. Although many of the long-term effects of anti-depressants on the baby are still unknown (Brockington, 2004b; Flynn, Henshaw, O'Mahen, & Forman, 2010; Leis, Mendelson, Tandon, & Perry, 2009) anti-depressant treatment is recommended for PND in the UK by NICE guidelines (NICE, 2007). However, women with symptoms are often reluctant to take medication, due to fear of dependency and possible effects on breastfed babies (Brockington, 2004). In a qualitative study, women’s views on taking anti-depressants
depending on the emotional and practical support they received from family, friends and, particularly, the view of their general practitioner (Turner, et al., 2008). Additional research also reports that anti-depressants were significantly less acceptable than two different forms of psychotherapy in the context of PND (Chabrol, Teissedre, Armitage, Danel, & Walburg, 2004) and that women prefer non-pharmacological interventions over anti-depressant treatment (Leis, et al., 2009).

Several small sample studies (see Table 1) have examined the efficacy of anti-depressants alone in the treatment of PND including fluvoxamine (Suri, Burt, Altshuler, Zuckerbrow-Miller, & Fairbanks, 2001), venlafaxine (Cohen et al., 2001), buproprion (Nonacs et al., 2005), nefazodone (Suri, Burt, & Altshuler, 2005). All studies reported improvements to depressive symptoms. However, sample sizes were small (N=4-15) and all studies lacked a control/comparison group.

Despite literature which suggests a preference for therapeutic methods over pharmacological treatment, there is some research which indicates that anti-depressant medication is at least as effective as therapeutic techniques (Misri, Rebye, Corral, & Mills, 2004; Pearlstein et al., 2006). A Canadian RCT study compared paroxetine with paroxetine combined with CBT and reported comparable outcomes on symptoms of depression and anxiety in both groups (Misri, et al., 2004). A further non-controlled pilot trial compared three conditions: sertraline only, IPT only and sertraline and IPT combined (Pearlstein, et al., 2006). Significant clinical improvements in depressive symptoms were observed across all three conditions.

Another trial comparing medication with eight (90 minute) non-directive counselling sessions, conducted by health visitors, found that medication was most effective at reducing depressive symptoms in the mother (Sharp et al., 2010). However, there were several limitations to the trial. Firstly, quality assurance was not guaranteed because it was not an RCT design, although it could be argued that it is more representative of what might follow outside a controlled study. Secondly, this study did not measure developmental outcomes. Therefore, although there was a reported improvement in depressive symptomatology in the mother, it is difficult to ascertain what effect the treatment had on the mother-infant relationship or infant development.

A number of the studies described did not have control groups, and few had long-term follow-ups making it difficult to attribute improvements in maternal mood to the treatment and not spontaneous recovery. However, some of the studies demonstrated that anti-depressant medication was at least as effective as psychotherapy. There is also preliminary evidence that anti-depressant medication has a positive impact on the maternal...
role (Logsdon, Wisner, & Hanusa, 2009). However, the impact on the mother-infant relationship and child developmental outcomes remain the subject of further research.
Table 1. Studies of anti-depressant medication for PND

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>N</th>
<th>Sample</th>
<th>PND based on</th>
<th>Intervention/s</th>
<th>Therapist/s</th>
<th>Outcome Measures</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suri et al. 2001</td>
<td>USA</td>
<td>Single group</td>
<td>6</td>
<td>PND</td>
<td>&gt;21 HAMD</td>
<td>8 week open trial of fluvoxamine</td>
<td>N/A</td>
<td>HAMD</td>
<td>Sig lower HAMD scores in responders</td>
</tr>
<tr>
<td>Cohen et al. 2001</td>
<td>USA</td>
<td>Open trial</td>
<td>15</td>
<td>PND</td>
<td>DSM-III major depression</td>
<td>8 week flexible dose of venlafaxine</td>
<td>N/A</td>
<td>HAMD, KSQ, CGI</td>
<td>12/15 pp remitted and sig improvement in HAMD, KSQ and CGI</td>
</tr>
<tr>
<td>Logsdon et al. 2003</td>
<td>USA</td>
<td>Double blind RCT</td>
<td>61</td>
<td>PND</td>
<td>DSM-IV major depression</td>
<td>8 weeks of treatment (nortriptyline vs. sertraline)</td>
<td>N/A</td>
<td>GAS, MSL, SPQ, IIP, ICQ, DQOLB</td>
<td>Improvements on all measures</td>
</tr>
<tr>
<td>Misri et al. 2004</td>
<td>CANADA</td>
<td>RCT</td>
<td>35</td>
<td>PND (comorbid anxiety)</td>
<td>DSM-IV major depression and comorbid anxiety disorder</td>
<td>Paroxetine only monotherapy group OR Paroxetine plus 12 sessions of CBT</td>
<td>Psychologist</td>
<td>HRSD, HRSA, YBOCS, CGL, EPDS</td>
<td>Both groups showed sig improvement to depression and anxiety symptoms</td>
</tr>
<tr>
<td>Nonacs et al. 2005</td>
<td>USA</td>
<td>Open trial</td>
<td>8</td>
<td>PND</td>
<td>SCID major depression and HAMD score &gt; 17</td>
<td>8 week open trial of bupropion SR for PND</td>
<td>N/A</td>
<td>HAMD</td>
<td>6/8 participants demonstrated &gt;50% decrease in HAMD scores</td>
</tr>
<tr>
<td>Suri et al. 2005</td>
<td>USA</td>
<td>Single group design (open label)</td>
<td>4</td>
<td>PND (comorbid anxiety)</td>
<td>SCID major depression and EPDS score &gt; 12, HAMD score &gt; 14</td>
<td>8 week open label trial of nefazodone</td>
<td>N/A</td>
<td>HAMD &amp; HAMR</td>
<td>3 participants improved each week and remission by week five</td>
</tr>
<tr>
<td>Pearlstein et al. 2006</td>
<td>USA</td>
<td>Open pilot trial</td>
<td>23</td>
<td>PND</td>
<td>Major depression diagnosis via clinical interview, BDI score &gt; 25 or HRSD score &gt; 14</td>
<td>Sertraline or IPT or both</td>
<td>ITP psychotherapist</td>
<td>HRSD, BDI and EPDS</td>
<td>Significant clinical improvement across all three groups</td>
</tr>
<tr>
<td>Logsdon et al. 2009</td>
<td>USA</td>
<td>Double blind RCT</td>
<td>27</td>
<td>PND</td>
<td>Depressive symptoms (SIGH-ADS)</td>
<td>8 week trial of 2 ADs (nortriptyline vs. sertraline)</td>
<td>N/A</td>
<td>HRSD, Secondary outcome: Gratification in the maternal role, ICS, videod mother-infant interaction (CCMR, NBCS)</td>
<td>Significant improvement of depression symptoms in both groups. Improved GRAT but not self efficacy or mother-infant interaction</td>
</tr>
</tbody>
</table>

ADs= Antidepressants; BDI= Beck Depression Inventory; CBT= Cognitive Behavioural Therapy; CCMR= Child and Caregiver Mutual Regulation System; CGI= Clinical Global Improvements Scale; DQOLB= Depression Specific Health Related Quality of Life Battery; EPDS= Edinburgh Postnatal Depression Scale; GAS= Global Assessment Scale; GRAT= Gratification in the Maternal Role; HAMD= Hamilton Depression Rating Scale; HRSD= Hamilton Rating Scale of Depression; HRSA= Hamilton Rating Scale of Anxiety; ICQ= Infant Characteristic Questionnaire; ICS= Infant Care Survey IIP= Inventory of Interpersonal Problems; IPT=
1.4.2 Interventions in the antenatal period

Antenatal depression is a known predictor for the occurrence of depression in the postnatal period (Beck, 2001). However, antenatal interventions have little established efficacy in reducing the incidence of PND (see Table 2). One study carried out with mothers at risk of PND found that recovery rates (based on Hamilton Rating Scale for Depression (HRSD) and Beck Depression Inventory (BDI) scores) were greater in a CBT treatment (postnatal) intervention group than a (antenatal) prevention intervention treatment group (Chabrol et al., 2002).

An Australian RCT compared a specially designed antenatal intervention with standard antenatal classes (Buist, Westley, & Hill, 1999). The specially designed antenatal intervention focused on preparing expectant mothers for the physical and emotional aspects of parenthood. They found that women receiving the new intervention reported significantly greater satisfaction with their social support when visited six months after childbirth. However, no other group differences were observed, including outcomes measuring symptoms of depression, anxiety, neuroticism and satisfaction with the marital relationship. It is possible that the sample size was too small (N= 38) and that symptom change was not large enough to detect any significant changes.

Similarly, another study with an at-risk PND population providing psychoeducation about PND (including numbers with contact details with support) found no significant differences on symptoms of depression (EPDS scores) between treatment group and control group at 16 weeks postpartum (Webster et al., 2003).

An RCT of an antenatal CBT skills group intervention reported no group differences but did report significant improvement in EPDS and State-Trait Anxiety Inventory (STAI) scores in both treatment and control groups (Austin et al., 2008). The antenatal CBT skills group consisted of six two-hour weekly sessions and one follow-up session. Austin and colleagues (2008) reported several reasons for absence of group differences. They suggested that lack of significant results may have been due to a short group intervention. It was also suggested that the treatment as usual (TAU) group, may have been equally effective and baseline symptoms too low.

The studies reviewed here provide little evidence in support of antenatal interventions in the reduction or prevention of PND. On that basis, it is tempting to conclude that antenatal interventions are ineffective at reducing the frequency of PND. However, there may be several explanations for absence of group differences. Firstly, the studies sample sizes may have been too small for the level of symptoms reported (N= 38,
132 & 371, respectively). Although eligibility criteria included risk of PND and antenatal depression is predictive, it is possible that some of the women did not go on to develop PND and that the differences between the groups too small. Secondly, two studies (Buist, et al., 1999; Webster, et al., 2003) used standard care as their comparison groups. Therefore, that the standard care interventions may have been similarly effective in reducing prevalence rates.
Table 2. Studies of antenatal interventions for PND

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>N</th>
<th>Sample</th>
<th>Screening measures</th>
<th>Intervention/s</th>
<th>Therapist/s</th>
<th>Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buist et al. 1999</td>
<td>Australia</td>
<td>RCT</td>
<td>38</td>
<td>Antenatal women at risk of PND</td>
<td>Study specific risk factor questionnaire</td>
<td>Antenatal intervention group focusing on physical and emotional preparation for parenthood.</td>
<td>midwife</td>
<td>Symptoms of depression (BDI, EPDS), anxiety (SAS), neuroticism (EPI), marital relationship (SDA) &amp; social support (SSS) measured at 6 weeks and 6 months postnatal.</td>
<td>Intervention group reported significantly greater satisfaction with social support a 6 month postnatal follow-up. No group differences on any other measures</td>
</tr>
<tr>
<td>Webster et al. 2003</td>
<td>Australia</td>
<td>RCT</td>
<td>371</td>
<td>Antenatal women at risk of PND</td>
<td>Risk factors (1) low social/partner support score ≤ 24 (2) past history of mental illness (3) family psychiatric history (4) past PND or (5) own mother diagnosis PND</td>
<td>IDEA trial: intervention: booklet about PND (including contact numbers; prenatal screening using EPDS; discussion with woman about risk of developing PND; letter to GP regarding woman’s risk for PND</td>
<td>N/A</td>
<td>EPDS at 16 weeks postnatal</td>
<td>No sig differences on EPDS scores between treatment group and care as usual at 16 weeks postnatal</td>
</tr>
<tr>
<td>Austin et al. 2008</td>
<td>Australia</td>
<td>RCT</td>
<td>132</td>
<td>Antenatal women at risk of PND</td>
<td>EPDS score &gt;10, ANRQ&gt; 23, or history of depression, assessed usinghour weekly sessions and MINI &amp; STAI (state only) follow-up session.</td>
<td>Antenatal CBT (skills based) group in primary care 6X2 hour weekly sessions and MINI &amp; STAI (state only) follow-up session.</td>
<td>Clinical Psychologist and specialist nurse as co-facilitator</td>
<td>EPDS, STAI assessed at pre intervention (T1). Post intervention (T2), 2 Months Postnatal (T3) and 4 Months Postnatal (T4)</td>
<td>No group differences on depression symptoms (EPDS). CBT group slightly (non-significant) lower anxiety (scores). No group difference in diagnosis of depression (MINI).</td>
</tr>
</tbody>
</table>

ANRQ= Antenatal Risk Questionnaires; BDI= Beck Depression Inventory; CBT= Cognitive Behavioural Therapy; EPDS= Edinburgh Postnatal Depression Scale; EPI- Eysenck Personality Inventory; HDRS= Hamilton Depression Rating Scale; ICQ= Infant Characteristics Questionnaire; IDEA=; MINI= Mini International Neuropsychiatric Interview; PND= Postnatal Depression; RCT= Randomised Controlled Trial; SAS= Spielberger Trait/State Anxiety scale; SDA= Spanier Dyadic Adjustment Scale; SIGH-D= Structured Interview Guide for the Hamilton Rating Scale; SSS= Sarason Social Support Scale; STAI= Spielberger Trait/State Anxiety scale.
1.4.3 Psychoeducation groups

Psychoeducation groups have been examined for efficacy in reducing symptoms of PND (see Table 3). One British study found that women with probable PND who attended a psycho-education group (8x2 hour sessions) scored significantly lower on the EPDS compared with a group of women receiving usual care only (Honey, Bennett, & Morgan, 2002). Although significant reductions in depressive symptoms were found in the treatment group, the sample had not received professional diagnoses of depression, making it difficult to generalise these findings to clinical populations. This research suggests that despite antenatal depression as a predictor of PND, preventative interventions in the antenatal period are not sufficient as standalone interventions to reduce PND symptomatology in the postpartum period. However, this does not rule out intervention in the antenatal period, especially for building rapport with clients (and their families) as this has been demonstrated to motivate clients, ultimately bolstering treatment compliance and outcomes (Davis & Dimidjian, 2012).

A recent study in China found a significant reduction in depressive symptoms of a group given an intervention of psychoeducation compared with a TAU only group (Ngai, Chan, & Ip, 2009). They also found an effect for group on learned resourcefulness and maternal role competence; group differences continued to be maintained at six weeks postpartum. They proposed that the benefit of the intervention may have been bolstered by utilisation of learned resourcefulness theory (Rosenbaum, 1990), defined generally as CBT skills for self-regulation. Therefore, the inclusion of learned resourcefulness theory may have contributed to the significant findings relative to other standard psychoeducation based interventions.

A small American RCT (N= 14) compared a new PND group named Gruen with a control group and looked at the differences in maternal depressed mood (Ugarriza, 2004). The Gruen PND group was designed as a 10-week-therapy focused on providing education and information, stress reduction techniques, developing a support system and cognitive restructuring. Although there were significant improvements in depressed mood (BDI-II) from pre-to post-test in the Gruen group, there were no significant group differences.

Further research conducted in Chile compared an intervention combining psychoeducation, treatment adherence support and pharmacotherapy (if needed) with usual care (Rojas et al., 2007). Symptoms of depression were measured at three and six months post-randomisation. Three months following randomisation significant improvements were
observed in the intervention group compared with usual care. These differences were not maintained at six-month follow-up.

The evidence to date would suggest that psychoeducation interventions are not sufficient to significantly reduce symptoms of PND. It is possible that some of the benefits were missed in two studies (Rojas, et al., 2007; Ugarriza, 2004) since they only measured depressed mood. However, if combined with or offered in addition to more intensive support it could be a promising treatment, though more research in this area is needed.
### Table 3. Studies of psychoeducation for PND

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>N</th>
<th>Sample</th>
<th>Screening measures</th>
<th>Intervention/s</th>
<th>Therapist/s</th>
<th>Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meager &amp; Milgrom, 1996</td>
<td></td>
<td>RCT</td>
<td>20</td>
<td>PND</td>
<td></td>
<td>Ten week treatment (educational, social support, and cognitive behavioural components) OR WLC</td>
<td></td>
<td>EPDS, BDI, POMS, SCSE, SPS, PSI &amp; DAS pre and post treatment.</td>
<td>Treatment associated with sig improvement in depressed mood</td>
</tr>
<tr>
<td>Honey et al. 2002</td>
<td>UK</td>
<td>RCT</td>
<td>45</td>
<td>Probable PND</td>
<td>EPDS scores&gt; 12</td>
<td>PEG (8 weekly, 2hrs) or RPC</td>
<td>Health Visitors</td>
<td>Depression symptoms (EPDS) social support (Duke-UNG), marital adjustment (DAS) &amp; coping (WCCR) completed at (T1) before treatment, (T2) end of treatment &amp; (T3) 6 month follow-up.</td>
<td>Treatment Group significantly lower scores on EPDS than TAU at all time points. No significant differences in (Duke-UNG), marital relationship (DAS) or coping scales (WCCR) at any time points.</td>
</tr>
<tr>
<td>Ugarriza, 2004 USA</td>
<td>RCT</td>
<td>14</td>
<td>Gruen PND group (N=6)</td>
<td>PND</td>
<td>Professional diagnosis of PND</td>
<td>10 week therapy, 4 components: education and info, stress reduction, development of support system, cognitive restructuring</td>
<td>Graduate mental health nursing student</td>
<td>BDI-II at pre and post-treatment</td>
<td>A significant difference between pre and post test BDI-II scores for Gruen PND group only.</td>
</tr>
<tr>
<td>Rojas et al. 2007</td>
<td>Chile</td>
<td>RCT</td>
<td>230</td>
<td>PND</td>
<td>EPDS scores&gt; 10</td>
<td>Multicomponent intervention (psychoeducation, treatment adherence support, pharmacotherapy)</td>
<td>Midwives or nurses</td>
<td>Depression symptoms (EPDS) 3 and 6 months after randomisation.</td>
<td>EPDS scores significantly better in intervention group compared with usual care at 3 months but not 6 months. Decreased AD in treatment group</td>
</tr>
</tbody>
</table>

BAI= Beck Anxiety Inventory; BDI= Beck Depression Inventory; CBT= Cognitive Behavioural Therapy; DAS= Dyadic Adjustment Scale; Duke-UNG= Social Support Questionnaire; EPDS= Edinburgh Postnatal Depression Scale; MINI= Mini International Neuropsychiatry Interview; PEG= Psycheducation Group; POMS= Profile of Mood States; PSI= Parenting Stress Index; PND= Postnatal Depression; RCT= Randomised Controlled Trial; SCSE= Stanley Coopersmith Self-Esteem Inventory; SPS= Social Provision Scale; TAU= Treatment As Usual; UCLA= UCLA loneliness scale; WCCR= Ways of Coping Checklist Revised; WLC= Wait-list Control
1.4.4 Cognitive behaviour therapy (CBT) for PND

Extensive research supports cognitive behaviour therapy (CBT) as an effective treatment for major depression. However, findings are mixed for the efficacy of CBT in the context of PND (see Table 4). A recent review assessed studies of CBT, psychodynamic therapy and nondirective counselling (Leis, et al., 2009). Two (Appleby, Warner, Whitton, & Faragher, 1997; Chabrol, et al., 2002) of the three CBT studies found statistically significant differences. The study by Chabrol and colleagues (2002) found that treatment intervention was associated with better recovery rates compared with a control group. The third, a small study in which women in the comparison group received parenting advice and non-specific emotional support, found non-significant differences in the predicted direction (Prendergast & Austin, 2001). It may be the case that the comparison group was too supportive. Only two (Chabrol, et al., 2002; Prendergast & Austin, 2001) of these studies followed their design protocols.

There have also been a number of multi-arm trials. A four-arm RCT (N=192) compared CBT with individual counselling, group counselling and treatment as usual (TAU) in women with a diagnosis of PND (Milgrom, Negri, Gemmill, McNeil, & Martin, 2005). Improvements in depressive symptoms were not maintained at 12-month follow-up. Milgrom and colleagues (2005) followed up participants in the CBT arm and trialled a parent-infant module (HUGS). They found a significant decrease in parenting stress following the ad-hoc module.

Another four-arm RCT comparing CBT, psychodynamic therapy, non-directive counselling and TAU to treat PND, showed a significant reduction in maternal depression symptoms across all treatment groups compared with TAU at post-intervention (Cooper, Murray, Wilson, & Romaniuk, 2003). However, improvements were not maintained at long-term follow-ups conducted 9, 18 and 60 months later. The dyad relationship and child developmental outcomes were also assessed (Murray, Cooper, Wilson, & Romaniuk, 2003). Murray and colleagues (2003) reported that all three treatments (CBT, psychodynamic therapy, non-directive counselling) were associated with significant benefit on maternal reports of difficult infant behaviour. Participants allocated to the counselling arm showed improved emotional ratings at 18-month follow-up and sensitive early dyad interactions. There were no significant findings related to any dyad relationship or child developmental outcomes at the five-year-follow-up (Murray, et al., 2003).

Cognitive behaviour therapy (CBT) has demonstrated efficacy in the short-term for PND. There is, however, little evidence of a sustained reduction in depressed mood.
compared with other interventions. Furthermore, the implications for the mother-child relationship and child development remain unclear, indicating the need for further research.
Table 4. Studies of cognitive behavioural therapy (CBT) for PND

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>N</th>
<th>Sample</th>
<th>PND based on</th>
<th>Intervention/s</th>
<th>Therapist/s</th>
<th>Outcome Measures</th>
<th>Main findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cambridge Treatment trial 1999</td>
<td>UK</td>
<td>RCT</td>
<td>171</td>
<td>Primiparous women</td>
<td>EPDS and SCID</td>
<td>Counselling, CBT, psychodynamic, TAU</td>
<td>6- varied skill and training levels</td>
<td>Maternal mood-EPDS. Dyadic interaction-video play session Infant cognitive and emotional development Stage IV Piaget’s Object Concept task and Bailey Scales Attachment- Strange situation</td>
<td>Non-significant effect of change best for CBT group. All treatment groups sped up natural remission rate significantly. No difference between treatment groups on Dyadic interactions. No difference between treatments for outcome measures of child development CBT especially effective at improving relationship problems</td>
</tr>
<tr>
<td>Prendergast &amp; Austin, 2001</td>
<td>Australia</td>
<td>RCT</td>
<td>37</td>
<td>PND</td>
<td>clinical interview using MADRS, DASS, PSI &amp; EPDS score ≥12</td>
<td>Treatment Group: 6 weekly (1hr) CBT in home. TAU: 6 weekly (20 min-1hr) clinic visits</td>
<td>5 Early Childhood Nurses (ECN)</td>
<td>MADRS, DASS, PSI &amp; EPDS at (T1)baseline, (T2) 6 weeks post treatment and (T3) 6 month follow up</td>
<td>At post treatment high rate of sig improvement in both groups (based on EPDS scores &lt;10) but no significant difference between groups. TAU possibly too supportive.</td>
</tr>
<tr>
<td>Chabrol et al. 2002</td>
<td>France</td>
<td>RCT</td>
<td>48</td>
<td>At risk mothers for PND</td>
<td>EPDS ≥11</td>
<td>Treatment Group: 1 CBT prevention session antenatal and CBT 5-8 weekly visits postnatal</td>
<td>MSc level students</td>
<td>HDRS, BDI, EPDS, SIGH-D, MINI at 10-12 weeks postnatal after completion of treatment</td>
<td>Recovery rates (HDRS &amp; BDI scores) greater in treatment intervention group Prevention intervention seemed to have no sig effect on recovery</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Study Design</td>
<td>Sample Size</td>
<td>Diagnosis Criteria</td>
<td>Therapy Interventions</td>
<td>Outcome Measures</td>
<td>Results</td>
<td></td>
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<td>-------------------------------------------</td>
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<td></td>
</tr>
<tr>
<td>Murray et al. 2003</td>
<td>UK</td>
<td>RCT</td>
<td>193</td>
<td>PND DSM-III_R major depressive disorder &amp; EPDS &gt;12</td>
<td>TAU, non-directive counselling, CBT or Psychodynamic therapy</td>
<td>Specialist therapists (in each treatment)</td>
<td>Mother-Infant Interaction, Strange Situation, BSID Follow-up: 4.5, 18 &amp; 60 months</td>
<td>All three treatments significant benefit on maternal reports of early reports of difficulties with infants. Counselling gave better infant emotional ratings at 18 months and sensitive early dyad interactions. No sig benefit maternal management of infant behaviour problems, security of dyad attachment, infant cognitive development or any child outcomes at 5 years.</td>
<td></td>
</tr>
<tr>
<td>Milgrom, Negri, Gemmill, McNeil &amp; Martin, 2005</td>
<td>Australia</td>
<td>RCT</td>
<td>192</td>
<td>PND CIDI to diagnose depression &amp; EPDS score ≥12</td>
<td>Programs= 9 weekly (90min) sessions with mothers, 3 with fathers</td>
<td>2 Senior Therapists</td>
<td>BDI, BAI, SPS collected at 12 weeks after treatment and 12 month follow up</td>
<td>Psychological therapies superior to RPC. Poor follow up rate but found individualised programs more efficacious than group delivered formats</td>
<td></td>
</tr>
<tr>
<td>Milgrom et al. 2006</td>
<td>Australia</td>
<td>RCT of CBT followed by single group design</td>
<td>22</td>
<td>PND DSM-IV diagnosis of depression &amp; EPDS scores ≥12</td>
<td>Pilot of specialised parent-infant intervention (HUGS) to enhance quality of mother-infant interaction</td>
<td>PSI, BDI</td>
<td>There was a statistically significant decrease in overall PSI scores.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ANRQ= Antenatal Risk Questionnaires; BAI= Beck Anxiety Inventory; BDI= Beck Depression Inventory; CBT= Cognitive Behavioural Therapy; CIDI= Composite International Diagnostic Interview; DASS= Depression Anxiety Stress Scale; DSM-IV= Diagnostic and Statistical Manual for Mental Disorders; ECN= Early Childhood Nurses; EPDS= Edinburgh Postnatal Depression Scale; HRSD= Hamilton rating Scale of Depression; MADRS= Montogomery & Asberg Depression Rating Scale; MINI= Mini International Neuropsychiatric Interview; PND= Postnatal Depression; PSI= Parenting Stress Index; SCID= Structured Clinical Interview for Diagnosis of DSM-IV Disorders; SIGH-D= Structure Interview Guide for Hamilton Rating Depression Scale; SPS= Social Provision Scale; STAI= State Trait Anxiety Inventory; RCT= Randomised Controlled Trial; RPC= Routine Primary Care; TAU= Treatment As Usual
1.4.5 Studies of interpersonal psychotherapy (IPT) for PND

Interpersonal therapy (IPT) focuses on interpersonal relationships and supports clients to manage relationships and/or their expectations about them (Stuart & O'Hara, 1995b). Interpersonal therapy (IPT) has been used successfully in the treatment of major depression outside of the perinatal context and is associated with reduced relapse rates (Weissman, Klerman, & Prusoff, 1981). Several pilot and controlled studies have been conducted to evaluate the efficacy of IPT in a sample of women with PND (see Table 5).

In a pilot study with a small sample (N= 6) improvements to depressed mood (BDI & HAMD) from pre-therapy to post-therapy were noted (Stuart & O'Hara, 1995a). Another single group design conducted in Austria found significant reductions in depressed mood from baseline to post-treatment, as well as maintenance at six month follow-up (Klier, Muzik, Rosenblum, & Lenz, 2001). However, there were no significant differences observed in relation to the marital relationship or interpersonal problems at any time points. Furthermore, these studies are limited by the fact that they did not utilise a control or comparison group.

Reay and colleagues (2006) conducted a single group design to investigate the efficacy of IPT in a group format. They reported significant improvements to depression symptoms (EPDS, BDI & HAMD) from pre to post-treatment. Improvements were also maintained at three-month-follow-up. There were, however, no significant changes to social adjustment (SAS-SR).

A larger RCT comparing IPT to waitlist controls (WLC) reported a significant improvement in depressed mood (BDI & HRSD) and high rates of recovery in women receiving IPT compared with those allocated to WLC (O'Hara, Stuart, Gorman, & Wenzel, 2000). Significant improvements to social and postpartum adjustment were also reported by women receiving IPT compared with those receiving WLC. There were, however, no significant changes found in relation to marital satisfaction.

An American trial compared mother-infant group therapy (MIT-G) with IPT and WLC (Clark, Tluczek, & Wenzel, 2003). At post-treatment, both interventions (women allocated to MIT-G and IPT), were associated with significantly fewer depression symptoms (CES-D) compared with those allocated to WLC. However, there were no significant group differences when the BDI was used to measure symptoms of depression. Significant improvements in parenting stress were also reported in both intervention groups at post-treatment. In terms of the mother-infant relationship, both MIT-G and IPT participants scored significantly higher on maternal positive affective involvement and
verbalisation (PCERA) compared with WLC. There were no differences found across any measures of child development.

A further American RCT carried out by Forman and colleagues (2007) compared IPT with WLC, they also included a non-depressed comparison sample. The IPT arm showed significant improvements to parenting stress compared with WLC but not with the comparison group. They also failed to find an effect of treatment on infant emotionality.

Another RCT investigated the efficacy of IPT in a group format (Mulcahy, Reay, Wilkinson, & Owen, 2010). Mulcahy and colleagues (2010) reported that women allocated to group IPT showed significantly greater improvements to depressed mood from pre to post-treatment and at three-month-follow-up when compared with women receiving usual care. Perceptions of infant care-giving, marital functioning and social support were also significantly improved from pre to post-treatment in women receiving IPT, compared with those receiving usual care. Observed improvements to these secondary outcomes were not maintained at three month follow-up. There were no group differences observed on perceptions relating to interpersonal support at any time point.

Based on the research of IPT reviewed here, it seems that it offers promising outcomes to women experiencing PND symptoms. However, when compared with other relational treatments, IPT does not compare favourably (Clark, et al., 2003). Of particular note, there is mixed evidence in relation to improvements in women’s perceptions of interpersonal support, which is a key focus of IPT. A number of the studies included in this section utilised single group designs. A key criticism of single group designs is that they do not account for natural remission of PND symptoms; therefore, it is difficult to ascertain whether improvements were the result of the intervention or natural remission. There is also limited evidence for improvements to child developmental outcomes.
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>N</th>
<th>Sample</th>
<th>Screening measures</th>
<th>Intervention/s</th>
<th>Therapist/s</th>
<th>Outcome Measures</th>
<th>Main Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stuart &amp; O’Hara 1995</td>
<td>USA</td>
<td>Single group design (pilot)</td>
<td>6</td>
<td>PND</td>
<td>DSM-IV diagnosis of major depression</td>
<td>IPT</td>
<td>N/A</td>
<td>BDI, HAMD pre and post therapy</td>
<td>All participants showed good response rates on both BDI and HAMD</td>
</tr>
<tr>
<td>O’Hara et al. 2000</td>
<td>USA</td>
<td>RCT</td>
<td>120</td>
<td>Treatment group (N= 51) WLC (N= 48)</td>
<td>IDD, SCID, HSRD score ≥12</td>
<td>12 weeks (IPT) -12X12 hour long individual session</td>
<td>10 therapists (doctoral degree)</td>
<td>HRSD, BDI, SASSR, DAS, PPAQ repeated measures pre-therapy and 4, 8 &amp; 12 weeks following treatment allocation</td>
<td>Significant decline in IPT group across BDI, HRSID scores. Significantly greater proportion of IPT group recovered based on HSRD scores. Significant improvements for IPT compared with WLC on SASSR and PPAQ but not DAS (except for dyadic satisfaction subscale).</td>
</tr>
<tr>
<td>Klier et al. 2001</td>
<td>Austria</td>
<td>Single group design</td>
<td>17</td>
<td>PND</td>
<td>SCID DSM-IV diagnosis of major or minor depression and HSRD ≥13</td>
<td>Group IPT</td>
<td>Trained IPT therapist</td>
<td>EPDS, HAMD, IIP &amp; DAS Pre, post treatment &amp; 6 months follow-up</td>
<td>Significant reductions in EPDS and HAMD scores from baseline to post-treatment and maintained at follow-up. No significant differences on IIP or DAS from baseline to post-treatment or follow-up. Both MIT-G and IPT groups reported significantly fewer depression symptoms (CES-D) than WLC. There were no significant differences in BDI scores between any of the groups. Significant differences were also reported on Parenting Stress MIT-G and IPT both showed significant improvements in perception of child adaptability and more reinforcement from their children. MIT-G and IPT groups both scored significantly higher on Maternal Positive Affective Involvement and Verbalisation compared with WLC. No significant differences were found across any groups on infant development</td>
</tr>
<tr>
<td>Clark et al. 2003</td>
<td>USA</td>
<td>sequential group assignment</td>
<td>39</td>
<td>Clinical Diagnosis, BDI scores ≥16</td>
<td>M-ITG, IPT OR WLC</td>
<td>M-ITG, IPT OR WLC therapists</td>
<td>Follow-up: none</td>
<td>Primary outcomes depression, Parenting Stress, Mother-Infant Interactions &amp; Infant Development via BDI, PSI, PCERA &amp; Mental scales of BSID respectively</td>
<td></td>
</tr>
</tbody>
</table>

Table 5. Studies of interpersonal therapy (IPT) for PND
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>Sample Size</th>
<th>PND</th>
<th>EPDS Score</th>
<th>Intervention</th>
<th>Follow-up</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reay et al. 2006</td>
<td>Australia</td>
<td>single group design</td>
<td>18</td>
<td>PND</td>
<td>EPDS score ≥12</td>
<td>Group IPT (2 individual sessions, 8 group sessions, 2 hours partner evening)</td>
<td>Depression symptoms (EPDS, BDI) and SASSR at baseline, week 4, week 8 and three month follow-up.</td>
<td>Significant improvements on depression symptoms (BDI, EPDS, HAMD) from pre to post-treatment.</td>
</tr>
<tr>
<td>Forman et al. 2007</td>
<td>USA</td>
<td>RCT</td>
<td>176</td>
<td>PND</td>
<td>IDD, HSRD &amp; diagnosis of major depression using SCID</td>
<td>12 wks IPT or WLC</td>
<td>PSI, IBQ, CBQ, AQS, CBC</td>
<td>IPT arm showed significant improvements on PSI compared with WLC, but not comparison group. No effect of treatment on any infant emotionality measures (IBQ, CBC, AQS, CBQ)</td>
</tr>
<tr>
<td>Mulcahy et al. 2010</td>
<td>Australia</td>
<td>RCT</td>
<td>50</td>
<td>PND</td>
<td>MCMI-III, HAM-D ≥14</td>
<td>8 week group IPT (IPT-G) or TAU</td>
<td>Primary outcome: Depression via EPDS, BDI-II &amp; HAM-D Secondary Outcome: Marital functioning, social support &amp; infant care-giving via DAS, ISEL &amp; MAI respectively. Follow-up: 3 months</td>
<td>IPT-G showed significant improvement in depression scores (EPDS, BDI-II, HAMD) compared with TAU. Improvement (BDI &amp; EPDS) maintained at 3 month follow up. IPT-G showed significant improvement in perception of infant care-giving (MAI), marital functioning (DAS) and social support but not interpersonal support (ISEL). No significant differences on secondary measures at follow-up but IPT-G showed positive trends.</td>
</tr>
</tbody>
</table>

AQS= Attachment Q-set; BSID= Bailey Scales of Infant Development; BDI- Beck Depression Inventory; CBC= Child Behaviour Checklist; CBQ= Child Behaviour Questionnaire; CES-D= Centre for Epidemiological Studies Depression Scale; DAS= Dyadic Adjustment Scale; DSM-IV= Diagnostic and Statistical Manual for Mental Disorders; HAMD= Hamilton Depression Rating Scale; HRSD= Hamilton Rating Scale of Depression; IBQ= Infant Behaviour Questionnaire; IDD= Inventory to Diagnose Depression; IIP= Inventory of Interpersonal Problems; IPT-G= Interpersonal psychotherapy- Group; IPT= Interpersonal Psychotherapy; ISEL= Interpersonal Support Evaluation List; MAI= Maternal Attachment Inventory; MCMI-II= Mullion Clinical multiaxial Inventory-III; M-ITG= Mother-Infant Therapy Group; PCERA= Parent-Child Early Relational Assessment; PND= Postnatal Depression; PPAQ= Postpartum Adjustment Questionnaire; PSI= Parenting Stress Index; RCT= Randomised Controlled Trial; SASSR= Social Adjustment Scale Self-Report; SCID= Structured Clinical Interview for Diagnosis of DSM-IV Disorders; WLC= Wait-list Control
1.4.6 Interventions with a relational (dyadic) focus

Studies show that mothers and babies are not always in harmony; they are often in states of dis-synchrony (Tronick & Reck, 2009). A key difference between depressed and non-depressed mothers is that non-depressed mothers are able to repair those moments of dis-synchrony with their baby, adjusting and responding to get back in tune (Tronick & Reck, 2009). Interventions which focus on the mother-baby relationship draw on theory and evidence regarding the role of the mother as a regulator of their baby’s affective states (see Table 6).

There is good evidence from programmes designed to support depressed or vulnerable mothers in their relationship with their baby that interventions focusing on the mother-baby relationship are helpful (Svanberg & Barlow, 2009). Some of these have focused on developing the knowledge, skills and communication of professionals who work with families and some have focused directly on families.

Using an RCT design, Horowitz and colleagues (2001) examined a dyadic treatment designed to promote maternal responsiveness towards the infant. Whilst both the intervention and control arms showed improvements in depressed mood, only the intervention group reported higher levels of responsiveness at post-treatment follow-up.

A Canadian intervention, Keys to Caregiving, consists of five weekly group session designed to help women with PND understand and respond to their infants. A before and after observational study showed that post-intervention, babies displayed an increase in interest and joy during interaction with their mothers. However, there was no comparison group in the study, which indicates the need for a controlled trial to verify the potential benefits of this intervention (Jung, Short, Letourneau, & Andrews, 2007).

Clark and colleagues (2008) compared group mother-infant therapy (MIT-G) with waitlist control (WLC) using sequential group assignment design. Women receiving the MIT-G group reported significantly fewer symptoms of depression, experienced infants as more reinforcing and parenting more rewarding, compared with women in the WLC. Following treatment, the MIT-G group was rated to engage in significantly more positive affective involvement and communication with their infant compared with the women assigned to the WLC group.

In a small RCT conducted in the Netherlands, 71 depressed mother-baby dyads were randomised to one of four groups 1) modelling; 2) cognitive restructuring; 3) practical support; 4) baby massage for 8-10 sessions or 5) control. Participants randomised to one of the treatment groups were video-taped and given feedback reflecting the content of the group they were allocated to. Mothers randomised to the control group were offered
practical parenting advice in three telephone calls (Van Doesum, Riksen-Walraven, Hosman, & Hoefnagels, 2008). At six-month-follow-up, dyads in the treatment groups were rated to be significantly higher in maternal sensitivity and showed better attachment and developmental outcomes for babies. Despite the positive outcomes, this study may have been under-powered. It has been suggested that at least 27 participants are required per group (Kazdin & Bass, 1989).

An Australian programme to educate mothers to facilitate a positive and interactive connection (EPIC) with their baby was piloted with 10 depressed mother-baby dyads aged under 12 months (Buultjens, Robinson, & Liamputtong, 2008). EPIC focuses on facilitating mother-child relationships through ‘education’ (social and learning activities), a ‘circuit of activities’ (guided stimulus for mum and baby) and ‘creativity’ (mother-centred activity). Interviews conducted at post-treatment suggest that women found this to be a highly acceptable intervention.

The theoretical and experimental literature provides a rationale for the mother-infant dyad as a point of focus for intervention in the context of PND. However, the studies presented in this section provide mixed evidence for a relational intervention in the treatment of PND. In relation to maternal mood, two studies did not find group differences in depressed mood. Comparison of the treatments is difficult since intervention content is varied. Furthermore, there were also mixed findings in relation to child development, for example, differences were only reported on certain subscales. It is possible that these studies are limited by their use of outcome measures. Specifically, the measures selected may not measure the variables that change following therapy.
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>N</th>
<th>Sample</th>
<th>Screening measures</th>
<th>Intervention/s</th>
<th>Therapist/s</th>
<th>Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horowitz et al. 2001</td>
<td>USA</td>
<td>RCT</td>
<td>117</td>
<td>Treatment group (N= 60)</td>
<td>Probable PND EPDS scores &gt;10</td>
<td>Coached behaviour to promote responsiveness OR support group</td>
<td>Home-visiting nurse</td>
<td>Symptoms of depression (EPDS), Beck Depression Inventory (BDI) &amp; mother infant relationship (DMC)</td>
<td>Follow-up: none; Treatment group showed significantly higher level of responsiveness at post treatment. Both groups demonstrated significant reduction in depression scores</td>
</tr>
<tr>
<td>Jung et al. 2007</td>
<td>Canada</td>
<td>Single group design</td>
<td>11</td>
<td>PND</td>
<td>EPDS, BDI-11</td>
<td>(KTC) designed to improve maternal sensitivity to infant</td>
<td>N/A</td>
<td>Still-Face paradigm</td>
<td>Post intervention infants displayed marked increase in interest and joy during interaction with mothers (Still Face).</td>
</tr>
<tr>
<td>Clark et al. 2008</td>
<td>USA</td>
<td>Sequential assignment group</td>
<td>32</td>
<td>PND</td>
<td>Clinical diagnosis of Depression</td>
<td>12 weeks manualised mother-infant therapy group (M-ITG) OR Wait List Control (WLC)</td>
<td>MIT-G trained psychologists/resident psychiatrists</td>
<td>Primary outcomes depression, maternal psychological functioning &amp; Mother-Infant Interactions via BDI, PSI, BSID &amp; PCERA respectively</td>
<td>Follow-up: none; M-ITG showed significant fewer depressive symptoms, experienced infants as more reinforcing and parenting more rewarding. MIT-G also exhibited significantly more positive affective involvement and communication after treatment.</td>
</tr>
<tr>
<td>Van Doesum, et al. 2008</td>
<td>Netherlands</td>
<td>RCT</td>
<td>71</td>
<td>PND</td>
<td>BDI scores&gt;14, DSM-IV diagnosis of major depression (MINI)</td>
<td>Mother-infant pairs videotaped - Trained graduates given feedback using one of four techniques (modelling, cognitive restructure, practical support &amp; baby massage) 8-10 (60-90 min) sessions. Initially weekly, then reduced to every 2 weeks. Control group - received min 3 (15 min max) phone calls providing practical parenting advice</td>
<td>Trained graduates</td>
<td>BDI, MINI, Survey of Recent Life Experiences, Mother-infant interaction assessed using EAS (six scales: parental sensitivity, structuring, non-intrusiveness, no hostility, child responsiveness, &amp; involvement) at pre-treatment, Increase in maternal sensitivity and post-treatment</td>
<td>Follow-up: Six month follow-up; AQS and ITSEA at follow-up, treatment group sig higher AQS scores than controls. treatment group sig more competent (ITSEA subscale) than control group, but no differences on other subscales. No group differences on depression symptoms</td>
</tr>
</tbody>
</table>

AFFEX= Systems for Identifying Affect Expressions by Holistic Judgements; AQS= Attachment Q-Set; BDI= Beck Depression Inventory; BSID=Bayley Scales of Infant Development; DMC= Dyadic Mutuality Code; EAS= Emotional Availability Scale; EPDS= Edinburgh Postnatal Depression Scale; ITSEA= Infant Toddler Social and Emotional Assessment; KTC= Keys to Care-giving; MINI= Mini International Neuropsychiatric Interview; MIT-G= Mother-Infant Psychotherapy Group; PND= Postnatal Depression; RCT= Randomised Controlled Trial; WLC= Wait-list Control
1.4.7 Baby massage

Not all women need or prefer an intensive intervention. Evaluations of baby massage have provided an alternative effective therapy for some women with PND (Underdown, 2009). Field and colleagues (1996) conducted one of the first RCTs of baby massage in a group of teenagers experiencing dysthymia. They compared a group version of baby massage with a rocking group offered two days per week over a course of six weeks. Although they did not investigate maternal mood, they had a battery of measures for infant sleep, cortisol, weight, formula intake, temperature and urine. They reported that compared with the rocking group, the infants of women taking part in the baby massage group were observed to be significantly more alert and less drowsy. Duration of crying and cortisol levels were also significantly more reduced in infants of the baby massage group compared with the rocking group. These findings are positive; however, as the sample was limited to teenagers, it is difficult to conclude whether these findings are generalisable. Furthermore, depression was assumed on the basis of a diagnosis of dysthymia and elevated BDI scores.

An RCT to test the efficacy of baby massage (five x 75 minute sessions) in the treatment of PND found significantly lower depression scores in the baby massage group and overall improved quality of mother-baby relationships compared with controls (Onozowa, Glover, Adams, Modi, & Kumar, 2001). These preliminary findings are promising, although the study reported a high dropout rate and did not measure long-term outcomes. The high dropout rate could have been due to low acceptability, or, as the study authors suggest, a result of inconvenient session times and travelling distance to attend the group.

A further RCT study by O’Higgins and colleagues (2008) compared baby massage with a support group and a non-depressed sample of women. Following post-treatment both the massage and support group were comparatively more depressed than the non-depressed sample. However, there was a greater (non-significant) decrease in depression in the massage group compared with the support group. Twelve months later, there was still a significant difference in depression scores between the non-depressed comparison group and women in both the massage and support groups. Interestingly, more of the women in the baby massage arm achieved clinical reductions in depression scores (EPDS) and had non-depressed levels of sensitivity during interactions with their infants compared with the support group.

These initial studies suggest that baby massage may be an effective treatment for improving the dyadic relationship. However, the inclusion criteria for mood are based on
elevated scores on screening measures (BDI-II, EPDS) which is less rigorous than establishing a professional diagnosis or using a clinical interview tool. As such, it cannot be confirmed that women were specifically experiencing PND per se; it is possible that they were experiencing a level of psychological distress. Furthermore, only one study (O'Higgins, et al., 2008) included a follow-up measure. Therefore, the long-term effectiveness of baby massage is not known.
### Table 7. Studies of baby massage for PND

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>N</th>
<th>Sample</th>
<th>Screening measures</th>
<th>Intervention/s</th>
<th>Therapist/s</th>
<th>Outcome Measures</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field, Grizzle, Scafidi et al. 1996</td>
<td>USA</td>
<td>RCT</td>
<td>40</td>
<td>Baby Massage Group (N= 20) Rocking group (N=20)</td>
<td>PND</td>
<td>Baby Massage OR Rocking 15 mins, 2 days per week over 6 weeks.</td>
<td>Trained therapist</td>
<td>Thomans’ system of sleep recording (to assess effect of intervention on sleep/wake behaviour), Salivary Cortisol (before &amp; after treatment sessions at baseline and post-treatment). Weight and formula intake, temperament ratings (CCTI), urine assays (norepinephrine, epinephrine &amp; serotonin)</td>
<td>Babies in massage therapy group were observed to be more awake and alert and less drowsy and sleepy than comparison (rocking)group. Crying and cortisol levels in the baby massage group also decreased compared with rocking group</td>
</tr>
<tr>
<td>Onozowa et al. 2001</td>
<td>UK</td>
<td>RCT</td>
<td>34</td>
<td>Baby massage group (N=19) Support group (15)</td>
<td>Probable PND</td>
<td>5 weeks of infant massage a support group OR support group only</td>
<td>Trained instructor</td>
<td>EPDS and videotaped mother-infant interaction using Global Ratings for Mother-Infant Interactions assessed on first day of massage and post-treatment.</td>
<td>Symptoms of depression (EPDS) decreased in both groups, superior in massage group. Significant improvement in mother-infant interaction in massage group compared with support group.</td>
</tr>
<tr>
<td>O’Higgins et al. 2008</td>
<td>UK</td>
<td>RCT</td>
<td>62</td>
<td>Baby massage (N= 31) Support group (N=31) Non-depressed sample (N=34)</td>
<td>PND</td>
<td>Baby Massage</td>
<td>Trained instructor</td>
<td>Symptoms of depression and anxiety (EPDS, SSAI)and subjective infant characteristics (ICQ). Mother-infant interactions (Global Ratings for Mother-Infant Interactions) at baseline and post-treatment</td>
<td>Post treatment both control and baby massage groups remained higher than non-depressed group. The massage group showed non-significant reductions on depression scales. At 12 month follow-up depressed group was still scoring significantly higher than non-depressed controls. Although, significantly more of the massage group achieved clinical reductions in EPDS scores and non-depressed levels of sensitivity in interactions with their babies compared with support group.</td>
</tr>
</tbody>
</table>

BDI= Beck Depression Inventory; CCTI= Colorado Child Temperament inventory; EPDS= Edinburgh Postnatal Depression Scale; ICQ= Infant Characteristics Questionnaire; PND= Postnatal Depression; RCT= Randomised Controlled Trial; SSAI= Spielberger State Anxiety Inventory
1.5 Summary
A range of treatments for PND were summarised to provide an introduction to the literature. Broadly speaking, the interventions have demonstrated some efficacy in the treatment of PND. However, despite the available evidence to date, there is insufficient evidence to recommend one intervention over another (Cuijpers, Brannmark, & van Straten, 2008; Dennis, 2004). This final section will summarise the limitations of current research and important considerations for treatment of PND in light of the literature. It will conclude with a rationale for subsequent chapters in this thesis.

1.6 Limitations
The main limitations to this area of research include poor research design, inadequate sample sizes and overall insufficient evidence for demonstrating efficacy and variance in reporting results (Boath & Henshaw, 2001; Dennis, 2005). Some of the studies reviewed here were pilot studies employing the use of single group designs or small sample sizes. These studies concluded that their studies were efficacious. However, women with PND do spontaneously recover (Campbell, Cohn, Flanagan, Popper, & Meyes, 1992). In order to confirm that recovery was associated with a given treatment, it would be necessary to compare it to women with PND who were not receiving support or those receiving usual services. With respect to participant characteristics there was wide heterogeneity in client inclusion criteria across studies. Specifically, some studies included clients with a professional diagnosis of PND or used clinical interviewing to verify a diagnosis. Other authors defined PND on the basis of elevated scores on self-report measures (i.e., EPDS, BDI-II, & HRSD). Despite the specificity of screening measures like the EPDS, researchers cannot conclude women were experiencing depression and cannot rule out the presence of co-morbid disorders.

Parity may also be another important factor. Disturbance to the mother-infant relationship may vary depending on whether mothers are primiparous or multiparous. Indeed, research has shown that primiparous and multiparous mothers experience different mother-infant relationship problems at three months postpartum (Righetti-Veltema, Conne-Perreard, Bousquet, & Manzano, 2002). This variance may be explained by differences between multiparous and primiparous mothers in adjustment to parenting trajectories (Gameiro, Moura-Ramos, & Canavarro, 2009). With respect to the studies reviewed here, parity may have implications for efficacy and is an important consideration for future research.
Many of the studies were conducted in Western countries. Despite demonstrated efficacy in some interventions, research remains to be conducted with clients from minority samples and hard to reach client groups with PND. The variance in inclusion criteria across studies poses a challenge in comparing studies.

Whilst some studies (mainly IPT) investigated the effect of treatment on the marital relationship, few interventions actually recorded paternal variables. Goodman and Gotlib (1999) theorized that paternal mental health may moderate the effects of PND on both mother and baby. Furthermore, fathers can also experience depression in the postnatal context.

One method for improving the quality of RCTs is to implicate the use of CONSORT. It outlines the gold standard for conducting RCTs and will enable direct comparison between efficacy of RCTs. Alternately, as suggested by Cuijpers, Brannmark and van Straten (2008) quality assurance may be achieved by adherence to the Cochrane Handbook which outlines four criteria in ensuring quality assurance.

Few studies investigated the acceptability of treatments reviewed. Therefore, it is unknown whether participants found them acceptable. Acceptability has important implications for retaining clients in therapy and should be considered in future studies. Given the variance with respect to inclusion criteria, types of assessments and methodology it is difficult to draw comparisons between studies.

1.7 Variables to target in the context of PND for change

There is debate about targeting maternal mood as a mechanism for change in the treatment of PND. Most research has exclusively focused on PND and has used the EPDS as the outcome measure. McLennan and Offord (2002) have suggested that further research is needed to establish the role of PND as a risk factor to determine whether it should be targeted for improving developmental outcomes. Dennis (2004) recommends decreasing exposure to risk factors or reducing the strength or mechanism of relation between risk factors and PND.

It has been suggested that improving the relationship of mother-infant dyads acts a preventative treatment and is more cost effective than any adult psychological and psychosocial treatments (Gerhardt, 2004). Indeed, treatments which have focused on fostering the mother-infant relationship have demonstrated effectiveness (Svanberg & Barlow, 2009). These interventions draw on theory and research focusing on the role of the parent as a regulator of their infant’s states.
While certain treatments have been shown to be effective for treating PND, it is still unclear where the benefits lie for the developing child, since an improvement in maternal mood does not always necessitate an improvement in developmental outcomes (McLennan & Offord, 2002). Future treatment research programmes need to measure developmental outcomes to establish a complete treatment picture for high risk families.

There is a necessity to acknowledge fathers when administering treatment. Treatments and research more widely have often neglected the role of the father in parenthood, despite a growing literature within this area. Since it is a period of adjustment, it is reasonable to accept that fathers will also face challenges in becoming new parents, including redefining their relationship and roles with their spouse and importantly learning to respond adaptively to their babies.

1.8 Parenting interventions in perinatal treatment

In the UK, Government policies provide frameworks for further promotion of mental health, highlighting the importance of promoting parenting skills and attachment and acknowledging the importance of a positive start in life (Department of Health, 2011; The Scottish Government, 2011; National Assembly for Wales, 2009). Reviews by Field (2010) and Allen (2011) have reinforced the importance of early intervention for families. Furthermore, the New Horizons document has proposed a public mental health framework to promote whole population mental health and well-being (Department of Health, 2009). Central to this aim is promoting a positive start in life. The document details that early intervention is the key to laying foundations to this aim. Furthermore, it asserts that good parenting skills are at the heart of laying positive foundations. At present, there is a huge unmet need for parenting interventions for PND (O'Hara, 2009) and a range of potential opportunities to explore including ‘non-traditional service providers, self-help interventions, and the media’ (Kazdin & Blase, 2011).

The role of parenting is central in promoting child development. Cooper and Murray (1997) suggested that impairments in parenting associated with PND are the major causes of risk to development. Likewise, Meany (2001) proposed a direct link between the nature of parental care and an increased risk of emotional and behavioural problems across child development (Craig, 2004). Warm and supportive families are protective for women and for children. For parents with mental health problems including PND it may be helpful to address parenting skills. This rationale will be outlined in Chapter 3.
1.9 Conclusion

This overview has introduced, defined and provided a background to PND. The implications for the mother, infant and mother-infant relationship have also been outlined. A range of approaches to treating PND and available evidence have been summarised. Much of the available treatment research is weak in terms of overall design, sample size and reporting (Boath & Henshaw, 2001; Dennis, 2005). As there is currently insufficient evidence to endorse one specific treatment or strategy (Cuijpers, et al., 2008; Dennis, 2005), further development of programmes and detailed research and evaluation are needed.

Few of the studies presented here included outcome or secondary measures related to the quality of the mother-infant relationship or child development, despite considerable evidence demonstrating the impact of PND on these outcomes. As the present review has identified an important gap within the literature, Chapter 2 is a systematic review with a primary focus of appraising the treatments which have included these specific outcomes.
References


Chapter 2

A systematic review of PND treatments which assess the mother-infant relationship and/or child developmental outcomes in addition to maternal mood

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Under review in Clinical Psychology Review, 2012
Abstract

Postnatal depression (PND) has wide and negative effects on maternal wellbeing, as well as implications for the mother-infant relationship, subsequent infant development and more generally, family functioning. Postnatal depression (PND) impacts on a mother’s ability to be a sensitive and responsive caregiver. This has direct implications for the infant’s development of self-regulatory skills, making the infant more vulnerable to later psychopathology. Given the intergenerational transmission of risk to the infant, the mother-infant relationship is a focus for treatment and research. However, few studies have assessed the effect of treatment on the mother-infant relationship and child developmental outcomes despite considerable research evidencing the impact on them. The main aim of this paper was to conduct a systematic review and investigate effect sizes of interventions for PND which assess the quality of the relationship between the mother-infant dyad and/or child outcomes in addition to maternal mood. Fifteen studies were selected for review and their methodological quality was evaluated using the Clinical Tool for Assessment of Methodology (CTAM, Tarrier & Wykes, 2004). Where possible, effect sizes across maternal mood, quality of dyadic relationship and child developmental outcomes were calculated. Finally, clinical implications in the treatment of PND are highlighted and recommendations made for further research.
2.1 Introduction
Approximately one in ten women suffer from Postnatal Depression (PND) (i.e., Milgrom, Martin & Negri, 1999). Beck (1996) reported that the best predictor of PND was depression in the antenatal period. However, psychosocial factors such as poverty, marital discord, life stressors (bereavement) have also been implicated and are thought to be more predictive of vulnerability to PND than biological or hormonal causes (Milgrom, Martin & Negri, 1999).

Postnatal depression (PND) has varied onset, chronicity, clinical presentation and course relative to major depression and other mood disorders in the postpartum period, including postnatal blues and puerperal psychosis (Williamson & McCutcheon, 2004). An episode of PND generally lasts from two to six months in duration and as long as one year in some cases (Cooper & Murray, 2007; Williamson & McCutcheon, 2004; Lee & Chung, 2007). According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV), women meet diagnostic criteria for PND if the onset is within the first four weeks postpartum, although this onset period has been extended in clinical practice with reports that 50% of cases start within three months and 75% of cases within seven months (Cooper, Campbell, Day, Kennerley & Bond, 1988). The DSM-IV criteria make limited reference to the infant, though the need for recognition of symptoms relating specifically to birth, labour and other aspects of being a new parent have been identified elsewhere (Barnett & Fowler, 1995).

Biopsychosocial models highlight the complexity and interaction between multiple systems implicated in PND. The model by Milgrom, Martin and Negri (1999) details vulnerability factors, precipitating factors (including those factors which may trigger PND onset: stress levels, stress-moderating variables of social support and coping skills) and biological factors. The model also explains that sociocultural factors may play a role in exacerbating and maintaining PND. Furthermore, it accounts for heterogeneity in vulnerability to experiencing PND across women.

An estimation suggested that the cost of care alone between women with PND and those without PND in a British community sample is significant (Petrou, Cooper, Murray, & Davidson, 2002). Petrou and colleagues (2002) have recommended that these are conservative estimates and that the excess cost is substantially more for women experiencing extended episodes of PND. Notwithstanding, there are further cost implications in terms of child and adolescent services assessed due to the increased risk associated with having a parent with PND. Treatment is, therefore, a major public health...
Considerable evidence suggests that PND has profound and widespread effects on the mother, the mother-infant relationship and serious implications for subsequent infant development and family well-being. Following an episode of PND, women are predisposed to future risk of depressive episodes with subsequent children. In addition to the effects on maternal mental health there are implications for the developing infant. Crucially, the first year is an important period for infants to develop self-regulatory skills. Adaptive development of self-regulatory skills in the infant is promoted by sensitive and responsive caregiving. Postnatal depression (PND) directly impacts on a mother’s ability to sensitively respond to her baby and therefore, the quality of the dyadic relationship is also affected. Interventions which focus exclusively on maternal depression do not necessarily confer benefit to infant development. In many instances, maternal mood may improve, but the intergenerational transmission of risk remains unchanged. Therefore, any intervention which takes a dyadic approach and puts the depressive episode into the context of the perinatal period stands in better stead to promote adaptive developmental pathways in the infant. It is necessary to measure outcomes in order to understand if interventions for PND are thwarting intergenerational transmission of risk to developing infants.

2.1 Intergenerational transmission of risk to children of women with PND

Goodman and Gotlib (1999) advised that there is a need for a developmental model which explains the transmission and manifestation of vulnerability in infants. The nature of the association between PND and infant development is especially complicated by limited understanding of the full impact and risk of maternal mood and cognitions on infant developmental pathways.

In their integrated model, Goodman and Gotlib (1999) detail how the effects of PND are implicated across the intergenerational gap (see Figure 1). The model reflects the complex interplay between quality of parenting and several factors which influence the developing infant. In their model, Goodman and Gotlib (1999) proposed four mechanisms implicated in the transmission of risk to children of depressed mothers including (1) *Heritability of depression* which proposes that PND may have higher heritability than depression occurring at other periods, implicating that other models for transmission in isolation may not be sufficient to explain elevated risk for developmental psychopathology of infants of PND mothers; (2) *Innate dysfunctional neuroregulatory mechanisms* suggest that this mechanism is restricted to infants whose mothers’ experience clinical depression
during the antenatal period; (3) *Exposure to negative maternal cognitions, behaviour and affect* highlights that the depressed parent cannot meet the social and emotional needs of the infant/child and finally; (4) *Stressful context of infant/child’s life* includes social risk factors such as Socio Economic Status (SES) and marital discord.

Goodman and Gotlib (1999) have also proposed three moderating risk factors related to transmission of vulnerability to child, including: (a) *Paternal health/involvement with infant/child* which details that paternal psychopathology may increase vulnerability of infant to PND. Conversely, healthy fathers may help reduce risk to vulnerability, because (b) *Course and timing of maternal depression* details that PND may have specific knock-on effects for future socio-emotional and cognitive development of infant. It specifies that infants may also generalize future contexts based on their experience with a mother affected by PND and that chronic PND may have more severe implications for their development. In addition, despite remitting of PND symptomatology in mothers, there is some evidence which suggests that infants may continue to be affected. Although this evidence is equivocal, (c) *characteristics of children* such as temperament, gender, intellectual and social-cognitive skills, may moderate, albeit weakly, the association of PND on maladaptive developmental outcomes.

Importantly, the impact of PND on development will vary given the dynamic nature of development. This makes it difficult to anticipate what the specific nature of the vulnerability to development may be across children, since PND and maternal mental illness in general will almost certainly impact each child differently.
2.1.2 Effect of PND on infant development

Evidence suggests that PND in the parent may contribute to serious effects on infant cognitive and emotional development and is associated with later psychopathology and atypical development (Cooper & Murray, 1998). Grace, Evindar and Stewart (2003) highlighted that the most significant effects of PND were on cognitive development including language development and intelligence. However, effects varied with characteristics of children involved, including gender and contextual factors as indicated by the aforementioned model. They also suggested that timing and course of PND were more pervasive in their effects on child development.

Research using the Face-to-Face video interaction paradigm has demonstrated that mothers with PND are more negative and their infants less positive than non depressed mother infant-dyads (Cohn, Campbell, Matias, & Hopkins, 1990). Longitudinal studies
have also shown a predictive link between early PND and problems much later in development (Hay, Pawlby, Angold, Harold, & Sharp, 2003; Murray et al., 2011).

Milgrom, Westley and Gemmil (2004) demonstrated the role of maternal responsiveness in atypical developmental patterns and increased temperamental difficulties in infants of mothers with PND at 48 months postpartum. They also found that full IQ scores were lower in children of mothers with PND, demonstrating the lasting effects of PND occurring early in the postpartum period. Research on the implications for the infant of early exposure to PND highlights the need for early effective treatment of PND where both the parent (usually the mother) and the infant are considered.

2.1.3 The protective role of the dyad relationship
Developmental literature has underscored the importance of early influence at protecting and promoting development. It has been widely recognised that the infant-caregiver relationship plays an important role in child development (Thompson, 1998). When the infant-caregiver relationship is perturbed, subsequent child development has been shown to be compromised. Cognitive deficits in infants presented earlier have been found to be significantly associated with the quality of the early mother-infant relationship, despite later remission of maternal PND. Given the evidenced impact of PND on infant emotional and cognitive development, studying the mother-infant relationship has the impetus to inform theory and clinical practice.

2.1.4 The impact of maladaptive care-giving
Murray and Cooper (1997) suggested that the effects of PND on infant development were mediated through an association with maternal cognitions and maladaptive parenting practices. Parental ability to regulate an infant’s affective state plays a key role in helping children to develop strategies for self-regulation (Crittenden, 2009; Gerhardt, 2004; Hay, 1997; (Crittenden, 2008; Meaney, 2001). At a neurochemical level, Gerhardt (2004) summarised the implications of failure of the caregiver to respond appropriately or “good enough” to her infant’s needs and the impact of prolonged increase of cortisol levels on the infant. Gerhardt (2004) reviewed evidence that prolonged levels of cortisol in early infancy have consequences for neural systems implicated in how infants tolerate stress later in life, namely the prefrontal cortex and HPA.

To illustrate this, van den Boom (1994) reported that educating vulnerable parents on how to respond appropriately and “optimally” to their temperamentally reactive infants was central to forming secure attachment bonds with their infant. This secure attachment which develops between the mother and infant also illustrates that the care the infant
receives can impact in a protective manner on the developing child. Consequently, it seems that at least optimal parenting is a key feature in a parent’s (namely the mother’s) ability to regulate and soothe their infant during periods of distress (Gerhardt, 2004).

If the effects of PND are mediated through parenting and negative parental cognitions, then maladaptive parenting might contribute to the lowering of an infant’s threshold for psychopathology and ability to self-regulate, thereby increasing the infant’s vulnerability to later psychopathology. This idea makes an argument for the importance of the quality of early parenting.

2.1.5 Interventions focusing on the mother-infant relationship
The link between early care and later psychopathology has been stressed in the literature (e.g., Gerhardt, 2004). It has been suggested that improving the quality of the mother-infant dyadic relationship acts as a protective factor and is more cost effective than psychological and psychosocial interventions later in life (Gerhardt, 2004). Indeed, interventions which have focused on fostering the mother-infant relationship have demonstrated effectiveness (Svanberg & Barlow, 2009). Interventions which focus on the mother-infant relationship as a mechanism for change typically involve working with the mother-infant dyad to improve relationship synchrony rather than treating the mother’s depression exclusively. These interventions draw on theory and research focusing on the role of the parent as a regulator of their infant’s states. Given the proposed mechanisms in the integrative model by Goodman and Gotlib (1999), a focus on the mother-infant relationship would be a favourable target to improve parenting difficulties in the context of PND.

2.1.6 Assessment of the dyadic relationship in interventions for PND
A significant proportion of PND treatment literature has focused on the mother’s depression in isolation, with few studies assessing the quality of the dyadic relationship as well as child developmental outcomes. They do not reflect the issues raised by Goodman and Gotlib (1999), nor do they target factors associated with transmission of risk to infants. It is therefore difficult to necessitate any benefit to the mother-infant relationship. Since the model proposes that PND may mediate maladaptive care-giving practices, it is an important empirical objective to measure the quality of the mother-infant relationship and infant development.

Given the role of the dyadic relationship in promoting adaptive development, the measurement of related outcomes has been sparse. There is an extensive literature of evaluation studies of various interventions. However, little is known about the benefit of
interventions to the quality of the mother-infant relationship and, moreover, child developmental outcomes. This review will systematically evaluate trials which assess the aforementioned. The primary aim of this literature review was to evaluate intervention research which has included outcomes measuring the quality of the mother-infant relationship and/or child developmental outcomes in addition to maternal mood. The methodological quality of the studies was reviewed using the Clinical Tool for Assessment of Methodology (CTAM) designed by Tarrier and Wykes’ (2004). This review will focus on the findings in relation to maternal mood, infant development and the quality of the mother infant relationship.

2.2 Method
2.2.1 Search strategy
The literature search included publications from 1999-2011 since an earlier review by Poobalan et al. (2007) reviewed studies from 1990s to 2005. In their 2007 review, Poobalan et al. (2007) assessed the quality of studies using a standard assessment adapted from the Cochrane Collaboration and Jadad Scale (Jadad et al., 1996) but they did not calculate effect sizes. The following databases were searched: Psych Info, Medline, Web of Science and Maternity & Infant Care. Boolean searches were conducted using combinations of the following (and related) terms: “treatment & postpartum depression” and “treatment & postpartum depression & mother child relations OR infant development”. The first combination of terms “treatment & postpartum depression” were exploded to include all related terms and then further refined with the second combination of terms “treatment & postpartum depression”. All titles and abstracts were initially scanned for relevance.

2.2.2 Inclusion criteria
Studies were considered for inclusion if they included a treatment or intervention which was delivered in the postnatal period, if the primary outcomes assessed maternal depression and mother-infant interaction and/or child outcomes. Both single group and RCT designs were considered for inclusion given the limited literature and quality of available evidence. A further inclusion criterion was that participants were experiencing low mood as indicated by a screening tool (i.e., Edinburgh Postnatal Depression Scale (EPDS)) or a professional diagnosis of depression.
2.2.3 Exclusion criteria
Studies were excluded if they were single case designs, reviews, book chapters and/or discussion papers, not in English language or peer reviewed.

2.2.4 Evaluation of quality of trial methodology
The CTAM is an assessment tool used to evaluate the quality of psychotherapeutic trials (Tarrier & Wykes, 2004). The CTAM has previously been used to evaluate methodological quality of intervention trials for schizophrenia and suicide. The evaluation is based on six areas of trial design, including: sample size and recruitment method, allocation to treatment, assessment of outcomes, control groups, description of interventions and analysis of data. There are a total of 15 items. Scores range from 0 to 100, scores over 65 are regarded as good quality.

Effect sizes indicate the magnitude of difference between two groups. In this review they were also calculated separately for maternal mood, quality of dyadic relationship and child developmental outcomes. Small effects where effect sizes (Cohen’s D) were between 0.2 to 0.3, medium effects where effect sizes were 0.5 and large effects equal to or greater than 0.8 as suggested by Cohen (1988). As advised by Cohen (1988) effect sizes were calculated individually given the heterogeneity of outcome measures and interventions. Effect sizes were calculated by the reviewer and not by the study authors. Effect sizes have only been calculated in studies where means and standard deviations were reported. Effect sizes have not been calculated in previous reviews of this literature.

2.3 Results
The initial search returned 749 articles. Five hundred and twenty-seven articles did not meet inclusion criteria on the basis of the title and/or abstract. A further 119 articles were excluded after more detailed examination of the title and abstract. Twenty-four articles were removed for being duplicates or triplicates. A further 10 articles were removed leaving 15 studies to be evaluated. See Figure 2, for a schematic diagram of the literature search. Only three studies (Forman et al., 2007; Murray, Cooper, Wilson, & Romaniuk, 2003; Van Doesum, Riksen-Walraven, Hosman, & Hoefnagels, 2008) assessed both the quality of the dyad relationship and child outcomes. Although there was great heterogeneity across studies and measures used for assessment, effect sizes for different outcomes (maternal mood, mother-infant relationship, child developmental outcomes) were calculated where possible.
Figure 2. Schematic diagram of literature search for studies on treatment for PND with outcomes assessing mother-infant interaction and/or child outcomes

2.3.1 Location and sample
From the 15 studies included in the review, six were carried out in the USA, four in the UK, two in the Netherlands, two in Australia and one in Canada.
2.3.2 Participant characteristics
Of the 15 studies, seven were carried out with a multiparous sample, two with a primiparous sample and five of the studies did not report parity. There was wide heterogeneity across study client inclusion criteria regarding how depressive diagnosis was determined. Nine studies included participants with a professional diagnosis of PND and six studies included participants with probable diagnosis through public health screening. There were also differences across characteristics of participants including, severity of depression, marital status and age of baby (see Table 1).
Table 1. Participant characteristics including: marital status, age of baby and mother and level of depression (at baseline) across all studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Marital status</th>
<th>Age of baby</th>
<th>Level of depression (baseline)</th>
<th>Age of mum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field et al. 1996</td>
<td>Single parents only</td>
<td>1-3 months (range)</td>
<td>Not reported</td>
<td>17.3 years (range= 14-19)</td>
</tr>
<tr>
<td>Horowitz et al. 2001</td>
<td>Not reported</td>
<td>4-18 weeks (range)</td>
<td>14.4 (mean BDI)</td>
<td>31 years (range= 17-41)</td>
</tr>
<tr>
<td>Onozowa et al. 2001</td>
<td>91% married/cohabiting</td>
<td>8.6-9.0 months (median range)</td>
<td>Baseline EPDS (median scores)</td>
<td>18-45 years (range)</td>
</tr>
<tr>
<td>Clark et al. 2003</td>
<td>84.6% married/cohabiting</td>
<td>8.9 months (range 1-24 months)</td>
<td>&gt;16 (BDI)</td>
<td>31.4 years (range= 19-44)</td>
</tr>
<tr>
<td>Murray et al. 2003</td>
<td>88% married/cohabiting</td>
<td>8 weeks</td>
<td>&gt;12 (EPDS)</td>
<td>27.7 years (range=17-42)</td>
</tr>
<tr>
<td><strong>Murray et al. 2003</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Cooper et al. 2003</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Milgrom et al. 2006</td>
<td>79.6% with partner</td>
<td>18.13 weeks (mean)</td>
<td>17.0 (mean BDI)</td>
<td>29.9 years</td>
</tr>
<tr>
<td>Jung et al. 2007</td>
<td>100% married/cohabiting</td>
<td>3.5 months (range=3-4 months)</td>
<td>&gt;10 (BDI/EPDS)</td>
<td>33 years (range=21-41)</td>
</tr>
<tr>
<td>Forman et al. 2007</td>
<td>100% married/cohabiting</td>
<td>6.1 months (mean)</td>
<td>Not reported</td>
<td>30.6 years</td>
</tr>
<tr>
<td>Clark et al. 2008</td>
<td>Not reported</td>
<td>6.4 months (range=1.00-24.26 months)</td>
<td>22.3 (mean BDI)</td>
<td>31.3 years</td>
</tr>
<tr>
<td>O’Higgins et al. 2008</td>
<td>87% married/cohabiting</td>
<td>19 weeks</td>
<td>13.5 (mean EPDS)</td>
<td>Not reported</td>
</tr>
<tr>
<td>Van Doesum et al. 2008</td>
<td>91.3% cohabiting</td>
<td>5.5 months (mean)</td>
<td>23.9 (mean BDI)</td>
<td>30.1 years</td>
</tr>
<tr>
<td>Logsdon et al. 2009</td>
<td>55.5% single</td>
<td>10 months (mean)</td>
<td>18.1 (mean HRSD)</td>
<td>24.5 years</td>
</tr>
<tr>
<td>*Kersten-Alvarez et al. 2010</td>
<td>40.7% married</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.7% divorced/separated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>85% married/cohabiting</td>
<td>6 months (mean)</td>
<td>23.8 (mean)</td>
<td>35.7 years(range=25-43)</td>
</tr>
<tr>
<td>Mulcahy et al. 2010</td>
<td>16% single</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>97.9% married/cohabiting</td>
<td>6.2 months (mean)</td>
<td>28.91 (mean BDI)</td>
<td>32.2 years</td>
</tr>
</tbody>
</table>
2.3.3 Treatment type, session length and total duration

The types of interventions evaluated in this review varied greatly. Session lengths ranged from 15 minutes to two hours and total treatment duration ranged from three to 12 sessions. Mode of delivery included both individual and group delivery as well as mixed individual and group. See Table 2 for a summary of type of treatment, session length and treatment duration, CTAM scores and domains of assessment (maternal affect, dyad relationship and child development) across all studies.
Table 2. type of treatment, session length and treatment duration, CTAM scores and domains of assessment

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>N</th>
<th>Study design</th>
<th>PND Diagnosis</th>
<th>Maternal Mood</th>
<th>Dyad assess</th>
<th>Child assess</th>
<th>Follow up</th>
<th>Treatment</th>
<th>TX length</th>
<th>CTAM score</th>
<th>Format</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clark et al. 2003</td>
<td>USA</td>
<td>39</td>
<td>SGA</td>
<td>y</td>
<td>Y</td>
<td>y</td>
<td>Y</td>
<td>N</td>
<td>M-ITG, IPT OR WLC</td>
<td>(1-1.5 hrs)</td>
<td>30</td>
<td>individual</td>
<td>Both MIT-G and IPT groups reported significantly fewer depression symptoms (CES-D) than WLC. No significant differences in BDI scores between any of the groups. Significant differences were also reported on</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>12 wks</td>
<td></td>
<td></td>
<td>Parenting Stress MIT-G and IPT both showed significant improvements in perception of child adaptability and more reinforcement from their children.</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>MIT-G and IPT groups both scored significantly higher on Maternal Positive Affective Involvement and Verbalisation than WLC.</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td>No differences were found across any groups on infant development M-ITG showed significant fewer depressive symptoms, experienced infants as more reinforcing and parenting more rewarding. MIT-G also exhibited significantly more positive affective involvement and communication after treatment.</td>
</tr>
</tbody>
</table>

Clark et al. 2008 | USA     | 32 | SGA          | Y             | Y             | Y            | N            | N         | MIT-G             | Part 1: 1.5 hrs (therapy group for mums, developmental therapy for infants) | 40         | Group       |        |                                                                                                                                 |
|             |         |    |              |               |               |              |              |           |                   | Part 2: 30 mins dyadic group therapy                          |            |            |        |                                                                                                                                 |


<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>N</th>
<th>Study design</th>
<th>PND Diagnosis</th>
<th>Maternal Mood</th>
<th>Dyad assess</th>
<th>Child assess</th>
<th>Follow up</th>
<th>Treatment</th>
<th>TX length</th>
<th>CTAM score</th>
<th>Format</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cooper et al. 2003</strong></td>
<td>UK</td>
<td>193</td>
<td>RCT</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>TAU, non-directive counselling, CBT or Psychodynamic therapy</td>
<td>Weekly from 8 wks to 18 weeks postpartum</td>
<td>72</td>
<td>individual</td>
<td>All treatments had sig impact on mood at 4.5 months. Psychodynamic therapy rate of reduction of depression sig greater than TAU. Benefit of treatment not maintained at 9 months. Treatment did not reduce subsequent episodes.</td>
</tr>
<tr>
<td>Field et al. 1996</td>
<td>USA</td>
<td>40</td>
<td>RCT</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Baby massage</td>
<td>15 mins 2 dys/week 6 weeks</td>
<td>46</td>
<td>group</td>
<td>Babies in massage therapy group were observed to be more awake and alert and less drowsy and sleeping than comparison group. Crying and cortisol levels in the baby massage group also decreased compared with rocking group</td>
</tr>
<tr>
<td>Forman et al. 2007</td>
<td>USA</td>
<td>176</td>
<td>RCT</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>IPT or WLC</td>
<td>12 weekly session</td>
<td>80</td>
<td>individual</td>
<td>Treatment was reported to only affect parenting stress. Women receiving IPT had significant improvements in parenting stress compared with WLC but not the non-depressed comparison sample. At 18 month follow up women who received IPT continued to rate their children lower in attachment security, higher in behavioural problems and more negative in their temperament compared with non depressed comparison sample.</td>
</tr>
<tr>
<td>Horowitz et al. 2001</td>
<td>USA</td>
<td>117</td>
<td>RCT</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Interactive coaching OR support group</td>
<td>15 mins 3 time points</td>
<td>77</td>
<td>Individual</td>
<td>Treatment group showed significantly higher level of responsiveness at post treatment. Both groups demonstrated significant reduction in depression scores</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>N</td>
<td>Study design</td>
<td>PND Diagnosis</td>
<td>Maternal Mood</td>
<td>Dyad assess</td>
<td>Child assess</td>
<td>Follow up</td>
<td>Treatment</td>
<td>TX length</td>
<td>CTAM score</td>
<td>Format</td>
<td>Key findings</td>
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<td>-----------------------------------------------------------------------------</td>
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<tr>
<td>Jung et al. 2007</td>
<td>CAN</td>
<td>11</td>
<td>SG</td>
<td>N</td>
<td>N</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Keys to Caregiving (understand and responding to baby behaviour)</td>
<td>5 weekly sessions</td>
<td>19</td>
<td>group</td>
<td>Post intervention infants displayed marked increase in Interest and Joy during interaction with Mothers</td>
</tr>
<tr>
<td>*Kersten-Alvarez et al. 2010</td>
<td>NED</td>
<td>58</td>
<td>RCT</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Mother-infant pairs videotaped - given feedback</td>
<td>(60-90 min) 8-10 sessions. Initially weekly, then reduced to every 2 weeks.</td>
<td>69</td>
<td>individual</td>
<td>No lasting effects of the intervention at five year follow up. However, the authors reported an effect for child externalising behaviour problems associated with family stressful life events. Children in the intervention group had fewer instances of externalising behaviour problems associated with family stressful life events.</td>
</tr>
<tr>
<td>Logsdon et al. 2009</td>
<td>USA</td>
<td>27</td>
<td>RCT</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Antidepressant medication</td>
<td>8 weeks of treatment</td>
<td>42</td>
<td>individual</td>
<td>Improved gratification of maternal role but not self efficacy or mother-infant interaction</td>
</tr>
<tr>
<td>Milgrom et al. 2006</td>
<td>AUS</td>
<td>117</td>
<td>RCT</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>CBT</td>
<td>12 weekly sessions</td>
<td>29</td>
<td>individual</td>
<td>There was a statistically significant decrease in overall parenting stress scores.</td>
</tr>
<tr>
<td><strong>Murray et al. 2009</strong></td>
<td>UK</td>
<td>193</td>
<td>RCT</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Non-directive counselling, CBT, psychodynamic therapy OR TAU</td>
<td>Weekly from 8 wks to 18 weeks postpartum</td>
<td>72</td>
<td>individual</td>
<td>All three treatments significant benefit on maternal reports of early reports of difficulties with infants. Counselling gave better infant emotional ratings at 18 months and sensitive early dyad interactions. No sig benefit maternal management of infant behaviour problems, security of dyad attachment, infant cognitive development or any child outcomes at 5 years.</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>N</td>
<td>Study design</td>
<td>PND Diagnosis</td>
<td>Maternal Mood</td>
<td>Dyad assess</td>
<td>Child assess</td>
<td>Follow up</td>
<td>Treatment</td>
<td>TX length</td>
<td>Format</td>
<td>Key findings</td>
<td></td>
</tr>
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<td>-----------------------</td>
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<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Mulcahy et al. 2010</td>
<td>AUS</td>
<td>50</td>
<td>RCT</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>IPT-G</td>
<td>(2 hrs) and 1x2 hr partner evening</td>
<td>54</td>
<td>Individual (2 session) and Group (8 session)</td>
<td>IPT-G showed significant improvement in depression scores compared with TAU. Improvement maintained at follow up. IPT-G showed significant improvement in perception of infant care-giving, marital functioning and social support. IPT-G showed non significant improvements at follow up.</td>
</tr>
<tr>
<td>O'Higgins et al. 2008</td>
<td>UK</td>
<td>62</td>
<td>RCT</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Baby Massage OR support group</td>
<td>(1 hr) 6 sessions</td>
<td>70</td>
<td>Group</td>
<td>Post treatment both control and baby massage groups remained higher than non-depressed group. The massage group showed non-significant reductions in depression scales. At 12 month follow-up depressed group was still scoring significantly higher than non-depressed controls. Although, significantly more of the massage group achieved clinical reductions in EPDS scores and non-depressed levels of sensitivity in interactions with their babies compared with support group. Significant improvement in Mother-Infant interaction only in massage group.</td>
</tr>
<tr>
<td>Onozowa et al. 2001</td>
<td>UK</td>
<td>34</td>
<td>RCT</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>Baby massage</td>
<td>(1 hr) 5 weekly sessions (60-90 mins)</td>
<td>45</td>
<td>Group</td>
<td></td>
</tr>
<tr>
<td>Van Doesum et al. 2008</td>
<td>NED</td>
<td>71</td>
<td>RCT</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Mother-baby intervention (quality of dyad relationship)</td>
<td>8-10 home visits over 3-4 months</td>
<td>62</td>
<td>Individual</td>
<td>At (T3) Treatment group sig higher AQS scores than controls. Treatment group sig more competent (ITSEA subscale) than control group, but no differences on other subscales. Increase in maternal sensitivity in treatment group.</td>
</tr>
</tbody>
</table>

**Note**: Report different outcomes from same study. *Reports reports dyad and child developmental outcomes of Van Doesum et al. (2008)*

ADS= Antidepressants, AQS=Attachment Q-Set, ASCT= Attachment Story Completion Task, BDI-II= Beck Depression Inventory, BSID= Bayley Scale of Infant Development, BSQ=Behavioural Screening Questionnaire, CES-D= Centre for Epidemiological Studies Depression Scale, CBCL= Child Behaviour Checklist, CBQ=Child Behaviour Questionnaire, CBC= Child Behaviour Checklist, CBT=Cognitive Behaviour Therapy, CCMRe= Child and Caregiver Mutual Regulation Coding Scale, CCQS= California Child Q-Set, CCI= Colorado Child Temperament Inventory, C-TRF= Caregiver-Teacher Report Form, DAS=Dyadic Adjustment Scale, DS= Diagnostic Interview Schedule, DMC= Dyadic Mutuality Code, EAS= Emotional Availability Scale, EPDS= Edinburgh Postnatal Depression Scale, HAMD= Hamilton Depression Rating Scale, IBQ= Infant Behaviour Questionnaire, IQ= Infant Characteristics Questionnaire, ICS=Infant Care Survey, IDD= Inventory to Diagnose Depression, IPT-G= Interpersonal Psychotherapy group, ISEL= Interpersonal Support Evaluation List, ITSEA= Infant Toddler Social and Emotional Assessment, LES= Life Experiences Survey, LES-C= Live Events Scale for Children, MAI= Maternal Attachment Inventory, MCMI-II= Million Clinical Multiaxial Inventory-III, MDD= Major Depressive Disorder, MINI= Mini International Neuropsychiatric Interview, M-ITG= Mother-Infant Therapy Group, NIBCS= Noldus Behavioural Coding Software, PCERA= Parent-Child Early Relational Assessment, PI=Puppet Interview, PPVT-R= Peabody Picture Vocabulary
Test-Revised, PSBQ= Preschool Social Behaviour Questionnaire, PSI= Parenting Stress Index, SCID= Structured Clinical Interview for Diagnosis of DSM-IV Disorders, SRS= Stress Response Scale, SSAI=Spielberger State Anxiety Inventory, and WLC= Waitlist Control
2.4 Methodological quality

Methodological quality of all studies was assessed by the first author (ZT) and a random sample of studies by a second, independent rater. Where there was disagreement between the raters, the original score (by the first author) was accepted. With respect to uncertainty regarding statistical analyses, a statistician was consulted. See Table 2 for a summary of CTAM scores across all studies assessed. Overall, most studies (ten of the 15 studies) included in the review had a CTAM score below 65, which is described as inadequate by the authors of the CTAM (see Tarrier & Wykes, 2004).

2.4.1 Sample

Most studies (11/15) used a convenience sample. Seven of the 15 studies (Cooper, Murray, Wilson, & Romaniuk, 2003; Forman, et al., 2007; Horowitz et al., 2001; Kersten-Alvarez, Hosman, Riksen-Walraven, van Doesum, & Hoefnagels, 2010; Murray, et al., 2003; O’Higgins, Roberts, & Glover, 2008; Van Doesum, et al., 2008) had a sample size greater than 27 in each treatment group. Numbers of less than 27 in each group is regarded as inadequate and does not score on the CTAM. Small sample sizes are a longstanding limitation within the PND literature. A large proportion of studies with PND populations often fail to recruit to target and as such are often under-powered. This is a difficulty experienced across trials.

2.4.2 Allocation

While most studies described whether there was true random allocation or minimisation allocation across treatment groups, only seven studies (Cooper, et al., 2003; Horowitz, et al., 2001; Logsdon, Wisner, & Hanusa, 2009; Mulcahy, Reay, Wilkinson, & Owen, 2010; Murray, et al., 2003; O’Higgins, et al., 2008; Van Doesum, et al., 2008) described the process of randomisation. Furthermore, two studies also (Logsdon, et al., 2009; Mulcahy, et al., 2010) indicated that the process of randomisation was carried out independently of the research team.

2.4.3 Assessment

All of the studies used standardized assessments to measure outcomes. All but two studies (Jung, Short, Letourneau, & Andrews, 2007; Onozawa, Glover, Adams, Modi, & Kumar, 2001) had assessors who were independent of treatment delivery (i.e., they were not therapist on the trial). Six studies (Horowitz et al., 2001; Cooper et al., 2003; Murray et al., 2003; Forman et al., 2007; O’Higgins et al., 2008; Kersten-Alvarez et al., 2010) reported
that assessments were carried out blind to treatment group allocation. However, only two studies (Horowitz et al., 2001; Onozawa et al., 2001) described the method of rater blinding and only one study (Onozawa et al., 2001) reported verification of rater blinding.

2.4.4 Control groups
While most studies utilised an RCT design, two studies (Forman et al., 2007; O’Higgins et al., 2008) reported using both, no treatment or waitlist control (WLC) group, as well as a control group that controlled for non-specific effects (i.e., non-depressed comparison group).

2.4.5 Analysis
All studies conducted appropriate analyses given their design and sample sizes. One study (Forman, et al., 2007) employed intention-to-treat analyses (including all participants as randomised) and four studies (Cooper, et al., 2003; Horowitz, et al., 2001; Mulcahy, et al., 2010; Murray, et al., 2003) had attrition of less than 15 percent. The remaining studies did not handle drop outs appropriately, had attrition of greater than 15%, or inappropriate samples sizes (i.e. less than 27 participants in each group).

2.4.6 Active treatment
All interventions examined were psychotherapy and or psychosocial interventions with the exception of one study (Logsdon et al., 2009), which was an evaluation of two types of antidepressant medications. Six of the studies (Clark, Tluczek, & Brown, 2008; Clark, Tluczek, & Wenzel, 2003; Cooper, et al., 2003; Kersten-Alvarez, et al., 2010; Mulcahy, et al., 2010; Van Doesum, et al., 2008) provided an adequate description of the treatment, reported the use of a protocol or manual, as well as an assessment of adherence to the protocol.

2.5 Maternal mood, dyadic relationship and developmental outcomes
2.5.1 Outcome measures
Various outcome measures were used across the studies to evaluate the efficacy of interventions in the domains of maternal affect, dyad relationship and child development (see Table 2).

2.5.2 Maternal mood
Studies used either the Beck Depression Inventory (BDI) or the Edinburgh Postnatal Depression Scale (EPDS) to assess maternal mood, with the exception of two studies
(Logsdon, et al., 2009; Mulcahy, et al., 2010) which used the Hamilton Rating Depression Scale (HAMD). The largest effect sizes, though moderate, in terms of effectiveness of treatment on improvement in maternal mood were reported by Horowitz et al. (2001) and Clark et al. (2008) (see Table 3 for effect sizes). Horowitz et al. (2001) evaluated the efficacy of a behavioural intervention delivered by advanced practice nurses and research assistants, which involved coaching designed to promote maternal responsiveness. Horowitz et al. (2001) reported that women who had received the behavioural coaching showed a significantly higher level of responsiveness post treatment. Clark et al. (2008) investigated the efficacy of a 12-week, manualised mother-infant therapy group (MIT-G) compared with WLC: women allocated to the MIT-G showed significantly fewer depressive symptoms, experienced their infants as more reinforcing and parenting more rewarding.

Smaller effect sizes (see Table 3) were calculated across several other studies (Clark, et al., 2003; Cooper, et al., 2003; Mulcahy, et al., 2010; O'Higgins, et al., 2008; Van Doesum, et al., 2008). Both Mulcahy et al. (2010) and Clark, Tluczek and Wenzel (2003) evaluated Interpersonal Psychotherapy (IPT), Mulcahy et al. (2010) in an RCT comparing group IPT with Treatment as Usual (TAU) and Clark et al. (2003) in an RCT comparing MIT, IPT with WLC. In Clark et al.’s (2003) study, a greater effect size was calculated for the group MIT than IPT. However, a greater effect size was calculated in the Mulcahy et al. (2010) study evaluating IPT.

Cooper et al. (2003) compared counselling, psychodynamic therapy and Cognitive Behaviour Therapy (CBT) with TAU. The largest effect size was calculated for psychodynamic therapy. They reported that psychodynamic therapy was associated with significantly greater reductions in depressive symptoms compared with TAU; however, the effects were not maintained at nine-month follow up.

No significant differences were found in symptoms of depression found between women who took part in an intervention working on the quality of the dyadic relationship compared with mothers receiving telephone parenting support only Van Doesum et al. (2008).

Three studies evaluated different delivery modalities of baby massage O’Higgins et al. (2008), Field et al. (1996) and Onozawa et al. (2001). No significant differences were found across measures of maternal mood between comparison groups and women receiving baby massage in the studies by O’Higgins et al. (2008) and Onozawa et al.
(2001). Field et al. (1996) did measure developmental but not maternal outcomes (but included women on the basis of formal diagnoses of major depression).

Cognitive Behaviour Therapy (CBT) supplemented with a mother-infant module (HUGS) were evaluated by Milgrom, Ericksen, McCarthy, and Gemmill (2006). The authors reported significant reductions in symptoms of depression following CBT and further significant drops in parenting stress following the mother-infant module. It was not possible to calculate effect sizes for this study due to missing information. Logsdon et al. (2009) also reported significant reductions in symptoms of depression following eight weeks of two antidepressant treatment (nortriptyline and sertraline).
<table>
<thead>
<tr>
<th>Author</th>
<th>Maternal Depression</th>
<th>mean</th>
<th>mean</th>
<th>SD TX</th>
<th>SD TAU</th>
<th>Cohen’s D</th>
<th>Effect size r</th>
<th>Dyad Measure</th>
<th>mean</th>
<th>mean</th>
<th>SD TX</th>
<th>SD TAU</th>
<th>Cohen’s D</th>
<th>Effect size r</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field et al. 1996</td>
<td>Not measured</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Horowitz et al. 2001</td>
<td>BDI</td>
<td>10.99</td>
<td>10.10</td>
<td>.96</td>
<td>.84</td>
<td>0.99</td>
<td>0.44</td>
<td>DMC</td>
<td>9.73</td>
<td>8.77</td>
<td>1.65</td>
<td>1.72</td>
<td>0.57</td>
<td>0.27</td>
</tr>
<tr>
<td>Onozowa et al. 2001</td>
<td>Insufficient information</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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**Cooper et al. 2003** reports the maternal mood data and **Murray et al. 2003** reports dyad and child outcome

**Kersten-Alvarez et al. 2010** reports the dyad and child developmental outcomes of **Van Doesum et al. 2008**

<table>
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<tr>
<th>Author</th>
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<th>mean TX</th>
<th>mean TAU</th>
<th>SD TX</th>
<th>SD TAU</th>
<th>Cohen’s d</th>
<th>Effect size r</th>
<th>Dyad Measure</th>
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<th>mean TAU</th>
<th>SD TX</th>
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<th>Cohen’s d</th>
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<td>BDI</td>
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<td><strong>Kersten-Alvarez et al. 2010</strong></td>
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<td>Attachment to mother</td>
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<td>5.35</td>
<td>10.14</td>
<td>0.60</td>
<td>0.29</td>
</tr>
</tbody>
</table>

*Cooper et al. 2003* reports the maternal mood data and *Murray et al. 2003* reports dyad and child outcome

**Kersten-Alvarez et al. 2010** reports the dyad and child developmental outcomes of *Van Doesum et al. 2008*
2.5.3 *Mother-infant relationship*

Of the 15 studies, 13 assessed dyadic relationship outcomes (see Table 2). The measures used to assess the dyadic relationship varied widely. The largest effect size on dyadic outcome was calculated for the study by Kersten-Alvarez and colleagues\(^2\) (2010). The intervention (video feedback) had a medium effect on index of the quality of interactive behaviour.

Clark and colleagues’ (2003) study had the second largest effect size calculated in the group that received IPT, but only for factor one (*Maternal Positive Affect Involvement and Verbalization*) of the Parent-Child Early Relational Assessment (PCERA, Clark, 1985). A later study carried out by Clark and colleagues (2008) found comparable findings using the PCERA, with largest effect size calculated on factor one (as above), followed by factor two (*Maternal Negative Affect and Behaviour*), six (*Infant Dysregulation and Irritability*) and seven (*Dyadic Mutuality and Reciprocity*) respectively.

In their uncontrolled study, Jung, Short, Letourneau and Andrews (2007) reported that post-intervention, infants displayed marked increase in interest and joy during interaction with their mothers.

In another RCT, mother-infant dyads were either video-tapped and given feedback using one of four techniques during 8-10 sessions, including: (1) modelling; (2) cognitive restructuring; (3) practical support; and (4) baby massage, or were provided with three sessions of practical parenting advice via telephone calls (Van Doesum, et al., 2008). It was reported that at six-month follow-up, the treatment group had higher Attachment Question-Set (AQS) scores and maternal sensitivity (on the Emotional Availability Scale (EAS) subscale) than controls. Small effect sizes were calculated for the video feedback intervention on child responsiveness and involvement, as well as maternal structuring and sensitivity EAS subscales. A small effect size was also calculated for the intervention on the AQS. A small effect of IPT on the Maternal Attachment Inventory (MAI) was also found in Mulcahy et al. (2010) RCT investigating the effectiveness of group IPT.

In the study by Horowitz et al. (2001), baby massage was found to have a small effect on the quality of the mother-infant relationship, as measured by the Dyadic Mutuality Code (DMC). In a recent RCT examining the effectiveness of baby massage in the treatment of PND, no differences in the quality of the mother-infant relationship (measured by Global Ratings) were found between women receiving baby massage and those receiving support only at post treatment (O’Higgins, et al., 2008). However, at one-

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\(^2\) Presents long term follow-up of mother-infant outcomes to study by Van Doesum et al. 2008
year follow-up depressed dyads who had participated in baby massage had comparable scores of maternal sensitivity with non-depressed dyads, whereas women who had received support only performed significantly less well.

In a double blind RCT of two antidepressants (nortriptyline and sertraline), the authors reported no significant differences in the improvement in the quality of the dyadic interaction on the Child and Caregiver Mutual Regulation Coding Scale (CCMR) (Logsdon, et al., 2009).

It was not possible to calculate the effect size of interventions on the mother-infant relationship in the remaining studies. In another trial of baby massage, the authors reported significant improvements in mother-infant interaction (assessed by global ratings for mother-infant interactions) in women who received baby massage compared with women who attend a support group only (Onozawa, et al., 2001).

In an RCT, Murray and colleagues (2003) reported limited short and long term improvements in the mother-infant interactive quality following treatment in either non-directive counselling, CBT, psychodynamic therapy or TAU. They reported improvements across all groups in face-to-face mother-infant interactions but no significant differences between groups. However, they did report that women allocated to the control group had higher levels of maternal sensitivity at baseline compared with the other groups. Interestingly, they also reported that women with high levels of social adversity who received counselling were found to have higher levels of maternal sensitivity. No other differences in treatment with respect to the quality of the mother-infant relationship were found.

In the study by Milgrom and colleagues (2006), which investigated CBT and the adjunct mother-infant intervention, significant marked (self reported) improvements in the function of mother-infant relationship following the mother-infant adjunct module were reported.

2.5.4 Child development
Four studies (Field, et al., 1996; Forman, et al., 2007; Murray, et al., 2003; Van Doesum, et al., 2008) measured child developmental outcomes. Measures used to assess child development varied making it difficult to compare effect sizes between studies. Across studies it was reported that infants improved on some subscales, but not others. See Table 4 for effect sizes calculated on child developmental variables across studies.
Table 4. Means, Standard deviations, Cohen’s D and effect sizes on measures of child development across studies

<table>
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<tr>
<th>Author</th>
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<th>mean TAU</th>
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<td>Forman et al. 2007</td>
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<td>Van Doesum et al. 2008</td>
<td>ITSEA (competence)</td>
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<td>1.22</td>
<td>.28</td>
<td>.30</td>
<td><strong>0.64</strong></td>
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</table>

Van Doesum et al. (2008) reported that infants in the treatment group (video feedback) were significantly more competent (measured by Infant Toddler Social Emotional Assessment (ITSEA) subscale scores) compared with infants in the control group.

In an RCT investigating the efficacy of IPT treatment for women with PND, a small effect size was calculated for IPT on CBC subscales of internalising and externalising respectively (Forman, et al., 2007). No differences on any of the other ITSEA subscales were found. It was not possible to calculate effect sizes for the remaining studies (Field et al., 1996; Murray et al., 2003).

In their RCT comparing group baby massage with a rocking group, Field and colleagues (1996) reported several outcomes related to infant behaviours, including Thoman’s system of sleep recording, salivary cortisol, weight, formula intake, temperament ratings and urine assays to measure hormones associated with stress. Babies in the massage group were observed to be significantly more awake and less drowsy compared with the rocking group. Crying and cortisol level in the baby massage group also decreased significantly compared with the rocking group. There were also significant changes in temperament. Babies in the massage group were observed to be significantly more sociable, more easily soothed and less emotional compared with babies who were in the rocking group.

Several child developmental and behavioural outcomes were measured at three time points: post treatment (4.5 months), at 18 months and five years later in the RCT by Murray and colleagues (2003). There was no significant effect of treatment group on early
management of infant behaviour following treatment (4.5 months). At 18-month follow-up there was a significant effect of counselling (after controlling for maternal age) on infant emotional and behavioural problems (measured by the Behavioural Screening Questionnaire (BSQ)). Five years later, a non-significant effect of CBT treatment was found on infant emotional and behavioural problems (measured by Rutter A2 Scale) but no differences across interventions on teacher reported child behavioural difficulties (measured by PBCL). There were no differences across the treatment groups on measures of cognitive development found at 18 month (Mental Development Index of the Bayley scales) and 5 year (General Cognitive Index of McCarthy Scales) follow-up.

2.6 Discussion
Given the considerable evidence of the impact of PND on the mother-infant relationship, child development and the limited understanding of conferred benefits of treatment for parental psychopathology to children the aim of this systematic review was two-fold. Firstly, effect sizes were calculated (where possible) to investigate the efficacy of interventions for PND which have assessed secondary outcomes, including: the quality of the mother-infant relationship and/or child developmental outcomes in addition to primary outcomes of maternal mood. Secondly, of the reviewed interventions, we set out to rigorously evaluate the methodological quality of the intervention studies. This is the first review that we know of in this literature to evaluate the methodological quality of studies using the CTAM and calculate effect sizes (where possible). This section presents a discussion of the findings, clinical implications and finally recommendations for future research in this area will be made.

Of the interventions reviewed here, those which have focused on the dyad relationship, namely mother-infant therapy (see Clark et al., 2003) and a coaching intervention, designed to promote maternal responsiveness (Horowitz, et al., 2001) had the greatest efficacy at reducing symptoms of PND (where it was possible to calculate effect sizes). However, effect sizes of the aforementioned studies for improvements in the quality of the mother-infant relationship were more modest by comparison. The intervention which focused on the quality of the dyad relationship demonstrated the largest effect size with respect to improvement in the quality of the mother-infant relationship. Indeed, changes were observed on some subscales and not others. While the majority (14/15) of studies measured mother-infant interaction outcomes, only four studies measured child developmental outcomes and effect sizes were small. This highlights an incongruence of therapeutic effect across child outcomes, despite overwhelming research evidencing the
impact of PND on short and long term developmental patterns. In terms of intergenerational transmission of risk to children, it is difficult to deduce whether reported improvements in mother-infant relationships were due to improvements in developmental outcomes or improvements in PND, or whether there is a bidirectional link (Poobalan, et al., 2007).

The findings from this review are comparable to those of Poobalan et al. (2007), an earlier review of eight RCTs aimed at treating PND through targeting the mother-infant relationship. Specifically, it confirms that improvements in dyadic interaction do not necessarily preclude improvement in child developmental outcomes. Strikingly, the size of the intervention effect on maternal outcomes was incongruent with those calculated on measures of infant development and the quality of the mother-infant interaction. Indeed, these findings may suggest that improvements in maternal mood may be necessary, but not sufficient to improve additional dyadic and/or child developmental outcomes alone. Reflecting on the mechanisms implicated in the intergenerational model of risk (by Goodman & Gotlib, 1999) this makes sense given the multiple mediating and moderating factors implicated in the transmission of psychopathological risk from mother to infant.

The findings presented here must be interpreted in light of several methodological limitations. A large proportion of the studies obtained inadequate scores on the CTAM. Many of the studies were characterised by small, biased sample sizes. This may yield false negative findings and an oversight of potentially effective treatments. Many also failed to describe the allocation and randomisation process, thereby reducing methodological rigour. Furthermore, whilst most studies employed the use of blind assessors, the process of blinding was not described. Although the majority of the studies used an RCT design many did not handle drop out appropriately (i.e., only analysing treatment completers). Furthermore, fewer than half of the included studies described intervention protocol and/or methods to ensure treatment fidelity; this highlights the lack of quality assurance. The methodological observations are comparable with the extant literature (Boath & Henshaw, 2001; Dennis, 2004).

The correlation between direction of effect size and strength of methodological quality is comparable to previous studies using the CTAM for assessment of trial methodological quality. An explanation for this may be due to the standard of reporting or length constraints of the journal in which they were published. One method for improving the quality of reporting RCTs is to implicate the use of CONSORT. It outlines the gold standard for conducting RCTs and will enable direct comparison between efficacy of RCTs. Alternately, Cuijpers, Brannmark and van Straten (2008) recommended using the
Cochrane Handbook to ensure quality. Only four studies in this review presented CONSORT or participant flow diagrams.

There were also several observations with regard to participant characteristics which warrant attention. Firstly, there was wide heterogeneity across study client inclusion criteria. Specifically, some studies included clients with a diagnosis of PND made by a professional while others, a probable diagnosis through screening measures alone, such as the EPDS. Although probable diagnosis is cost and time effective, there is a limitation that researchers who rely exclusively on screening questionnaires for eligibility are including participants who are experiencing co-morbid diagnoses which may invariably influence treatment efficacy. Secondly, we observed homogeneity in marital status, with a large proportion of women being in married/cohabiting relationships. The proportion of partners who are supportive is also unclear. Thirdly, there was a large degree of variability with regard to variables including age of the infant. There were also heterogeneity in terms of the severity and course of the depressive episode.

An additional observation is the impact that parity has on outcomes. For example, difficulties experienced may vary depending on whether mothers are primiparous or multiparous. Indeed, research has shown that primiparous and multiparous mothers experience different mother-infant relationship problems at three months postpartum (Righetti-Veltema, Conne-Perreard, Bousquet, & Manzano, 2002). This variance may be explained by differences between multiparous and primiparous mothers in adjustment to parenthood (Gameiro, Moura-Ramos, & Canavarro, 2009).

These methodological observations make it difficult to determine what to target in treatment, how long to do it for and what delivery modality. McLennan and Offord (2002) have suggested that further research is needed to establish the role of PND as a risk factor to determine whether it should be targeted for improving developmental outcomes.

The necessity to integrate a developmental perspective into the conceptualisation of how PND affects the mother and infant is clearly indicated. Without such integration, treatment research will remain limited. The role parents’ play in regulating their infants’ emotional states may be a key element in improving treatment efficacy and promoting long-term effectiveness (Goodman, Broth, Hall, & Stowe, 2008). There is a strong impetus for focusing on parenting skills and strategies as a medium for strengthening and protecting the mother-infant relationship, and supporting vulnerable parents as they adapt to parenthood. Despite significant reductions in depressive symptomatology, effect sizes (calculated where possible) are generally modest. While improvements to maternal mental
health have been assessed, it remains important to also assess both short and long term
benefits, if any, to the mother’s ability to respond sensitively to her infant.

The transition to parenthood is a period marked by significant role adjustment for
the whole family. In the context of PND, parenting is proposed to be sub-optimal. Meany
(2001) proposed a direct link between the nature of parental care and atypical
developmental outcomes. The central assertion is that maladaptive parenting behaviours
increase the risk of psychopathology, such as depression and anxiety. Conversely, it has
been proposed that warm and supportive or optimal families tend to promote resilience to
stress-related illnesses. This is a pertinent issue in primary caregivers (namely the mother)
who are experiencing mental health difficulties.

The benefits of interventions for PND to child development remain limited given
research. It remains difficult to draw conclusions from the research or compare studies as a
result of study limitations which prevent researchers and clinicians from doing so. There
are several limitations in the context of the present review. Firstly, it was not possible to
calculate all effect sizes, which made it difficult to make comparisons across all studies
reviewed.

The findings from this review have implications for the psychological treatment of
PND and future research. While certain interventions have been shown to be effective for
treating PND, it is still unclear where the benefits lie for child development and the quality
of the dyadic relationship. This is evidenced by incongruence between effect sizes for
improvements in maternal mood and dyad and developmental outcomes. Indeed, an
improvement in maternal mood did not necessitate an improvement in developmental
outcomes (i.e., McLennan, & Offord, 2002) as illustrated by the disparity in maternal, dyadic
and child outcomes reported in the present review. However, the incongruence
between early outcomes may also be the result of a time delay between improvements in
maternal mood and expectations from the infant resulting in the observed discrepancy.
There may be a period of adjustment for the baby following improvements in maternal
mood resulting in an observed dis-synchrony between the dyad. In order to investigate this,
long term follow-ups of the mother-infant relationship are warranted.

Future research should continue to include developmental and predictive measures
of vulnerability towards future developmental psychopathology (Carter, Briggs-Gowan,
Jones, & Little, 2003). Although more costly, by including these measures we are able to
answer questions about long-term effectiveness. There is also a need to acknowledge
fathers when administering treatment. The Goodman and Gotlib (1999) model details that
fathers may moderate the transmission of risk. Interventions and research more widely
have often neglected the role of the father in parenthood. Since it is a period of adjustment, it is likely that fathers will also face challenges in becoming new parents, including redefining their relationship and roles with their spouse and importantly learning to respond adaptively to their babies.

There is a further need to think about the method of intergenerational transmission of risk from parent to infant. In doing so, research will need to consider the dyadic relationship and interactions between the parent (most commonly the maternal caregiver) and the developing infant. Risk factors (i.e., socio-demographics) associated with PND as well as the concept of sensitive periods in development and resilience to adversity (infants are particularly vulnerable to PND, due in part to development of neuro-regulatory mechanisms) need to be kept in mind (Goodman & Gotlib, 1999; Meaney, 2001). In summary, interventions need to acknowledge the mother as an individual agent but also the role of mother as a regulator of the infant state.

Research with clients from under-represented groups with PND including black and ethnic minority populations is warranted. We found no studies, within the limits of our search criteria, which investigated effectiveness of interventions for PND in low income or developing nations populations. For instance, two interventions; either monthly supportive visits or community group drop in session or TAU, given to women from culturally diverse backgrounds failed to produce significant change in main outcomes (child injury, maternal smoking, maternal depression) at 12-month and 18-month follow-ups (Wiggins et al., 2005). As such, the effect size data should be considered in light of the limitations and wide variety of interventions.

The findings from this review are subject to some limitations. Firstly, strict search terms were used due to the volume of papers returned in initial searches, as such, it is possible that some studies were excluded. Secondly, it was not possible to calculate effect sizes across all domains (maternal mood, mother-infant relationship, child developmental) of assessment due to missing data. Thirdly, having included studies which assessed participant eligibility through the use of screening measures may affect the reliability with which the results are interpreted. For example, we cannot be certain that participants were experiencing major depression exclusively.

Despite the evidence for the benefits, the review literature on the subject has highlighted that there is insufficient evidence to recommend a specific treatment and further research is warranted (Cuijpers, et al., 2008; Dennis, 2004; Poobalan, et al., 2007). The understanding of efficacious interventions for PND is further complicated by poor methodological quality.
Maternal wellbeing and child development are inextricably linked. Our review has highlighted the relative neglect of this link when intervening and the limitation in research methodologies. This review underscores the need for further research to continue to measure the quality of the mother-infant relationship, but also to add measurements of child development and long-term outcomes to their research programmes. Further research which addresses the highlighted methodological limitations is warranted. Until then, we can make no recommendation for any intervention over another.
References


Chapter 3

Relevance of targeting parenting in PND and an introduction to the Triple P framework and the Baby Positive Parenting Programme
3.1 Introduction
The previous chapters of this thesis have outlined the implications postnatal depression (PND) has on the mother and her relationship with her infant as well as child developmental outcomes. In Chapter 2, a poverty of interventions targeting parenting in the treatment of PND was identified, despite the link to adverse child outcomes. Children of parents with mental health difficulties, including PND, are at increased risk of atypical social and emotional development. Although parental mental illness may remit, the impact of the quality of early parenting may continue to manifest itself across the lifespan.

The present chapter has the following aims: 1) to outline a rationale for why the Baby Positive Parenting Programme (Baby Triple P) may be helpful for women with PND, 2) to provide an overview of the Triple P Positive Parenting Programme system, and finally, 3) to detail the structure and summarise the session content of Baby Triple P.

3.2 The application of Baby Triple P to PND
The National Society for Prevention of Cruelty to Children (NSPCC) has raised awareness about the vulnerability of infants. Specifically, infants under one make up eight to 12% of child protection cases (DHSSPSNI, 2008), 47% of serious case reviews (Department for Education, 2010) and are eight times more likely than children of other ages to be the victim of homicide (Department for Education, 2010). Policy makers have also heeded that good parenting sets the foundation for a positive start in life (Allen, 2011; Field, 2010). Consequently, the antepartum and postnatal year have been identified as “windows of opportunity” for intervention and support to parents (p.4, Cuthbert, Rayns, & Stanley, 2011). Furthermore, based on Heckman’s economic modelling of rates on return of investment of human capital, the early years is a favourable period of time to focus on (Heckman & Masterov, 2004).

Considerable research has established that parental psychopathology can affect the quality of parenting (Belsky, Conger, & Capaldi, 2009; Manning & Gregoire, 2006; Meaney, 2001). In the context of PND, difficulties in practical parenting practices related to breastfeeding (Dennis & McQueen, 2007; McLearn, Minkovitz, Strobino, Marks, & Hou, 2006a, 2006b), sleep (Dennis & Ross, 2005; Hatton, Harrison-Hohner, Dorato, Curen, & McCarron, 2005; Hiscock & Wake, 2001), infant healthcare (Minkovitz et al., 2005) and safety practices (McLearn, et al., 2006a, 2006b; Zajicek-Farber, 2009, 2010), have been reported. Child developmental literature also highlights that while there are many factors which influence developmental pathways, maladaptive parenting practices act as a major
risk factor for atypical development, making children more vulnerable to psychopathology (Meaney, 2001).

Research also indicates that targeting parental psychopathology alone may not be sufficient to improve child outcomes (McLennan & Offord, 2002; O’Hara, 2009; Poobalan et al., 2007). Additionally, there is little evidence in favour of one treatment in particular. Since the quality of the mother-infant relationship is an important factor in child development, an intervention targeting parenting may be helpful at promoting more adaptive parenting behaviours and therefore the quality of mother-infant relations.

Given the difficulties women with PND experience with parenting and the poverty of parenting interventions in this area, the focus of this thesis was to investigate the acceptability and efficacy of a new variant of the Triple P Positive Parenting Programme. Baby Triple P was designed specifically for new parents. For the purposes of this thesis Baby Triple P was piloted in a sample of women experiencing PND. All sessions were therefore delivered in the postnatal period, once women with PND had been identified.

Earlier Triple P research carried out by Sanders and McFarland (2000) found that depressed mothers of older children (aged 3-9 years, M= 4.39 years) with disruptive behaviour experienced reductions in depressed mood and child disruptive behaviour following participation in both Behavioural Family Intervention (BFI) and Cognitive Behavioural Family Intervention (CBFI). They also found sustained improvements at six-month-follow up and favourable outcomes in the CBFI compared with BFI. The outcomes from this research suggest that a parenting intervention could be sufficient to alleviate depressive symptomatology without necessarily focusing exclusively on maternal mood.

3.3 An overview of the Triple P Positive Parenting Programme

Triple P is a system of parent training programmes with varying levels of intensity depending on the level of need of individual families (Sanders, 2012). For example, some families may need support pertaining to specific problems, whereas other families experience more severe levels of disturbance across many domains. The theoretical foundations are largely grounded in learning theory (Baer, Wolf, & Risley, 1968), cognitive social learning theory (Bandura, 1995), developmental research (Hart & Risley, 1975), developmental psychopathology (Patterson, 1982; Rutter, 1985) and public health models (Mazzucchelli & Sanders, 2010).

There are five levels in the Triple P system, outlined in Figure 1. The levels increase in intensity, including the following: very low level of intensity aimed at the universal population (Level 1), low level of intensity (Level 2), low to moderate level
intensity (Level 3), moderate to high intensity (Level 4) and highest intensity appropriate for parents with marked levels of family distress and dysfunction (Level 5). The rationale for the separate levels in the intervention is based on the principle of minimal sufficiency, to provide a level of support which is “enough” to promote change (i.e., parents practising more adaptive parenting behaviours) and not more than is required. Some parents will require less intense interventions in order to meet their goals for change. This public health approach is also economical and maximises population reach (Kazdin, 2011).

Figure 1. The Triple P intervention system

The same five core principles guide intervention at every level of the programme, these include 1) ensuring a safe and engaging environment, 2) providing a positive learning environment, 3) using assertive discipline, 4) having realistic expectations of yourself as a parent, and 5) taking care of yourself as a parent. The operationalisation of these principles is flexible in order to suit the needs of individual families but ultimately the integrity of the intervention is preserved. For example, at various levels of the intervention there may be subtle differences in how the skills are explained and implemented. Flexibility has been highlighted as one of the major advantages of the Triple P system (Kazdin & Blase, 2011; Mazzucchelli & Sanders, 2010). However, the varying degrees of intervention intensity, targets and delivery formats of the various levels in the Triple P system present a challenge for evaluation.
3.4 Possible mechanisms involved in Triple P

Improvements following Triple P treatment and long-term maintenance of effects are thought to be associated with increased parental self-regulation (Sanders, Mazzucchelli, & Ralph, in press). Self-regulation is defined as “those processes, internal and/or transactional, that enable an individual to guide his/her goal directed activities over time and across changing circumstances. Regulation implies modulation of thought, affect, behaviour or attention via deliberate or automated use of specific mechanisms and supportive metaskills. The process of self-regulation is initiated when routine activity is impeded or when goal directedness is otherwise made salient” (p. 25; Karoly, 1993).

Within the context of Triple P, increases in self-regulation are thought to arise through parents modifying their parenting behaviours. Adaptive self-regulation is thought to involve operationalising of four concepts (p. 6, Sanders, Markie-Dadds, & Turner, 2001), including; 1) self-sufficiency: self sufficient parents have resilience, resourcefulness, knowledge and skills to parent with confidence, 2) parental self-efficacy: parents believe that they can overcome and deal with problem behaviours, 3) self-management: tools and skills that parents can use to become more self-sufficient including: self-monitoring, self-determination of goals and performance standards, self evaluation of their own performance against performance criterion and self selection of change strategies, and 4) personal agency: attribution of changes or improvements in their child’s behaviour or their own rather than to chance, age, maturational factors or other uncontrollable events. It is thought that parents’ generalise skills and knowledge acquired in the programme beyond context of the intervention itself. Furthermore, this generalisation of skills and knowledge is associated with long term maintenance of intervention effects.

3.5 The Triple P evidence base

Triple P is supported by over 30 years of clinical efficacy and effectiveness trials (Sanders, 2012). The majority of research exists for parents of children aged two to 18 years of age. The core Triple P Programmes include the following: Universal Triple P (Level 1), Selected Triple P, including: Seminar Series and Brief Primary Care Triple P (Level 2), Primary Care Triple P (Level 3), Standard Triple P, including: Group and Self-Directed Triple P (Level 4) and Enhanced Triple P (Level 5). Adaptations across levels have also been made to meet the needs of parents of children with learning disabilities (Stepping Stones; Sanders, Mazzucchelli, & Studman, 2003; Whittingham, Sofronoff, Sheffield, & Sanders, 2009), obesity (Lifestyle Triple P; West, Sanders, Cleghorn & Savies, 2010), teenagers (Teen Triple P; Sanders & Ralph, 2001), parents in the workplace, and parents...
from Australian indigenous communities (visit http://www.pfsc.uq.edu.au/research/current.html for more details of these programmes).

Foundational research for further adaptations are also in progress and include (not limited to) programmes to meet the needs of grandparents (Triple P for grandparents; Kirby & Sanders, 2012), children who are bullied (Resilience Triple P; Healy & Sanders, under development) and parents during the transition to parenthood, (Baby Triple P; Spry, Morawska & Sanders, 2009). There is comparatively less research which has investigated the efficacy and clinical effectiveness of Triple P for parents of children under the age of two. However, the biggest return on investment into services is in the early years (0-2; Heckman & Masterov, 2004). The focus of this thesis is on a new variant of Triple P developed for parents with infants (0-12 months).

Despite the proposed strong evidence base, there have been a number of criticisms of Triple P. A recent metanalysis and systematic review by Wilson and colleagues (2012) reported a number of limitations to the Triple P evidence base. They suggested that recruitment methods were primarily by self-selection and media, which introduces a sampling bias. However, in their reply, Sanders et al. (2012) argued that the nature of the randomised design would minimise the impact of any sampling bias.

Wilson et al. (2012) also highlighted that there is little Triple P research with paternal data, although this appears to be a limitation of the parenting literature. Further outlined limitations included that there were no studies comparing Triple P to other parenting programmes, that many of the study designs are limited to waitlist control, there are limited long-term maintenance effects reported within the literature and that many of the studies are developer-led (Wilson et al., 2012). The assertions relating to design and long-term maintenance effects were challenged by Sanders et al. (2012) in their reply. For example, there are a mixture of developer led and non-developer led research studies reporting maintenance effects lasting between six months and three years (Bodenmann, Cina, Ledermann, & Sanders, 2008; Dean, Myors & Evans, 2003; Magarey et al., 2011; Naumann, Kuschel, Bertram, Heinrichs, Hahlweg, 2007; Plant & Sanders, 2007; Sanders, Bor & Morawska, 2007; Sanders & McFarland, 2000; Sanders, Stallman, & McHale, 2011).

With respect to the criticism relating to Triple P studies being developer led, Sanders and Kirby (2012) have outlined a comprehensive process for ensuring quality in the programme development process. Furthermore they indicated that while 80 of 140 trials had involvement of developers at some level of programme development of Triple P, 60 have had no developer involvement at any level (i.e., the study is conducted at an
independent institution, the developer is not involved in the publication or any stage of the research process; Sanders & Kirby, 2012).

3.6 Parenting programmes with variants for new parents
Chapter 1 and 2 sought to review the available research on range of a) treatments for PND, and b) treatments for PND which had also assessed child developmental outcomes and the mother-infant relationship in addition to maternal mood. Parenting specific programmes were not identified through the above searches. Therefore, additional searches were undertaken to find parenting programmes. As previously introduced in this chapter, the bulk of parenting interventions have mainly focused on children over the age of two years of age. Variants of parenting programmes specifically for women with PND are less well known and under researched compared with their contemporary treatments (CBT, IPT, anti-depressants, psychoeducation, etc.). Nonetheless, there are several adaptations which are under development or in the initial stages of efficacy trials. There are further programmes which are targeted at the universal level these will not be considered here. Three variants are described here including, Incredible Years; Mellow Parenting; and the Parent-Baby Game.

All of Incredible Years (Webster-Stratton & Reid, 2003), Mellow Parenting (Puckering, Rogers, Mills, Cox, & Mattson-Graff, 1994) and the Parent-Child Game (McMahon & Forehand, 2003) have adaptations for parents with babies; the Incredible Years Parent and Baby Programme (Webster-Stratton, 2008), Mellow Babies (Puckering, McIntosh, Hickey, & Longford, 2010) and the Parent/Baby Game (Jenner, 2008) respectively.

The Incredible Years Parent and Baby Programme variant focuses on six aspects of the transition to parenthood, including learning to make sense of infant signals and cues, responding appropriately, gaining an understanding of infant development (specifically, neural development and development of object and other), providing infants with stimulating environment, learning to communicate with the infant and making time for the self. The programme was piloted in Essex, UK with a community sample of 11 parents (Gordon & Richards, 2008). The findings suggested that the intervention was acceptable to parents who took part. However the reported findings are preliminary and limited by the small sample size, lack of control group and absence of validated outcome measures. The programme was not carried out with a clinical sample and so the findings are limited in their generalisability. Furthermore, there was no demographic information available. Further investigations are required.
Mellow Babies is an intensive, 14-day programme designed to 1) enhance mother-infant attunement, and 2) address maternal distress (Puckering, et al., 2010). There is one small wait-list controlled trial of Mellow Babies in a PND sample (Puckering, et al., 2010). It was reported that women who attended Mellow Babies reported significantly lower levels of depression (as measured by the EPDS) and greater positive interaction (as measured by the Mellow Parenting observation coding scheme) with their babies compared with wait-list controls at post-intervention (Puckering, et al., 2010). These findings are subject to limitations in the reporting of methodological information, including participant characteristics, sampling procedures and methods used to collect the data. Additional limitations include the small sample size (N=17), and that PND was determined by EPDS scores alone (which does not confirm major depressive illness or rule out co-morbid conditions).

The Parent/Baby game is based on social learning theory, child development theory and attachment (Jenner, 2008). The therapy involves the same ‘bug in the ear’ technique (used in the Parent/Child game) to guide parents to interact more sensitively with their infants. Despite its successful use with parents of older children (Kotler & McMahon, 2004) the Parent/Baby game has yet to be trialled in new mothers and, more specifically women with PND.

The aforementioned programmes have been used successfully with parents of older children. However, there have been no published effectiveness or dissemination trials on any of these programmes. Moreover, they have not been subject to investigation within the target population: women with PND. Therefore the following section provides an overview of the prospective programme, Baby Triple P, which will be piloted in a sample of women with PND.

3.7 An overview of Baby Triple P
The Baby Positive Parenting Programme (Spry, Morawska & Sanders, 2009) is a newly developed group variant (Level 4) of the Triple P system for expectant and new parents. Baby Triple P maintains the same core principles as Triple P, with the exception of using assertive discipline; instead the core principle is creating a predictable environment.

The intervention consists of eight sessions, including Positive Parenting (Session 1), Responding to your baby (Session 2), Survival skills (Session 3), Partner support (Session 4), Implementing parenting routines 1 (Session 5), Implementing parenting routines 2 (Session 6), Implementing parenting routines 3 (Session 7), Implementing parenting routines 4 and programme closure and maintenance (Session 8). Sessions 1-4 are designed
to be delivered antenatally and Sessions 5-8 (the four implementing parenting routines sessions) are delivered via telephone consultation in the postnatal period.

Sessions 1 and 2 cover all Triple P strategies identified to be appropriate for parents of babies and include 1) developing a positive relationship: spending time with baby, communicating with baby, affection; 2) responding to baby: encourage contentment, settling techniques, diversion, establish limits and 3) teaching new skills and behaviours: praise, attention, interesting activities and flexible routines. Sessions 3 and 4 were adapted from Level 5 (Enhanced Triple P) and designed to meet additional risk factors including parental mood and couple conflict. Session 5 to 8 are brief consultations designed to address remaining issues parents have through promoting parental self-regulation (content for each session is detailed in Table 1).

3.7.1 Promoting self-regulation using the self-evaluation framework

In order for the parent to successfully change their parenting behaviours and maintain those changes, as well as generalisation of skills to other contexts, it is proposed that parents undergo improvements in their self-regulatory skills (defined earlier). During the session the role of the Triple P practitioner is not to advise or instruct the parent, but to aid the parent in reflecting on their performance in the parenting role. This involves using the self-evaluation framework. For example, a parent may have practiced implementing a routine, for example a bedtime routine. Following the implementation of the routine, the role of the practitioner is to prompt the parent to reflect on how they went by asking a series of questions designed to instigate reflection. The question framework for the practitioner is as follows

A. How did that go?
B. What did you do well?
C. What didn’t go so well?
D. What could you do differently next time?

This same framework is used after every practice or parenting issue the parent undertakes, with the aim to promote an adaptive way of thinking about a parenting problem or issue. If parents can identify what they are doing well in a parenting situation and what they might adapt in future then they can improve their problem solving and their belief in their ability to problem solve. This pattern of problem solving reflects the core of self-regulation.
### Table 1. Baby Triple P session content

<table>
<thead>
<tr>
<th>Session title</th>
<th>Content</th>
<th>Triple P strategies</th>
<th>Session duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session 1</strong></td>
<td><strong>Positive parenting</strong></td>
<td>- Spending time with baby&lt;br&gt;- Communicating with baby&lt;br&gt;- Showing affection</td>
<td>1-1.5 hrs</td>
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<td></td>
<td>- Introduces parents to the aims of the positive parenting programme as an approach to parenting&lt;br&gt;- Provides an overview of factors that impact on baby development and strategies for promoting development and relationship with baby&lt;br&gt;- Parents set goals for relationship with baby and family</td>
<td>- Praise&lt;br&gt;- Attention&lt;br&gt;- Providing interesting activities&lt;br&gt;- Encouraging contentment&lt;br&gt;- Settling techniques&lt;br&gt;- Diversion&lt;br&gt;- Establishing limits</td>
<td></td>
</tr>
<tr>
<td><strong>Session 2</strong></td>
<td><strong>Responding to your baby</strong></td>
<td></td>
<td>1-1.5 hrs</td>
</tr>
<tr>
<td></td>
<td>- Introduces strategies for responding to baby and teaching new behaviours and skills through praise, attention, providing interesting activities and routines&lt;br&gt;- Covers why babies sleep and cry and strategies for managing infant distress and sleeping difficulties as well as strategies for promoting adaptive sleeping routines</td>
<td>- Coping statements&lt;br&gt;- Relaxation and stress management&lt;br&gt;- Abdominal breathing&lt;br&gt;- Finding out what you need to know&lt;br&gt;- Support&lt;br&gt;- Coping plans for high-risk situations&lt;br&gt;- Catching/challenging unhelpful thoughts</td>
<td></td>
</tr>
<tr>
<td><strong>Session 3</strong></td>
<td><strong>Survival Skills</strong></td>
<td></td>
<td>1-1.5 hrs</td>
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<td></td>
<td>- Focuses on common experiences of new parents when having a baby (i.e., parenting traps- unhelpful ways of thinking about parenting which make parenting more difficult and may lead to negative emotions)&lt;br&gt;- Also covers what unpleasant emotions (i.e., anger, sadness, depression and anxiety) are and explores how they work and how they affect parenting&lt;br&gt;- Socialisation to ABC model&lt;br&gt;- Identification of negative automatic thoughts&lt;br&gt;- Coping strategies are covered (i.e., catching unhelpful thoughts, abdominal breathing, positive self talk, social support, developing personal coping plans)</td>
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110
<table>
<thead>
<tr>
<th>Session title</th>
<th>Content</th>
<th>Triple P strategies</th>
<th>Session duration</th>
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</table>
| Session 4 Partner Support  | - Covers common experiences of couples during the transition to parenthood (i.e., partner traps- unhelpful ways of thinking about the partner relationship which lead to difficulties in the partner relationship)  
- Also covers the importance of communication skills, maintaining relationship happiness, negotiating household and baby care tasks | - Improving communication  
- Giving and receiving constructive feedback  
- Having casual conversations  
- Supporting each other when problem behaviour occurs  
- Problem solving  
- Improving relationship happiness | 1-1.5 hrs |
| Session 5 Implementing parenting routines 1 | - These sessions employ the use of the self-evaluation framework. The practitioner prompts self evaluation in the parent to promote parental self-regulation  
- The practitioner aims to give little prompting to promote self-regulation. | - As above | 30-40 mins |
| Session 6 Implementing parenting routines 2 | - As above (session 5) | - As above | 30-40 mins |
| Session 7 Implementing parenting routines 3 | - As above (session 5) | - As above | 30-40 mins |
| Session 8 Implementing parenting routines 4 and maintenance and closure | - Final implementing parenting routines session (as above)  
- Client progress is reviewed and goals for future set  
- Covers phasing out the programme and identifying obstacles (high risk times) and strategies for maintaining change | - As above | 1 hr |
3.7.2 Possible mechanisms involved

The mechanisms of adaptive self-regulatory processes were introduced earlier in this chapter. Triple P proposes that change is brought about by increased ability to self-regulate. Bandura (1991) explained that just as functional self-regulatory processes promote self-sufficiency and psychological well-being, dysfunctional self-regulatory mechanisms can promote negative affect. Specifically, he argued that depression was associated with a negative misperception of achievements and that successful treatment would repair the self-regulatory dysfunction (Bandura, 1991). The dysfunctional parenting practices and difficulties within the mother-infant interaction associated with PND could be explained as the product of dysfunctional self-regulatory processes. Within this conceptual framework there is a negative bias on Bandura’s (1991) subfunctions, 1) self-monitoring of behaviour, 2) judgement of behaviour, and 3) affective self-reaction.

Although this conceptual framework offers a compelling potential explanation of the possible mechanisms and processes involved in changes associated with participation in a parenting programme such as Triple and more specifically within the context of PND, there are some limitations. For example, although it appears to be a widely defined concept, there is little empirical evidence to support the theoretical framework of self-regulation and its operation in the context of clinical intervention. Indeed, whilst there are some measures of aspects of self regulation (i.e., self-sufficiency), to date there is no comprehensive, reliable measure of self regulation (Sanders & Mazzucchelli, under review), although this is the subject of Chapter 5 of this thesis.

In line with the limited empirical support for self-regulation, there could be other explanations for behavioural change in the context of parenting interventions. For example, attachment theory (i.e., Ainsworth, Blehar, Waters, & Wall, 1978; Bowlby, 1978) provides an additional explanation for changes associated with participation in parenting programmes (O’Connor, Matias, Futh, Tantam & Scott, 2012). Within the attachment framework adaptive development is promoted by responsive and sensitive parenting which leads to the child internalising a sense of the parent as reliable. The internalisation is described as an internal working model (O’Connor et al., 2012). Further support for an attachment explanation is evidenced in a meta-analysis which reported improvements across attachment measures in behaviourally targeted interventions (Bakermans-Kranenburg, van Ijzendoorn, Juffer, 2003).
3.8 Summary

The aim of this chapter was to provide an overview of the Triple P Positive Parenting Programme. It follows on from the previous PND treatment review chapters to highlight that despite the evidence supporting the difficulties women with PND experience, parenting has been relatively neglected from the treatment of PND. For this reason, an outline of the rationale for the application of a new variant of Triple P, Baby Triple P for the treatment of women with PND has been provided. The following chapters will detail the methodology utilised in this thesis as well as two empirical papers: one focusing on the development of a measure of self-regulation, while the second paper details the results of a pilot trial of Baby Triple P in a sample of women with PND. The final chapter will serve as a critical discussion of the findings from this thesis as well as providing a projection of future research.
References


Chapter 4

Methodology for Chapters 5 & 6
4.0 Overview

The following chapter provides comprehensive details of the methods utilised in two studies: (1) the validation of the Parenting Beliefs Scale for Parents with Babies (PBS-b; Sanders, 2012) and (2) the methods for the main study, the pilot trial of the Baby Positive Parenting Programme (Baby Triple P) in women with Postnatal Depression (PND). These include the research design, participant characteristics (i.e., eligibility and inclusion criteria), sampling procedures (i.e., sampling method, sample size and power), measures and ethical considerations. This chapter serves as a supplement to the shorter empirical papers.

4.1 Methodology for validation of Parenting Beliefs Scale for Parents- baby version

4.1.1 Design

This was a single group design to explore the factor structure and psychometric properties of a measure of self-regulation, the PBS-b (Sanders, 2012). All participants completed questionnaires at two times points, nine weeks apart (to examine the scale’s repeatability). Face validity of the scale was determined by refining items in order to establish agreement on their meaning, i.e., that the items reflected the parenting concepts they purported to measure. This was achieved through MS, a parenting expert constructing the items and labelling them and then ZT verifying them to reach agreement. Labelling of items was guided by the theoretical model of self-regulation (Sanders & Mazzucchelli, under review).

4.1.2 Measures

4.1.2.1 The Parenting Beliefs Scale-Baby

The Parenting Beliefs Scale-Baby (PBS-b; Sanders, 2012) (Appendix, p. 219) is a 22-item self-report measure designed to assess self-regulation around parenting adapted for new parents. Statements are rated on a 6-point Likert scale. The central tenets of the effectiveness of Triple P Programmes posit that programme success is related to a change which occurs in parents’ ability to self-regulate. Self-regulation is proposed to be made up of four concepts (sub-scales), including parental self-sufficiency, personal agency, parental self-efficacy and self-management. Increases in parental ability to self-regulate are proposed to be related to successful uptake and long-term maintenance of the strategies implicated in Triple P.

4.1.2.2 The Edinburgh Postnatal Depression Scale

The Edinburgh Postnatal Depression Scale (EPDS; Cox, Holden & Sargovsky, 1987) (Appendix p. 210) is a 10-item self report measure of postnatal depression related
symptoms rated over the past seven days. Scores range from 0 to 30, a score of 12 indicates probable depression. The EPDS was designed to eliminate somatic factors associated with the postnatal context which might confound scores (Flynn, Henshaw, O'Mahen, & Forman, 2010). It has demonstrated good psychometric properties in PND samples, internal consistency was 0.87 (Cox, et al., 1987) and scale repeatability between .87 and .88 (Dennis, 2004). Sensitivity ranges between 34-100% and specificity, between 44-100% (Gibson, McKenzie-McHarg, Shakespeare, Price, & Gray, 2009). It has been shown to be the most effective tool in identifying probable symptoms specific to PND and has been validated and used widely as an outcome measure in randomised controlled trials (RCTs) (Hanusa, Scholle, Haskett, Spadaro, & Wisner, 2008; Lee & Chung, 2007) and as a routine screening tool in the NHS. For the purposes of this study it was used to screen for increased risk of PND.

4.1.2.3 The Family Background Questionnaire
The Family Background Questionnaire (FBQ; Sanders, Markie-Dadds & Turner, 2001) (Appendix, p.219) is a self-report questionnaire used to collect demographic and psychosocial information. The FBQ is routinely used in Triple P research and clinical practise. It was modified for use with postnatal women to collect information surrounding pregnancy and birth.

4.1.3 Participant characteristics
4.1.3.1 Inclusion and exclusion criteria
In order to be eligible for inclusion, prospective participants had to be female, between the ages of 18 and 45 years, with a healthy baby (no known developmental delay or disability) under 12 months of age, and obtain an EPDS score below 10. A score of 10 was used in accordance with the literature which suggests that a score of 9/10 indicates mild symptoms (Gibson, et al., 2009). To complete the questionnaires, participants had to be proficient in English. Both primiparous and multiparous women were included. Participants were excluded if they did not meet all of the inclusion criteria.

4.1.4 Sampling procedures
4.1.4.1 Sampling method and recruitment
A convenience sample of mothers were recruited through various routes including the University of Manchester email system, NCT mother-baby groups, online parenting forums, word of mouth, baby massage groups, etc.
4.1.4.2 Sample size
For the purposes of validating a 22-item questionnaire with approximately four factors, it was determined that 100 participants (around 4-5 participants per item) would be needed. This assumption was based on heuristics for ensuring stable factor structures as suggested by (Ferguson & Cox, 1993). They suggested a minimum number of participants (100-200), a participant to item ratio of between 2:1 and 10:1, a proportion of items to expected factors and subjects to expected factors to be between 2:1 and 6:1. For the purposes of assessing repeatability of the PBS-b, at least half of the sample (50 participants) would need to be retained at Time 2 (9 weeks later).

4.1.5 Procedure
The majority of participants completed the study online. An information sheet (Appendix, p. 229) was provided and participants agreed to take part before continuing. Participants were free to withdraw at any time. Data from participants who completed the study online was stored on a secure server and paper data was stored in accordance with the university regulations. Contact details were stored separately to the main datasets. Participants who consented to being contacted for a follow-up were invited to complete the PBS-b at a second time point (9 weeks later).

4.1.6 Ethical considerations
This study involved a healthy control sample, therefore, ethical approval was granted by a University of Manchester research ethics committee. Since there was a possibility that some women may have screened positive for depressive symptoms, all participants were provided with information (Appendix, p.263) detailing the symptoms of PND and several support links.

4.2. Methodology for pilot trial of Baby Triple P in women with PND
4.2.1 Design
This was a randomised controlled trial (RCT), stratified for severity of maternal depression, which compared the effectiveness of adding Baby Triple P to treatment as usual (TAU) in a sample of women with PND. A 2 (groups: intervention versus TAU) x 3 (assessment time points: pre- and post-treatment phase and 3-months) longitudinal design was used. Baby Triple P, originally developed as a group programme, was delivered in eight individual sessions facilitated by the Triple P accredited practitioner (ZT) (see Chapter 3).
4.2.2 Measures

Assessment and confirmation of diagnosis

4.2.2.1 Edinburgh Postnatal Depression Scale (EPDS)

Please see section 1.3 for a description of the EPDS (Appendix, p. 210; Cox, et al., 1987). For the purposes of this study it was used as a preliminary eligibility screen to assess for probable PND (scores of $\geq 10$).

4.2.2.2 Structured Clinical Interview for DSM Disorders (SCID-PND$^3$)

The SCID-PND (Gorman et al., 2004) is an adapted version of the SCID, which was developed for use with a PND population in a transcultural study of PND. It is a structured clinical interview used to verify a diagnosis of depression. A clinical diagnosis of depression is sought to ensure symptoms severity is due to depression and not a general set of symptoms of psychological distress related to different psychopathology (Lovejoy, Graczyk, O'Hare, & Neuman, 2000). The SCID was also used to eliminate false positives associated with using the EPDS as a diagnostic tool (Gibson, et al., 2009).

Major adaptations include deletion of certain modules and the addition of screening questions that were not part of the original SCID, alternative psychotic and mania screening questions, insertion of a smoking history module, and replacement of the summary scores sheets with a newly developed SCID recording form. Minor adaptations include rewording the original screening questions for alcohol abuse/dependence, substance abuse/dependence, and obsessive-compulsive disorder and revising the overview section to include only education history and an expanded section on psychiatric treatment history. Permission was given to use the SCID-PND protocol for this research. In the present study screening modules for Mood Episodes (A), Mood Differential (D), Post Traumatic Stress Disorder (PTSD) (F 106-135), Generalised Anxiety Disorder (F 137-153) and Mixed Anxiety and Depression Disorder (J.21-J.38) were included. Anxiety was screened for because of its high prevalence in women experiencing PND.

4.2.2.3 Family Background Questionnaire (FBQ)

Please see section 1.3 for a description and use of the FBQ (Appendix, p.213; Sanders et al., 2001).

$^3$ The SCID-PND does not appear in the appendices due to copyright law.
Mood

4.2.2.4 Beck Depression Inventory (BDI-II)

The BDI-II (Beck, Steer, & Brown, 1996) is a 21-item self report measure which assesses severity of depressive symptoms on a 4-point scale. Scores range from 0 to 63, where high scores reflect increasing severity of symptoms. The BDI-II has been validated in women experiencing postnatal depression and has been widely used in postpartum samples (Boyd, Zayas, & McKee, 2006) and as a primary outcome measure across several treatment trials (Chabrol et al., 2002; Clark, Tluczek, & Brown, 2008; Clark, Tluczek, & Wenzel, 2003; Meager & Milgrom, 1996; Milgrom, Negri, Gemmill, McNeil, & Martin, 2005; Mulcahy, Reay, Wilkinson, & Owen, 2010; O'Hara, Stuart, Gorman, & Wenzel, 2000; Pearlstein et al., 2006; Stuart & O'Hara, 1995).

It has excellent psychometric properties. In a review of the BDI-II in postpartum samples internal consistency was 0.91 (Boy et al., 2006). Test-retest correlation was .93 in a general American outpatient sample (Becket et al., 1996). Although the BDI-II has been criticised for the inclusion of items which measure somatic symptoms, it was selected as the main outcome measure over other depression measures (i.e., the EPDS) for its favourable sensitivity to symptom severity. It has also been widely used as an index of clinically significant change (Kazdin, 2001).

4.2.2.5 Oxford Happiness Inventory (OHI)

The (OHI; Argyle, Martin, & Crossland, 1989) is a 29-item self report measure which measures broad personal happiness. The measure is made up of a reversal of BDI-II items and eight additional items to cover aspects of subjective wellbeing not measured by the BDI-II. The OHI has not been used in PND samples. Psychometric information is available from healthy samples. Internal consistency was 0.92 in an undergraduate sample (Argyle et al., 1989). The OHI was included since psychotherapeutic efficacy trials commonly prioritise the measurement of symptom reduction. There is little clinical research which measures happiness following intervention. Therefore, the OHI was used in this thesis to investigate any changes in positive emotional and cognitive state (Joseph, Linley, Harwood, Lewis, & McCollam, 2004).

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4 The BDI-II does not appear in the appendices due to copyright law.
4.2.3 Mother-infant interaction

4.2.3.1 The CARE Index
The CARE Index (Appendix, p.225; Crittenden, 2004) is a 3 to 5 minute, observer-rated video-taped interaction between mother-infant dyads. Video footage is taken in the home. Participants are instructed to interact with their baby in a way that is typical for them while the researcher films the interaction for 3-5 minutes. To capture typical behavior, infants’ must be awake, alert and not being fed. It provides information on 7 subscales including: maternal sensitivity, control, unresponsiveness and infant co-operation, compulsive/difficult responses or passivity. Scores on each of the sub-scales range from 0 to 14, where higher scores indicate higher sensitivity. It is suitable for infants up to the age of 15 months. It is a robust indicator of current dyadic synchrony and future attachment. The inclusion of this observer-rated parent-infant interaction is novel in the evaluation of Triple P outcomes.

4.2.3.2 Postpartum Bonding Questionnaire (PBQ)
The Postpartum Bonding Questionnaire (PBQ; Brockington et al., 2001) (Appendix, p.212) is a 25-item self report questionnaire which assesses change in subjective bonding perception between mother-infant dyads. The measure is scored on a 6-point scale where respondents indicate how true (from 0= always to 5=never) each statement is for them. Scores range from 0 to 125. High scores indicate greater psychopathology. There are four sub-scales, including impaired bonding, rejection and anger, anxiety about care of baby and risk of abuse. Only the total score was used since previous research has raised disagreement related to the accuracy of individual subscales (Wittkowski, Williams, & Wieck, 2010). It has been validated in mothers experiencing postnatal depression with and without bonding difficulties and is positively correlated with the BDI-II (Wittkowski, et al., 2010). It has demonstrated good psychometric properties in an inpatient postnatal sample, internal consistency was .79 and test-retest (1 week) reliability was between 0.77 and 0.95 (Brockington et al., 2001).

4.2.4 Parenting competence, cognitions, attitudes and emotional responses
4.2.4.1 What Being the Parent of a New Baby is Like (WPL)
The What Being the Parent of a New Baby is Like (WPL; Pridham & Chang, 1989) (Appendix p.221) is a 26-item self report measure which assesses three major aspects (subscales) of the parenting experience, including parenting evaluation, infant’s centrality in parent’s thought and action and the life change the parent has experienced. Twenty-five items are scored on a 9-point scale and there is a final qualitative question prompting
parents to describe what being a parent of a new baby is like for them. Psychometric properties are between good and excellent in an analogue sample. Internal consistency was between 0.77 and 0.90 (Pridham & Chang, 1989).

4.2.4.2 Brief Parenting Beliefs Scale-baby version (BPBS-b)
Please see section 1.3 for a description of the BPBS-B (Appendix, p.219; Tsivos & Sanders, 2012). In this study the BPBS-b was used to investigate whether parental self-regulation was a mechanism associated with change following Baby Triple P.

4.2.5 Acceptability of Baby Triple P
4.2.5.1 Client Satisfaction Questionnaire (CSQ)
The Client Satisfaction Questionnaire (CSQ; Sanders, Markie-Dadds & Turner, 2001) (Appendix, p.226) is a 16-item self-report questionnaire which assesses how well the intervention met the needs of the parents and families. There are 13-items which are rated on a 7-point scale and three open response questions. Scores range from 13 to 91. High scores reflect high client satisfaction. The CSQ was used to evaluate client satisfaction with the programme (Baby Triple P group only) and how well it met the needs of the parents. The CSQ is used routinely in Triple P clinical practise and research.

4.2.6 Symptomatology across treatment sessions
4.2.6.1 Outcome Questionnaire 30 (OQ-30)\(^5\)
The Outcome Questionnaire 30 (OQ-30; Lambert, Burlingame & Reisinger, 1998) is a 30-item self-report measure designed to assess psychotherapy outcome. Items assess three domains (sub-scales) in mental health including: subjective discomfort, interpersonal relations and social role performance. It was selected as it has been validated in clinical populations and has good psychometric properties (Ellsworth, Lambert, & Johnson, 2006). In a sample of individuals attending a mental health outpatient clinic internal consistency was good to excellent, alpha coefficients were: symptom distress (0.91), interpersonal functioning (0.74), social role performance (0.71) and for the total score (0.93). Test-retest reliability was also good to excellent in a undergraduate sample, symptom distress (0.78), interpersonal functioning (0.80), social role performance (0.82) and total score (0.84). The OQ-30 has also demonstrated sensitivity to significant change (across all four subscales) in clinical outpatient samples following a minimum of seven psychotherapy sessions.

\(^5\) The OQ-30 does not appear in the appendices due to copyright law.
The OQ-30 was used before every Baby Triple P session to measure participant mental state and mood throughout therapy until completion.

4.3 Participant characteristics

4.3.1 Inclusion and exclusion criteria

Participants had to be female, between the ages of 18 and 45, with a healthy baby (no known developmental delay or disability) under 12 months of age, and obtain an EPDS score over 10 to be considered eligible for inclusion. Prospective participants also had to read and write English to a local standard (in order to complete assessments and use the Baby Triple P workbook (if allocated to treatment)).

Initially, only primiparous women were included, however due to recruitment difficulties and a number of multiparous referrals it was decided that multiparous women would also be considered for inclusion. This decision was taken to improve the generalisability of the findings and to maximise sample size. Women had to meet criteria for a primary diagnosis of major depressive illness (determined by SCID). Axis II disorders were not assessed for due to time constraints.

4.4 Sampling procedures

4.4.1 Sampling method and recruitment

This research study was presented to health care professionals (health visitors, GPs, midwives, primary care psychologists) across the ten primary care trusts in Greater Manchester. Health care professionals who agreed to recruit gave study information to prospective participants (leaflets or participant information sheets (PIS)). Prospective participants could then contact the researcher to provide consent or give consent for their health care professional (this was most common) to contact the researcher. Prospective participants could also contact the researcher to ask any questions.

Consent was obtained and women were interviewed using a telephone screening module (Appendix, p. 206). If initial eligibility was met, EPDS was administered. If prospective participants obtained a score of \( \geq 10 \) a (SCID) diagnostic interview was carried out to verify a diagnosis of depression.

Eligible women then completed baseline assessments (T1). Women were subsequently randomised to either the treatment arm plus TAU or TAU only arm. Both groups were assessed at T2 (post-treatment for the treatment group or 8–10 weeks for the TAU group) followed by the final T3 assessments (3 months follow-up for both groups). See Figure 1 which details the procedure for involvement of participants through study.
4.4.2 Power calculation

Based on previous studies in the psychological treatment of depression and PND, which used the BDI-II as an outcome measure, with 30 subjects in each group the study would have 80% power to detect differences of 5.1 or more between the groups (with a simple t-test, estimated standard deviation of 7, and using the conventional 5% significance level).

4.4.3 Randomisation Method

The randomisation method was by simple block randomisation, stratified for severity of depression, as measured by the BDI-II. A separate randomisation block was produced for two levels of depression severity (2 levels; low severity indicated by BDI-II scores ≤19, high severity indicated by BDI-II scores ≥20). This method was chosen to ensure that
depression severity was balanced between the treatment and TAU group. The severity of depression for each mother was known at Time 1 (baseline) prior to randomisation, so the correct randomisation list was used. Age of baby was identified as an additional stratification variable. However, it was decided that this would not have been feasible with the small sample size. Instead, age of baby would be entered as a covariate in the analyses if there was a significant difference between the two groups.

**4.5 Ethical considerations**

Since this study involved vulnerable National Health Service (NHS) clients, ethical approval was granted by an (NHS) research ethics committee (NHS Northwest 6, ref: 10/H1003/73) (Appendix, p. 257). All prospective participants were provided with an information sheet (Appendix, p. 232) detailing involvement in the study. In all study advertising materials it was ensured that any potential treatment benefits were balanced against the benefit of usual services. Prior to screening and assessment all participants gave informed consent (Appendix, p. 238). All participants consented to their General Practitioner (GP) being notified of their participation in the research (Appendix, p. 236).

Information shared during assessment and/or Baby Triple P sessions was held confidentially. However, clients consented to involvement of their health care professional in the event of disclosure of risk or harm to self or other. All participants were informed that they could terminate their involvement in the study at any time and were provided with contact details in the unlikely event of adverse experience or complaints.

As with any RCT, design half of the sample would not receive the Baby Triple P sessions. The prospect of receiving psychological support can be a motivating factor which may influence the decision to participate in a research trial. The randomisation process was discussed with all prospective participants so that they understood that they were not guaranteed allocation to the Baby Triple P arm. It was also made clear that although there are Triple P Programmes with demonstrated efficacy and effectiveness, there was no guaranteed benefit of Baby Triple P as it was in efficacy trial stage.

Clients involved in the treatment (Baby Triple P) arm of the study were monitored on a session by session basis (using the OQ-30). All data and any identifiable data was anonymised and hard copies were stored in a secure setting. Observational (CARE-Index) data and session audio recordings could not be anonymised, however these were stored on an encrypted server and in a secure setting. Observational data for coding was transported (hand delivery) on an encrypted USB device. Finally, since assessments and Baby Triple P sessions took place in the participants’ homes, the researcher followed the NHS lone
working policy (see http://www.nhsdirect.nhs.uk/About/FreedomOfInformation/FOIPublicationScheme/~/media/Files/FreedomOfInformationDocuments/OurPoliciesAndProcedures/HealthAndSafetyPolicies/National_Lone_Working_Policy.ashx)
References


Chapter 5

The factor structure and psychometric properties of a brief measure of parental self-regulation in new mothers

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Abstract

Background: The quality of parenting in early life can facilitate or divert the course of adaptive development. Self-regulation may be an important mechanism in adaptive parenting and is the target of parenting interventions. Self-regulation is theorised to be comprised of four constructs, including self-efficacy, self-sufficiency, personal management and personal agency. Whilst there are measures of self-efficacy, there is no measure of self-regulation in new mothers. This study aimed to develop a questionnaire to measure self-regulation and investigate its factor structure and psychometric properties.

Methods: Ninety-nine new mothers scoring less than 10 points on the Edinburgh Postnatal Depression Scale (EPDS; Cox, Holden & Sargovsky, 1987) completed the newly developed, 22-item Parenting Beliefs Scale-Baby version (PBS-b) online at two time points. Demographic information was also collected using the Family Background Questionnaire (FBQ; Sanders, Markie-Dadds & Turner, 2001).

Results: An initial Exploratory Factor Analysis (EFA) resulted in a poor fit six factor solution. Inspection of the Scree plot suggested a three or four factor solution. EFA forcing a three factor solution resulted in the best fit. The three emergent factors, personal agency, self-efficacy and self-management, accounted for 49.4% of the total variance. This resulted in a 19-item scale following the deletion of items that did not load on to any factor. Further inspection resulted in the deletion of three items which lowered the internal consistency of the personal agency subscale. The final scale consisted of 16 items.

Conclusion: Although the self-regulatory concepts clustered into the theorised categories, they did not form four discrete factors. There was overlap between self-efficacy and self-sufficiency items. Following refinement, the final scale consisted of 16 items and was renamed the brief Parenting Beliefs Scale-baby version (BPBS-b). This new scale is recommended as an outcome measure to assess changes in parental self-regulation in parenting intervention research.

Keywords: Parenting Beliefs Scale- Baby version; self-regulation; factor analysis; Triple P positive parenting programme
5.1 Introduction

The transition to parenthood brings with it a period of significant adjustment for the parent. Considerable research has established that the quality of parenting is central in promoting adaptive development (Salonen et al., 2010). Whilst warm and supportive parenting promotes adaptive development insensitive, obtrusive and punitive parenting may undermine development. Infants, in particular, are susceptible to the effects of early parenting practices.

Bandura (1977) proposed that a parent’s belief in their ability to successfully perform a specific parenting behaviour is central to the implementation of that behaviour, which is referred to as self-efficacy (Bandura, 1977). Maternal parental self-efficacy is implicated in adaptive parenting practices (Bryanton, Gagnon, Hatem, & Johnston, 2008; Sanders & Woolley, 2005). There is considerable evidence to suggest that self-efficacy is associated with level of parental competence and more limited evidence of it’s relationship with parental wellbeing (for a review, see Jones & Prinz, 2005). In an operational sense, parents with low self-efficacy tend to struggle to implement positive parenting practices, whereas those with high self-efficacy utilise positive parenting strategies more competently (Jones & Prinz, 2005). The term self-efficacy has however been difficult to distinguish from self-sufficiency, and the terms are not well defined (Reck, Noe, Gerstenlauer, & Stehle, 2012).

Although there are existing measures of self-efficacy, Sanders (2012) has argued for a self-regulation model of parenting. Self-regulation comprises four central theoretical concepts, in addition to parental self-efficacy, including parental self-management, personal agency and self-sufficiency. Self-efficacy is the parental belief in self-ability and skill to overcome difficulties with parenting. Parental self-management is defined as the tools and skills that parents use to change their parenting practices; these include monitoring of self-determined goals and evaluating personal performance. Personal agency is the attributional belief that changes in parenting and child behaviour are the result of efforts by the parent (self) and not an external uncontrollable factors or events. Finally, self-sufficiency details that parents have the knowledge and skills to parent confidently.

According to Bandura (1991) self-regulatory control is the process by which people “regulate their activities” (p. 1425). Karoly (p. 25, 1993) referred to self-regulation as “those processes, internal and/or transactional, that enable an individual to guide his/her goal directed activities over time and across changing circumstances or contexts. Regulation implies modulation of thought, affect, behaviour, or attention via deliberate or automated use of specific mechanisms and supportive metaskills. The processes of self-
regulation are initiated when routinized activity is impeded or when goal-directedness is otherwise made salient (e.g., the appearance of a challenge, the failure of habitual action patterns, etc.).” It has been suggested that Triple P Programmes help parents to develop more functional self-regulatory skills related parenting (Sanders, 2012a).

Increases in parental self-regulation capacity are proposed to mediate improvements in parenting practices. Indeed, parents who experience problems with their parenting have benefit from parenting programmes grounded in social learning theory (i.e., Triple P Positive Parenting Programme, Incredible Years; Webster-Stratton & Reid, 2003 & Mellow Parenting; Puckering, Rogers, Mills, Cox & Mattson-Graff, 1994). It has been proposed that improvements following parenting programmes are associated with increases in parental self-regulation (Mazzucchelli & Sanders, in preparation).

Although there is an extensive evidence base for the efficacy of parenting programmes grounded in social cognitive learning theory in terms of other outcomes assessing variables including frequency of child behaviour problems and parental mood (Sanders & McFarland, 2000), there are no reported studies that have directly measured the changes in parental self-regulation.

Parental psychopathology is a known risk factor associated with psychopathology in the developing child. Postnatal depression (PND) impacts on a mother’s ability to respond in a way that is “good enough” to meet her infant’s needs which means parenting becomes more difficult (Murray, Cooper, & Hipwell, 2003). It also affects the way women view their abilities as a parent. Negative mood states can undermine parental self-efficacy (Haslam, Pakenham, & Smith, 2006; Leahy-Warren & McCarthy, 2011; Leahy-Warren, McCarthy, & Corcoran, 2012). Indeed, negative mood states are thought to be responsible for deficits in self-regulatory processes (Bandura, 1991). Recent research suggests that parental self-efficacy mediates the relationship between psychological symptoms and parents’ beliefs about their competence in the parenting role (Pennell, Whittingham, Boyd, Sanders, & Colditz, 2012).

The present study aimed at validating a brief self-report measure of parental self-regulation in order to increase our understanding of the mechanisms of change following participation in parenting programmes, such as Triple P. The Parenting Beliefs Scale- baby version (PBS-b; Sanders, 2012b) is a 22-item self-report measure developed to assess self-regulation in the parenting context. The main aim of this study was to explore the factor structure, collect psychometric information and validate the PBS-b. An Exploratory Factor Analysis was carried out in order to refine the scale and determine its factor structure. It was hypothesized that there would be a four factor structure. In order to assess the
reliability of the scale, repeatability and split half reliability analyses were carried out. It was hypothesised that similar ratings would be obtained at a second time-point (9 weeks later) and that full and individual subscales would result in acceptable alpha. It was not possible to conduct formal content validity checks; however, these could be the subject of further investigations.

Since early parenting is particularly important in promoting adaptive development, the target sample was a community sample of new mothers (healthy volunteers) who were in their first postnatal year. A community sample was decided upon due to the high number of participants required to conduct the factor analysis. Subsequent analyses will involve women with PND.

5.2 Method
5.2.1 Research design
A cross-sectional design was utilised. Ethical permission was granted by the University of Manchester Research Ethics Committee.

5.2.2 Participant characteristics
Inclusion criteria
To be included, prospective participants had to be between 18-45 years of age, with a baby under 12 months of age. They had to obtain a score $\leq 10$ on the Edinburgh Postnatal Depression Scale (EPDS, Cox, Holden & Sargovsky, 1987). The cut-off EPDS score of 10 was set to ensure that participants were representative of a non-depressed sample.

5.2.3 Procedure
Participants were recruited through various routes including the University of Manchester email system, online parenting forums, word of mouth and nurseries. Following informed consent procedures, participants completed the PBS-b, Family Background Questionnaire (FBQ; Sanders, Markie-Dadds, & Turner, 2001) and Edinburgh Postnatal Depression Scale (EPDS; Cox, Holden & Sargovsky, 1987). Nine weeks later they were contacted (via email) a second time to complete the PBS-b in order to assess for test-retest reliability. Most participants completed the study online with the exception of two participants who opted to complete the study by pen and paper method. Participants were not given any payment but were entered into a draw for a high street voucher (worth £25) at the conclusion of the study.
**Sample size, power and precision**

For the purposes of validating a 22-item questionnaire with around four factors, a total of 100 participants (around 4-5 participants per item) was needed. This assumption was based on heuristics for ensuring stable factor structures (Ferguson & Cox, 1993). Ferguson and Cox (1993) suggested a minimum number of participants (100-200), with a participant-to-item-ratio of between 2:1 and 10:1, a proportion of items to expected factors and subjects to expected factors to be between 2:1 and 6:1.

**5.2.4 Measures**

5.2.4.1 *The Parenting Beliefs Scale* – baby version (PBS-b; Sanders, 2012b) is a 22-item self-report measure designed to assess parental self-regulation. The 22 items are designed reflect the four self-regulatory constructs including parental *self-sufficiency*, *personal agency*, *parental self-efficacy* and *self-management*. Some items were reworded (with author permission by the first author) to make the statements relevant for women in the postnatal period (i.e., changing child to baby). Participants were asked to rate their agreement with statements (i.e., item 22: *I have the knowledge I need to complete most of my parenting responsibility*, item 16: *I know how to congratulate myself when I have achieved my parenting goals*, item 15: *I know when I have achieved the parenting goals I have set myself*) on a 6-point Likert scale (strongly agree (1) to strongly disagree (6)). Scores range from 22 to 132, with high scores reflecting greater self-regulation. Sixteen items are reverse scored to prevent response biases.

5.2.4.2 *The Family Background Questionnaire* (FBQ; Sanders et al., 2001) is a self-report questionnaire used to collect demographic and psychosocial information. The FBQ is routinely used in Triple P research and clinical practice. It was modified for (the purposes of the present study) postnatal women and includes items relevant to pregnancy (i.e., whether pregnancy was planned, length of time before falling pregnant), birth (method of delivery) and any complications experienced.

5.2.4.3 *The Edinburgh Postnatal Depression Scale* (EPDS; Cox, Holden & Sargovsky, 1987) is a 10-item self-report measure of postnatal depression related symptoms over the past seven days. Scores range from 0 to 30, where a score between 12 and 13 suggests probable depression. The EPDS was designed to eliminate somatic factors associated with the postnatal context which might confound scores (Flynn, Henshaw, O'Mahen, & Forman, 2010). It has been shown to be the most effective tool in identifying probable symptoms specific to PND and has been validated and used widely as an outcome measure in
randomised controlled trials (RCTs; Lee & Chung, 2007; Hanusa, Scholle, Haskett, Spadaro & Wisner, 2008). In the present study the EPDS, a routinely used screening tool in the NHS was used to screen for increased risk of PND.

5.2.5 Data analysis
SPSS (version 16) for Windows was used to analyse all data. Descriptive statistics were conducted for participant characteristics and data were inspected for suitability for undertaking a factor analysis. Although the scale items were based on theoretical constructs, an Exploratory Factor Analyses (EFA) method was chosen as it is the preferred method for developing new scales and using new samples (Worthington & Whittaker, 2006).

5.3 Results
5.3.1 Participant characteristics
Ninety-nine predominantly (87.8%) British women took part in the study. The average age was 33.3 (sd= 10.4) years. Women gained average scores of 6 (sd= 4.9) on the EPDS and 84.4 (sd= 8.6) on the PBS-b respectively. The average baby age was 6.5 (sd= 5.2) months (see Table 1 for additional participant and perinatal characteristics).
Table 1. Socio demographics and characteristics of mothers and their infants at baseline

<table>
<thead>
<tr>
<th>Maternal characteristics</th>
<th>Total (n =99)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years) (SD)</td>
<td>33.3 (10.4)</td>
</tr>
<tr>
<td>Partner mean age (years) (SD)</td>
<td>36.1 (11.3)</td>
</tr>
<tr>
<td>EPDS mean (SD)</td>
<td>6 (4.9)</td>
</tr>
<tr>
<td>PBSb mean (SD)</td>
<td>84.4 (8.6)</td>
</tr>
<tr>
<td><strong>Relationship status (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>59.3%</td>
</tr>
<tr>
<td>Living together</td>
<td>36.3%</td>
</tr>
<tr>
<td>Other</td>
<td>4.4%</td>
</tr>
<tr>
<td><strong>Ethnicity (%)</strong></td>
<td></td>
</tr>
<tr>
<td>British</td>
<td>87.8%</td>
</tr>
<tr>
<td>Other white background</td>
<td>6.7%</td>
</tr>
<tr>
<td>African</td>
<td>1.1%</td>
</tr>
<tr>
<td>White and Black Caribbean</td>
<td>1.1%</td>
</tr>
<tr>
<td>Irish</td>
<td>1.1%</td>
</tr>
<tr>
<td>Indian</td>
<td>1.1%</td>
</tr>
<tr>
<td>Other Asian background</td>
<td>1.1%</td>
</tr>
<tr>
<td><strong>Highest level of education (%)</strong></td>
<td></td>
</tr>
<tr>
<td>No qualifications</td>
<td>1.1%</td>
</tr>
<tr>
<td>GCSEs, CSEs or O-levels</td>
<td>8.9%</td>
</tr>
<tr>
<td>A levels/BTEC</td>
<td>17.8%</td>
</tr>
<tr>
<td>Trade/apprenticeship</td>
<td>1.1%</td>
</tr>
<tr>
<td>University Degree</td>
<td>50%</td>
</tr>
<tr>
<td>Postgraduate degree</td>
<td>13.3%</td>
</tr>
<tr>
<td>Other</td>
<td>7.8%</td>
</tr>
<tr>
<td><strong>Family Income (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>28.2%</td>
</tr>
<tr>
<td>Middle</td>
<td>38.8%</td>
</tr>
<tr>
<td>High</td>
<td>32.9%</td>
</tr>
<tr>
<td><strong>Maternal employment (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Full time</td>
<td>14.3%</td>
</tr>
<tr>
<td>Part time</td>
<td>9.9 %</td>
</tr>
<tr>
<td>Home duties</td>
<td>14.3%</td>
</tr>
<tr>
<td>On maternity leave</td>
<td>57.1%</td>
</tr>
<tr>
<td>Unemployed</td>
<td>4.4%</td>
</tr>
<tr>
<td><strong>Infant characteristics</strong></td>
<td></td>
</tr>
<tr>
<td>Mean age in months (SD)</td>
<td>6.5 (5.2)</td>
</tr>
<tr>
<td>Primiparous (%)</td>
<td>74.7%</td>
</tr>
<tr>
<td><strong>Delivery (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>54.9%</td>
</tr>
<tr>
<td>Assisted delivery (forceps)</td>
<td>20.9%</td>
</tr>
<tr>
<td>Emergency caesarean</td>
<td>19.8%</td>
</tr>
<tr>
<td>Planned caesarean</td>
<td>2.2%</td>
</tr>
<tr>
<td>Other</td>
<td>2.2%</td>
</tr>
<tr>
<td><strong>Perinatal complications (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>30.8%</td>
</tr>
<tr>
<td><strong>Planned pregnancy (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>75%</td>
</tr>
</tbody>
</table>
5.3.2 Exploratory factor analysis

5.3.2.1 Assessment of the factorability of the correlation matrix

The data were first inspected for normality. Descriptive statistics suggested slight positive skew (skewness statistic= 0.21) for PBS-b total data indicating eligibility for Factor Analysis.

Data on the PBS-b was otherwise normally distributed as indicated by the Kolmogorov-Smirnov statistic (0.08), df= 99 (p= 0.18) and by visual inspection of the data in histogram format. There were data from n= 6 participants who had a baby >12 months of age. As their data did not appear as outliers, all datasets were retained and used in the analysis.

The total sample size was n= 99. Following inspection of communalities all were > 0.6, apart from one, which suggests this total sample size would be acceptable to conduct an EFA (MacCallum, Widaman, Zhang, & Hong, 1999). The data satisfied Kaiser-Meyer-Olkin measure of sampling adequacy (MSA= 0.75) and Barlett’s test of sphericity ($\chi^2$(920) = 231, p= 0.001) criteria for suitability of factor analysis, which also indicates that the correlation matrix was not an identity matrix (Pett, Lackey, & Sullivan, 2003).

5.3.2.2 Exploratory factor analysis

Exploratory factor analysis (EFA) was selected because it is the recommended method for scale development (Pallant, 2007; Pett, et al., 2003; Tabachnick & Fidell, 2003; Worthington & Whittaker, 2006). Principal components factor analysis (PCA) was used to extract factors along with direct oblimin rotation to improve meaningfulness and interpretation of the factors (Pett, et al., 2003).

Exploratory factor analysis using direct oblimin rotation resulted in a six-factor solution. However, there were few items loading on to the fifth (n= 2) and sixth (n= 3) factors. Furthermore, the scree plot suggested a solution between three and four factors. Internal consistency (Cronbach’s alpha) was investigated using the total scale with all items. The analysis suggested that the reliability of the scale would increase after deleting item 1 (There is no such thing as good or bad babies- just good or bad parents), which resulted in this item being deleted prior to conducting the subsequent EFA analyses.

Due to the poorly-fit-six-factor solution a further EFA was undertaken forcing a four-factor-solution and again forcing a three-factor-solution. The four-factor-solution did not meet the criteria of four variables per factor (Fabrigar, Wegener, MacCallum, & Stahan, 1999) since the fourth factor had only three items. The three-factor-solution made the most theoretical and statistical sense (see Table 2). The three factors produced eigenvalues over
one and explained 49.4% of the total variance. Factor labels were based on the original self-regulatory constructs (see Table 2 for original item labels).

Factor 1, labelled *personal agency*, consisted of eight items accounted for 28.3% of the total variance. Factor 2, *self-efficacy* consisted of six items and explained 12.5% of the total variance. The 3rd and final factor, *self-management*, consisted of five items and accounted for 8.6% of the total variance. Two further items (item 2, *When my baby is content it is because he/she is responding to my efforts* & item 11, *I know what I need to do differently to get on better with my baby*) did not load on to any factors, therefore both items were not included in subsequent reliability analyses.

In order to confirm the factor structure, a sensitivity analysis was also conducted using an orthogonal (Varimax) rotational technique (Pallant, 2007). Pedhazur and Selminkin (1991) argue that orthogonal rotations are unrealistic for behaviour data, however, they are easier to interpret than oblique rotations (Tabachnick & Fidell, 2003). The orthogonal rotations resulted in a very similar solution. However, the oblique rotation was easier to interpret.
Table 2. Loadings for fixed rotated three-factor solution for the PBS-B in a healthy non-depressed sample (n= 99)

<table>
<thead>
<tr>
<th>Item #</th>
<th>Item</th>
<th>Original construct</th>
<th>Personal agency</th>
<th>Factors</th>
<th>Self-management</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Parents who can’t get their baby to settle don’t understand how to get along with their baby&lt;sup&gt;a&lt;/sup&gt;</td>
<td>PA</td>
<td>.69</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>The difficulties I have with my baby are no one’s fault but my own&lt;sup&gt;a&lt;/sup&gt;</td>
<td>PA</td>
<td>.79</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Capable people who fail to become good parents have not followed through on their opportunities&lt;sup&gt;a&lt;/sup&gt;</td>
<td>PA</td>
<td>.61</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Parents whose babies make them feel helpless just aren’t using the best parenting techniques&lt;sup&gt;a&lt;/sup&gt;</td>
<td>PA</td>
<td>.44</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>The misfortunes and successes I have had as a parent are the direct result of my own behaviour&lt;sup&gt;a&lt;/sup&gt;</td>
<td>PA</td>
<td>.72</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Difficulties people have with their babies are often due to the mistakes their parents made</td>
<td>PA</td>
<td>-.63</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Most difficulties people experience with their baby would not have developed if their parents had better parenting skills</td>
<td>PA</td>
<td>-.63</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>I am responsible for my baby’s behaviour&lt;sup&gt;a&lt;/sup&gt;</td>
<td>PA</td>
<td>-.69</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>I am confident in the parenting choices I make&lt;sup&gt;a&lt;/sup&gt;</td>
<td>SE</td>
<td>.63</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19</td>
<td>I prefer to solve baby behaviour problems by myself&lt;sup&gt;a&lt;/sup&gt;</td>
<td>SE</td>
<td>.61</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>I feel I have the skills to accomplish my everyday parenting responsibilities&lt;sup&gt;a&lt;/sup&gt;</td>
<td>SE</td>
<td>.46</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22</td>
<td>I have the knowledge I need to complete most of parenting responsibilities&lt;sup&gt;a&lt;/sup&gt;</td>
<td>SE</td>
<td>.64</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>I seek the advice of experts regarding my parenting problems</td>
<td>SS</td>
<td>.66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21</td>
<td>When it comes to difficult parenting issues I seek advice from others rather than attempt to deal with the problem myself</td>
<td>SS</td>
<td>.55</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>I can set parenting goals to improve my relationship with my baby&lt;sup&gt;a&lt;/sup&gt;</td>
<td>SM</td>
<td>-.68</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>I have the skills to develop a practical parenting plan to solve most of the difficulties I experience with my baby’s behaviour&lt;sup&gt;a&lt;/sup&gt;</td>
<td>SE</td>
<td>-.73</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>I am able to monitor or keep track of my own parenting behaviours that affect my relationship with my baby&lt;sup&gt;a&lt;/sup&gt;</td>
<td>SM</td>
<td>-.80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>I know when I have achieved the parenting goals I have set for myself&lt;sup&gt;a&lt;/sup&gt;</td>
<td>SM</td>
<td>-.81</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>I know how to congratulate myself when I have achieved one of my parenting goals&lt;sup&gt;a&lt;/sup&gt;</td>
<td>SM</td>
<td>-.76</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Eigenvalue | 5.9 | 2.6 | 1.8 |
| Percentage of variance accounted for | 28.3 | 12.5 | 8.6 |
| Internal consistency (cronbach’s alpha) | -.2 | .7 | .9 |
5.3.3 Internal consistency

A reliability analysis was conducted on the full scale resulting from the three factor (oblique rotated) solution as well as the three individual subscales (factors). The full scale had acceptable internal consistency alpha= 0.61. Individual subscale alphas were good for self-efficacy (alpha= 0.7) and excellent self-management (alpha= 0.9). However, personal agency (alpha= -0.2) demonstrated unacceptable reliability. Three personal agency items (6, 8, 9) contributed to the low internal consistency of the personal agency subscale. Following the deletion of these problematic personal agency items, the alpha for the total scale increased to (alpha= 0.8) and personal agency subscale to (alpha= 0.7).

5.3.4 Test-Retest reliability

Test re-test reliability was also performed on the full scale. A sample of 39 participants completed the PBS-b a second time, nine weeks following the first administration. A Pearson product moment correlation was conducted between first administration (Time 1) and second administration (Time 2) of the PBS-b. Based on Cohen’s (1998) correlational guideline, there was a large positive correlation between time points $r= 0.74$, $n=39$, $p<0.0001$. A paired samples T-test was also carried out. There was a statistically significant increase in PBS-b scores from the first administration ($M=61.79$, $SD= 8.69$) to the second administration ($M=66.28$, $SD= 8.79$), $t(39)=-4.46$, $p=0.001$. The mean increase in scores was 4.49. Confidence intervals ranged from -6.52 to -2.45.

5.4 Discussion

The aim of this study was to investigate the factor structure and psychometric properties of a measure designed to assess self-regulatory concepts, including self-sufficiency, self-efficacy, self-management and personal agency in new parents. The final 16-item scale represents a brief reliable measure of self-regulation and was renamed the Brief Parenting Beliefs Scale babe version (BPBS-b) accordingly. To our knowledge this is the first study to measure self-regulation in new parents.

Although the factor analysis indicated a three-factor-solution and theoretical concepts did appear to cluster together, they did not fall into the four discrete factors, reflecting each of the self-regulatory constructs originally outlined. With respect to self-regulatory concepts, personal agency and self-management were captured in the resultant factor structure. Self-regulatory theory suggests that self-sufficiency and self-efficacy items would form separate factors. However, items reflecting self-sufficiency and self-efficacy loaded on to the same factor. This is observation is consistent with Reck and colleagues’ (2012) finding that self-efficacy and self-sufficiency may be related constructs.
Alternatively, it is possible that the wording of the items did not capture the intended meaning of the constructs.

One of the challenges to designing behavioural scales is that there will ultimately be subjective variation in responses. The literature on self-efficacy and self-sufficiency in the transition to parenthood explicated that the concepts are related and difficult to distinguish (Reck, et al., 2012). For example, several variables may have an impact on maternal self-efficacy, including socio demographics, maternal mood and characteristics of the infant (Leerkes & Burney, 2007).

With respect to test-retest reliability, the findings were mixed. The correlational analysis did suggest a strong positive association between first and second administrations of the PBS-b. However, the paired t-test indicated that participants scored significantly higher on the second administration, which may be the result of the time between administrations (9 weeks). Nine weeks may have been a sufficient amount of time for self-regulatory skills to improve resulting in the significant increase in the total scores. Indeed, maternal parental self efficacy has been found to increase across time as confidence in child care grows (Leahy-Warren & McCarthy, 2011). Future studies may decrease the amount of time between PBS-b administrations to re-examine repeatability.

5.4.1 Clinical implications
Leahy-Warren and McCarthy (2011) suggested that positive mood states lead to increased self-efficacy, while negative mood states lead to a decrease in self-efficacy. By investigating self-regulatory skills in a healthy postnatal population we anticipated to gain insight into whether self-regulation is an important variable in women experiencing PND. Furthermore, low maternal self-efficacy has been specifically implicated in the depressive experience during the transition to parenthood in women (Reck, et al., 2012).

This measure could also be used to signpost parents with low self-regulation in the parenting role to services. Interventions for PND could be designed to target these parental self-regulatory constructs in order to improve the experience of the transition to parenthood for mothers and outcomes for the infants of mothers experiencing depression.

5.4.2 Limitations
In terms of participant characteristics, infant gender was not recorded in this sample. Additionally, the findings here are based on data from a predominantly white British sample. It is unknown whether the present findings would generalise to Black and ethnic minority (BME) or a more socioeconomically diverse sample. Although the aim was to use
this scale in a sample of women with PND, the data presented here were drawn from a 
non-depressed sample for the purposes of validating the scale, collecting normative data 
for future analyses and due to the size of the sample required. Furthermore, the target 
sample was new others and therefore it is unclear whether fathers would respond in the 
same vain. The findings reported in this study are also limited to new mothers, and may not 
generalise to mothers of older children.

An additional limitation of the measure was that one sub-scale in particular, 
*Personal agency* gained a negative alpha score due to some negatively correlated items, 
however, these items were removed to improve the internal consistency. Field (2005) 
suggests that this is a common problem due to wording of items.

### 5.4.3 Future research

Since the transition to parenthood is one of the most significant adjustments in the lifespan 
it is possible that maternal self-regulation may vary with age of the infant. Future studies 
could investigate changes in self-regulation across the first postnatal year. A 
recommendation for future research is to investigate group differences, as well as any 
(infant) gender differences. It is our intention to extend this research to investigate the 
factor structure and psychometric properties of the BPBS-b with fathers.

Future research could also use the BPBS-b to assess changes in self-regulation 
following parenting interventions. The inclusion of this measure could be used to explore 
self-regulation as a mechanism implicated in change following parenting interventions. 
Since the present findings are limited to new parents, future research may explore self-
regulatory constructs and the factor structure of the PBS in parents of older children.

### 5.5 Conclusion

This is the first study to date to explore the factor structure of a new measure to assess self-
regulation as a unitary construct in new parents. The resulting factor structure reflects two 
of the theorised parental self-regulatory constructs (self-management, personal agency) and 
indicates that self-efficacy and self-sufficiency form one construct. Future studies could 
use the BPBS-b to assess for change in self-regulation following administration of a 
parenting intervention.
References


Chapter 6

A pilot randomised controlled trial to evaluate the efficacy and acceptability of the Baby Positive Parenting Programme compared with treatment as usual in a sample of women with Postnatal Depression

Zoe-Lydia Tsivos\textsuperscript{a}, Anja Wittkowski\textsuperscript{a,*}, Rachel Calam\textsuperscript{\textsuperscript{a}}, & Matthew R. Sanders\textsuperscript{a,b}

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Abstract
Objective: As few interventions for Postnatal Depression (PND) have focused on parenting difficulties, the aim of this research was to evaluate the efficacy and acceptability of a parenting intervention (Baby Triple P) in women with PND.

Methods: This study was a pilot randomised controlled trial to evaluate the efficacy and acceptability of the newly developed Baby Triple P compared with treatment as usual (TAU) in women with PND. Twenty-seven female participants between 18 and 45 years of age (mean age= 28.4 years, SD= 6.1) with a primary diagnosis of major depression and an infant under 12 months (mean age= 6.2, months, SD= 3.2) were recruited from primary care trusts in Greater Manchester, UK. Following baseline (Time 1) assessment, participants were randomly allocated to receive either eight Baby Triple P sessions in addition to TAU or TAU only. They were assessed at post-treatment (eight weeks for TAU) (Time 2) and three months post-treatment (Time 3) using self-report measures, including the Beck Depression Inventory (BDI-II; Beck et al., 1996), the Oxford Happiness Inventory (OHI; Argyle, Martin & Crossland, 1989), the What being the Parent of a new baby is Like (WPL; Pridham & Chang, 1989), the Postpartum Bonding Questionnaire (PBQ; Brockington, 2001), and the Brief Parenting Beliefs Scale- baby version (BPBS-b; Tsivos & Sanders, 2012). An assessor-rated observational measure of mother-infant interaction, the Care Index (Crittenden, 2001), was also included. A measure of intervention acceptability was also completed.

Results: Significant improvements from baseline to post-treatment and baseline to three-month follow-up were observed across both groups. Although women allocated to Baby Triple P showed more favourable improvements, the between-group differences were not significant. Baby Triple P did not have an additive effect to TAU, however, Baby Triple P was found to be highly acceptable to women with PND.

Conclusions: There are several alternative explanations for the non-significant findings. For example, the level of support received by the TAU group and low power. A larger scale randomised controlled trial may be indicated.

Keywords: intervention; mother-infant relationship; parenting; postnatal depression; randomised controlled trial.
6.1 Introduction

Postnatal depression (PND) affects approximately 10-15% of new mothers (Cooper & Murray, 1997). It is well documented that PND has an impact on maternal quality of life, and may increase vulnerability to subsequent episodes of depression. In addition to the impact and future risk for maternal mood, the infants of women with PND are at elevated risk of psychopathology (Goodman & Gotlib, 1999).

Postnatal depression (PND) is similar to major depression occurring at other times in a woman’s life (Cooper, Campbell, Day, Kennerley, & Bond, 1988; O'Hara, 1994). However, the role of the primary caregiver (usually the mother) is central in promoting adaptive development in the infant and establishing positive foundations for continued social and emotional development and affect regulation (Tronick & Reck, 2009; Tronick & Weinberg, 1997). This has implications for intervention where maternal mental health is affected. With this view, the relationship between the mother and infant dyad and parenting behaviours are important foci for interventions (O'Hara, 2009).

Considerable research has established the impact of parental psychopathology, particularly depression on child development. Specifically, PND may act as a risk factor for atypical socio-emotional and cognitive development in infants (Feldman et al., 2009; Hay, Pawlby, Angold, Harold, & Sharp, 2003; Kim-Cohen, Moffitt, Taylor, Pawlby, & Caspi, 2005; Stein, Malmberg, Sylva, Barnes, & Leach, 2008). Cognitive deficits in infants have been significantly linked to the quality of the early mother-infant relationship, despite later remitting of maternal PND (Murray & Stein, 1991).

Problems may also persist long after remission of maternal depressive symptoms. Indeed, longitudinal research has shown that children of women with depression remain vulnerable to parental psychopathology (Hay, et al., 2003). Preliminary intergenerational research has also shown that the daughters of women with PND attain heightened scores on the Edinburgh Postnatal Depression Scale (EPDS; Cox, Holden & Sargovsky, 1987) when they become parents themselves (Sejourne, Alba, Onorrus, Goutaudier, & Chabrol, 2011).

The prevalence and pervasive generational impact of PND makes it a significant public health problem requiring early effective intervention. In two systematic reviews of interventions for PND, which assessed maternal mood and mother-infant outcomes and/or child developmental outcomes, it was noted that while some studies had demonstrated efficacy for reducing maternal depressive symptoms, few studies demonstrated comparable findings in child related outcomes (Poobalan et al., 2007; Tsivos, Wittkowski, Calam, & Sanders, submitted). This finding suggests that improvements in maternal mood do not
necessarily translate into benefits to the mother-infant relationship and/or child development. In their review, Tsivos et al. (submitted) also highlighted the unmet need for effective parenting interventions for women experiencing PND.

Maladaptive parenting has been implicated as a mechanism by which risk is transmitted across the generational gap, from parent to child (Meaney, 2001). There is mounting evidence that women with PND may experience marked difficulties in practical care-giving tasks including breastfeeding (Dennis & McQueen, 2007; Field, 2010; Hart, Jackson, & Boylan, 2011; McLearn, Minkovitz, Strobino, Marks, & Hou, 2006a, 2006b), infant sleeping (Dennis & Ross, 2005; Field, 2010; Hatton, Harrison-Hohner, Dorato, Curen, & McCarron, 2005; Hiscock & Wake, 2001; McLearn, et al., 2006a, 2006b), displaying more risky parenting behaviours (Zajicek-Farber, 2010), fail to attend well child visits (Minkovitz et al., 2005; Zajicek-Farber, 2009), implementing household safety practices (McLearn, et al., 2006a, 2006b; Zajicek-Farber, 2009) and difficulties bathing the infant (Righetti-Veltema, Conne-Perreard, Bousquet, & Manzano, 2002).

Evidence also exists for a positive association between prolonged infant crying and maternal depressive symptoms (Vik et al., 2009). Additionally, Reck and colleagues (p.524, 2011) reported that during interactions, infants and their depressed mothers were observed to display “less coordinations of positive matched states and took longer to move from mismatched states into positive matched states”. Furthermore, depressed mothers are less likely to identify happy infant faces compared with their non-depressed peers (Arteche et al., 2011). Parenting practices may, therefore, be an important target in protecting and promoting adaptive development (Craig, 2004; O’Hara, 2009).

The Triple P Positive Parenting Program is a system of interventions with impressive theoretical, scientific and clinical foundations (Sanders, 2012; Sanders, Markie-Dadds, & Turner, 2003; Turner & Sanders, 2006). Its aims include 1) enhancing parental knowledge and resourcefulness; 2) promoting nurturing, low conflict environments for children; and 3) promoting children’s social, emotional and intellectual competencies through positive parenting practices (Sanders, et al., 2003). The Triple P framework offers accessible, multi-level interventions increasing in intensity for parents with different needs, regardless of socio-cultural boundaries, age and gender (Sanders, Markie-Dadds, Tully, & Bor, 2000).

Earlier research which evaluated two types of behavioural family intervention (Triple P) in depressed mothers of children aged three to nine years ($M=4.39$ years) with behavioural difficulties demonstrated reductions in depressed mood and in frequency of difficult behaviour in their children (Sanders & McFarland, 2000).
Baby Triple P has been developed to enhance the knowledge, skills and confidence of new parents. The present study is the first pilot randomised controlled trial (RCT) to examine the efficacy and acceptability of Baby Triple P compared with treatment as usual (TAU) in the treatment of women with PND.

The primary aim of this study was to evaluate whether Baby Triple P was sufficient to reduce the severity of depressive symptoms and improve the quality of the mother-infant relationship, particularly maternal sensitivity. In line with the primary aim, it was hypothesised that compared with women receiving TAU only, women receiving Baby Triple P (in addition to TAU) would report (a) a significant reduction in depressed mood and improvements in positive mood, (b) that women allocated to Baby Triple P would be observed to interact more sensitively with their infants compared with women receiving TAU only and, (c) women receiving Baby Triple P would also report significant improvements in subjective bonding experience and increases in parental confidence. We also hypothesised that these improvements would be sustained at three-month follow-up.

Bandura (1991) theorised that dysfunctional self-regulation (i.e., parents’ belief in their ability to plan and execute goals successfully) was implicated in depressed mood. As it has been suggested that parenting programmes function to improve self-regulatory skills (Mazzucchelli & Sanders, in preparation), a secondary aim was to explore whether any reported improvements were associated with increases in self-regulation. It was, therefore, predicted that if there were improvements in the Baby Triple P arm, that these would be related to increases in parental self-regulation. A final aim was to investigate the acceptability of Baby Triple P to women with PND.

6.2 Method
6.2.1 Research design
This was a pilot randomised controlled trial (RCT) comparing the effectiveness of adding Baby Triple P to TAU in mothers with PND. This was a 2 (groups: intervention versus TAU) x 3 (assessment time points: pre- and post-treatment phase and three-month follow-up) longitudinal design. Group assignment was by true block random allocation, stratified for severity of depression (i.e., low severity indicated by BDI-II scores of ≤ 19 and high depression severity by BDI-II scores of ≥ 20). High and low severity were determined by BDI-II scores categories in the BDI-II manual scores from 0-13 indicate mild symptoms, 14-19 indicate mild, 20-28 indicate moderate and 29-63 indicate severe symptoms (Beck, Steer, & Brown, 1996). Average scores in similar studies (Milgrom, Negri, Gemmill, McNeil, & Martin, 2005; O'Hara, Stuart, Gorman, & Wenzel, 2000; Van Doesum, Riksen-
Walraven, Hosman, & Hoefnagels, 2008) were also used to determine the cut-off point for severity.

Randomisation lists for low and high depression severity were computer generated by a statistician external to the research team. The process of randomisation was carried out using sealed opaque envelopes. Assignment to condition was concealed until group allocation (i.e., after baseline assessment). Eligibility screening, assessment, and Baby Triple P sessions were conducted by the first author (ZT). Rating of the CARE Index observations were conducted by a Clinical Psychologist who was an experienced qualified rater, external to the research team and blind to depression diagnosis and treatment allocation participants. It was not possible to verify the ratings due to the cost associated with rating the observations.

6.2.2 Measures
6.2.2.1 Clinical assessment measures

6.2.2.1.1 The Structured Clinical Interview for Diagnosing DSM-IV disorders (SCID) was used to confirm a primary diagnosis of major depression. The SCID-PND is an adapted version of the SCID, which was developed for use with a PND population in a transcultural study (Gorman et al., 2004). A clinical diagnosis of depression was sought to ensure symptom severity was due to depression and not a general set of symptoms of psychological distress related to different psychopathology (Lovejoy, Graczyk, O’Hare, & Neuman, 2000). In the present study, screening modules for Mood Episodes (A), Mood Differential (D), Post Traumatic Stress Disorder (PTSD) (F 106-135), Generalised Anxiety Disorder (F 137-153) and Mixed Anxiety and Depression Disorder (J.21-J.38) were included. Anxiety was screened for because of its comorbidity in women experiencing PND.

6.2.2.1.2 The Family Background Questionnaire (FBQ; Sanders, Markie-Dadds & Turner, 2001) is a self-report structured questionnaire which was used to collect demographic and psychosocial information (e.g., parent’s and infant’s age, onset of illness and duration). The FBQ is routinely used in Triple P research and clinical practise. It was modified for use with perinatal populations by accounting for factors associated with the perinatal context (e.g., antenatal complications, type of delivery, whether pregnancy was planned).
6.2.2.2 Mood

6.2.2.2.1 The Beck Depression Inventory (BDI-II; Beck, Steer & Brown, 1996) is a 21-item self-report measure of severity of depressive symptoms on a 4-point scale. Scores range from 0 to 63, with high scores indicating greater severity of symptoms. Although the BDI-II includes items which measure somatic symptoms, it was selected over other depression measures because of its demonstrated sensitivity to symptom severity. The BDI-II has also been validated in women experiencing PND and has been routinely used in perinatal research as a primary outcome measure (e.g., Boyd, Zayas, & McKee, 2006). It has high internal consistency (0.91) and test-retest reliability (0.93; Beck et al., 1996). Internal consistency for the current study was 0.88.

6.2.2.2.2 The Oxford Happiness Inventory (OHI; Argyle, Martin & Crossland, 1989) is a 29-item self-report measure of broad personal happiness. It consists of a reversal of BDI-II items and eight additional items to cover aspects of subjective wellbeing not measured by the BDI-II. It has high internal consistency (0.92; Argyle et al., 1989). Internal consistency for the present study was 0.88.

6.2.2.3 Mother-infant relationship

6.2.2.3.1 The CARE Index (Crittenden, 2004) is a 3 to 5 minute, observer-rated video-taped interaction between mother-infant dyads. The CARE Index is comprised of seven subscales including maternal sensitivity, control, unresponsiveness and infant co-operation, compulsive/difficult responses or passivity. Scores range from 0 to 14, with higher scores indicating higher sensitivity. It is suitable for infants up to the age of 15 months. It is a robust indicator of current dyadic synchrony and future attachment behaviours (Crittenden, 2008).

6.2.2.3.2 The Postpartum Bonding Questionnaire (PBQ; Brockington et al., 2001) is a 25-item self-report questionnaire which assesses change in bonding between mother-infant dyads. It is scored on a six-point scale (from 0= always to 5=never) where respondents indicate how true each statement is for them. High scores indicate greater psychopathology. It has good internal consistency (0.79; Wittkowski, Williams & Wieck, 2010) and high test re-test reliability on total scale scores (0.95; Brockington et al., 2001). Internal consistency for the present study was 0.92.
6.2.2.4 Parenting competence, cognitions, attitudes and emotional responses

6.2.2.4.1 The What being the Parent of a new baby is Like (WPL; Pridham & Chang, 1989) is a 26-item self-report measure which assesses three major aspects of the parenting experience, including parenting evaluation, infant’s centrality in parent’s thought and action and the life change the parent has experienced. The WPL contains 25 items scored on a nine-point scale and one open question prompting parents to describe what being a parent of a new baby is like for them. Internal consistency across the three subscales ranges from medium to high (0.77-0.90; Pridham & Chang, 1989). Internal consistency in the present study was 0.87.

6.2.2.4.1 The Brief Parenting Beliefs Scale- baby version (BPBS-b; Tsivos & Sanders, 2012) is a reliable 16-item self-report measure which assesses self-regulation around parenting. Self-regulation is proposed to consist of four central concepts, including parental self-sufficiency, personal agency, parental self-efficacy and self-management. Increased ability to self-regulate is thought to be related to maintenance improvement following parenting interventions. The BPBS-b was validated in a non-depressed sample of women and has good internal consistency (alpha= 0.80; Tsivos, Wittkowski, Calam & Sanders, submitted). Internal consistency for the present study was good (alpha= 0.70).

6.2.2.5 Intervention arm specific measures

The Client Satisfaction Questionnaire (CSQ; Sanders, et al., 2001) is a self-report questionnaire which assesses the acceptability of the intervention. There are 13 items rated on a seven-point scale and three open ended questions. Total scores range from 13 to 91 and higher scores represent higher acceptability. The CSQ is used routinely in Triple P clinical practise and research.

6.2.2.5.2 The Outcome Questionnaire-30 (OQ-30; Lambert, Burlingame & Reisinger, 1998) is a 30-item self-report measure designed to assess psychotherapy outcome. Items assess three domains (sub-scales) in mental health including subjective discomfort, interpersonal relations and social role performance. It was selected because it has been validated in clinical populations and has good psychometric properties (Ellsworth, Lambert, & Johnson, 2006). It is also sensitive to depressive and anxious symptoms. The OQ-30 was used before every Baby Triple P session to measure participant mental state and mood throughout the intervention until completion.
6.2.2.6 Intervention protocol and therapist preparation

Baby Triple is a strengths-based intervention which aims at promoting 1) healthy infant development, 2) reducing of family risk factors and 3) parental psychopathology. Baby Triple P consists of eight individual sessions delivered by a trained Triple P practitioner. The sessions are: 1: Positive Parenting, 2: Responding to your baby, 3: Survival skills, 4: Partner support, 5: Implementing parenting routines (1), 6: Implementing parenting routines (2), 7: Implementing parenting routines (3), 8: Implementing parenting routines (4) and maintenance and closure. The Implementing Parenting Routines sessions involve active skills practise between the mother-infant dyad. During these sessions the role of the practitioner is to provide feedback and prompt self-evaluation in the parent.

All sessions were delivered by a trained Triple P accredited practitioner (ZT). Baby Triple P sessions took place in participants’ home. The first four sessions lasted between 1 to 1.5 hours and the remaining four sessions lasted between 40 minutes and one hour. A workbook (Spry, Morawska, & Sanders, 2009) detailing the session content was provided for the participant and a manual and session checklist were used by the practitioner during each session. The practitioner also received weekly supervision from a clinical psychologist (AW), who was also trained and accredited in Baby and Standard Triple P.

6.2.3 Participants

Participants were eligible for inclusion if they met risk indicators for PND (i.e., scores of > 10) on the Edinburgh Postnatal Depression Scale (EPDS; Cox et al., 1987) and a primary diagnosis of PND, based on confirmation of major depression on the SCID. In addition, their infants had to be less than 12 months of age. A further inclusion criterion was that they lived in the geographical recruitment area (Greater Manchester, UK) and were proficient in English (for the purposes of using the written workbook during intervention). Table 1 shows the major participant demographic and perinatal characteristics at baseline.

6.2.4 Sampling procedures

Participants were drawn from a convenience sample (i.e., they were referred through health visitors, general practitioners (GPs), midwives). In order to optimise recruitment, additional efforts included self-selection via public advertisement and social media. Since the study team was only notified of individuals who chose to opt in to the study, there is no information on the number of individuals approached but declining to take part in the research. All screening was done over the phone or directly with the participants. All baseline, post-treatment and three-month-follow up assessments were done in the participants’ home or a place of their choice. No monetary incentive for taking part was
offered; however, travel was reimbursed. Participants randomised to TAU received a copy of the *Triple P: Every Parents Self-Help Workbook* (Markie-Dadds, Sanders, & Turner, 1999) on completion of the study at the follow-up. The research was reviewed and approved by an NHS research ethics committee (North West 6, ref: 10/H1003/73, see p. 257).

### 6.2.5 Sample size and power

The intended sample size was N=60, as identified by a power analysis of previous studies in the psychological treatment of depression and PND, which used the BDI-II as an outcome measure. With 30 subjects in each group the study would have 80% power to detect differences of 5.1 or more between the groups (with a simple t-test, estimated standard deviation of 7, and using the conventional 5% significance level).

### 6.2.6 Planned analyses

In order to test that the proposed hypotheses that Baby Triple P was associated with favourable outcomes compared with TAU, Analysis of Covariance (ANCOVA) was performed on each variable (BDI-II, OHI, BPBS-b, PBQ, etc.) from baseline to post-treatment (controlling for baseline scores of the given measure) and from baseline to three-month follow-up. When data did not meet assumptions of parametric testing, changes from baseline to post-treatment and changes from baseline to three-month follow-up were calculated for each group separately and then compared using Mann-Whitney U analysis (to compare changes between Baby Triple P and TAU, respectively).

### 6.3 Results

Twenty-seven women met eligibility criteria for the present study and completed baseline assessments and were subsequently randomised to condition (see Figure 1 for CONSORT diagram detailing flow of participants through the study). Participants were recruited on a rolling basis between December 2010 and May 2012. Thirteen women were randomised to Baby Triple P+TAU and 14 to TAU only. Two women dropped out of Baby Triple P after sessions two and three, respectively. They could not be contacted, and therefore, were not assessed at post-treatment and three month-follow-up. Of the drop-outs described from the Baby Triple P condition, one participant reported an adverse life event and the other lost contact. Three participants from the TAU group dropped out before post-treatment assessment and contact was lost with one further participant before the three month follow-up assessment. With respect to the TAU drop outs, one participant moved and the other three could not be contacted. At post-treatment, data were analysed from Baby Triple P
(n=12) and TAU (n=10). Following the three-month follow-up, data were analysed from Baby Triple P (n=12) and TAU (n=9). Participant characteristics and demographics are presented in Table 1.

Figure 1. CONSORT diagram of participant involvement through study progress
Table 1. Socio demographics and characteristics of mothers and their infants in Baby Triple P and treatment as usual (TAU) at baseline (Time 1).

<table>
<thead>
<tr>
<th>Maternal characteristics</th>
<th>Treatment as Usual (n = 13)</th>
<th>Baby Triple P (n = 14)</th>
<th>( \chi^2 )</th>
<th>( t(df) )</th>
<th>( p )</th>
<th>Total (n = 27)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years) (SD)</td>
<td>26.7 (sd = 6.2)</td>
<td>30.7 (sd = 5.8)</td>
<td>-1.5 (25)</td>
<td>0.16</td>
<td></td>
<td>28.4 (sd = 6.1)</td>
</tr>
<tr>
<td>Partner mean age (years) (SD)</td>
<td>28.15 (sd = 6.5)</td>
<td>34 (sd = 5.0)</td>
<td>-2.6 (25)</td>
<td>0.02*</td>
<td></td>
<td>31.2 (sd = 6.4)</td>
</tr>
<tr>
<td>Depression (BDI-II)</td>
<td>32 (sd = 9.6)</td>
<td>32.8 (sd = 9.7)</td>
<td>-0.21 (25)</td>
<td>0.83</td>
<td></td>
<td>32.4 (sd = 9.5)</td>
</tr>
<tr>
<td>EPDS</td>
<td>19 (sd = 5.2)</td>
<td>19.2 (sd = 4.8)</td>
<td>-0.11 (25)</td>
<td>0.91</td>
<td></td>
<td>19.1 (sd = 4.9)</td>
</tr>
<tr>
<td>History of depression (%)</td>
<td>0.00</td>
<td>1.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On antidepressant medication (%)</td>
<td>53.8% (n = 7)</td>
<td>57.1 (n = 8)</td>
<td>0.32</td>
<td>0.57</td>
<td></td>
<td>56% (n = 15)</td>
</tr>
<tr>
<td>Relationship status (%)</td>
<td>0.47</td>
<td>0.79</td>
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<tr>
<td>Married</td>
<td>53% (n = 7)</td>
<td>42.9% (n = 6)</td>
<td>48.1 % (n = 13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Living together</td>
<td>38.5% (n = 5)</td>
<td>42.9% (n = 6)</td>
<td>40.7 % (n = 11)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Separated/divorced</td>
<td>7.7% (n = 1)</td>
<td>14.3% (n = 2)</td>
<td>11.1 % (n = 3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnicity (%)</td>
<td>8.3</td>
<td>0.14</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>British</td>
<td>53.8% (n = 7)</td>
<td>100% (n = 14)</td>
<td>77% (n = 21)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other white background</td>
<td>7.7% (n = 1)</td>
<td>3.7% (n = 1)</td>
<td>3.7% (n = 1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other black background</td>
<td>7.7% (n = 1)</td>
<td>3.7% (n = 1)</td>
<td>3.7% (n = 1)</td>
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<tr>
<td>Other mixed background</td>
<td>7.7% (n = 1)</td>
<td>3.7% (n = 1)</td>
<td>3.7% (n = 1)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Bangladeshi</td>
<td>7.7% (n = 1)</td>
<td>3.7% (n = 1)</td>
<td>3.7% (n = 1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other ethnic background</td>
<td>15% (n = 2)</td>
<td>7.4% (n = 2)</td>
<td></td>
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<td></td>
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<tr>
<td>Education level (%)</td>
<td>2.4</td>
<td>0.79</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>No qualifications</td>
<td>7.7% (n = 1)</td>
<td>3.7% (n = 1)</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>GCSEs, CSEs or O-levels</td>
<td>15.4% (n = 2)</td>
<td>21.4% (n = 3)</td>
<td>18.5 % (n = 5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A levels/BTEC</td>
<td>23.1% (n = 3)</td>
<td>14.3% (n = 2)</td>
<td>18.5 % (n = 5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade/apprenticeship</td>
<td>7.7% (n = 1)</td>
<td>7.1% (n = 1)</td>
<td>7.4% (n = 2)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>University Degree</td>
<td>46.2% (n = 6)</td>
<td>50% (n = 7)</td>
<td>48.1 % (n = 13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family income (%)</td>
<td>2.6</td>
<td>0.3</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Low</td>
<td>38.5 (n = 5)</td>
<td>14.3% (n = 2)</td>
<td>35.9% (n = 7)</td>
<td></td>
<td></td>
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<tr>
<td>Middle</td>
<td>30.8 (n = 4)</td>
<td>57.1 (n = 8)</td>
<td>44.4% (n = 12)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>High</td>
<td>30.8 (n = 4)</td>
<td>28.6% (n = 4)</td>
<td>29.6% (n = 8)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Maternal employment (%)</td>
<td>3.4</td>
<td>0.49</td>
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</tr>
<tr>
<td>Full time</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Part time</td>
<td>7.7 % (n = 1)</td>
<td>14.3% (n = 2)</td>
<td>11.1% (n = 3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home duties</td>
<td>30.8% (n = 4)</td>
<td>7.1% (n = 1)</td>
<td>18.5% (n = 5)</td>
<td></td>
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<tr>
<td>On maternity leave</td>
<td>46.2% (n = 6)</td>
<td>50% (n = 7)</td>
<td>48.1% (n = 13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>15.4% (n = 2)</td>
<td>21.4% (n = 3)</td>
<td>18.5% (n = 5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infant characteristics</td>
<td>-0.81 (25)</td>
<td>0.43</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age (months) at baseline</td>
<td>5.7 (sd = 3.1)</td>
<td>6.7 (sd = 3.4)</td>
<td>6.2 (sd = 3.2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female (%)</td>
<td>46.2% (n = 6)</td>
<td>64.3% (n = 9)</td>
<td>0.31</td>
<td>0.58</td>
<td>56% (n = 15)</td>
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<tr>
<td>Primiparous (%)</td>
<td>76.9% (n = 10)</td>
<td>71.4% (n = 10)</td>
<td>.00</td>
<td>1.0</td>
<td>74.1% (n = 20)</td>
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<tr>
<td>Pregnancy characteristics (%)</td>
<td>0.52</td>
<td>0.92</td>
<td></td>
<td></td>
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<tr>
<td>Delivery (%)</td>
<td></td>
<td></td>
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<tr>
<td>Vaginal</td>
<td>61.5% (n = 8)</td>
<td>71.4% (n = 10)</td>
<td>67% (n = 18)</td>
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<tr>
<td>Assisted delivery (forceps)</td>
<td>15.4% (n = 2)</td>
<td>7.1% (n = 1)</td>
<td>11.1% (n = 3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency caesarean</td>
<td>15.4% (n = 1)</td>
<td>14.3% (n = 2)</td>
<td>15% (n = 4)</td>
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<tr>
<td>Planned caesarean</td>
<td>7.7% (n = 1)</td>
<td>7.1% (n = 1)</td>
<td>7.4% (n = 2)</td>
<td></td>
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<tr>
<td>Perinatal complications (%)</td>
<td>0.94</td>
<td>0.33</td>
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</tr>
<tr>
<td>Yes</td>
<td>38.5% (n = 5)</td>
<td>57.1 (n = 8)</td>
<td>48.1% (n = 13)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Planned pregnancy (%)</td>
<td>0.00</td>
<td>1.0</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Yes</td>
<td>69.2% (n = 9)</td>
<td>64.3% (n = 9)</td>
<td>66.7% (n = 18)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*SD= standard deviation, n= number, m= mean

*Fisher's exact probability test
6.3.1 Treatment as usual

Although treatment as usual (TAU) varied amongst participants, the most common treatment was anti-depressant medication (i.e., sertraline, fluoxetine, citalopram). Of the 27 women in this study, a total of 21 women (TAU= 9; Baby Triple P + TAU = 12) were receiving antidepressant medication. Four women (TAU=2; Baby Triple P= 2) were also receiving some form of psychological support (CBT, counselling) in addition. A total of 11 participants (TAU=5; Baby Triple P= 6) had been referred by a specialist health visitor following the completion of a postnatal support group.

6.3.2 Statistical analysis

Preliminary checks of the data indicated skewness and kurtosis on some of the outcome measures. Log (ln) transformations were performed successfully on data which violated the assumptions of non-parametric testing. Where data could not be transformed successfully, non-parametric tests (Mann-Whitney U) were used to compare group differences on change scores. Preliminary analysis of baseline characteristics revealed no differences on any variables except for age of partner, therefore, only baseline scores were entered as covariates for ANCOVA analyses due to the small sample size.

Individual missing items from self-report questionnaires (i.e., where one or two questions were missed) were handled by adding all available responses (i.e., all the questions that were answered) and then dividing by the total number of items in the questionnaire to obtain an average item score. The average item score then replaced missing item scores. Analyses followed intention-to-treat (ITT) protocol and included all participants as randomised. However, it was only possible to include participants who had been assessed at least at two time-points. Complete data from baseline to post-treatment were available for 22 participants (TAU=10, Baby Triple P=12). Complete datasets from baseline to follow-up were available for 21 participants (TAU=9, Baby Triple P=12). It was not possible to perform multiple imputations on the data given the small sample size. Sensitivity analyses were carried out using the Last Observation Carried Forward (LOCF) method for handling missing data.

6.3.3 Maternal mood

There were no significant differences between conditions on depressed mood at post-treatment (Baby Triple P, \(m=9.39, CI=5.5-16.1\); TAU, \(m=11.23, CI= 6.3-20.3\)), \(F(1,19)= 1.9, p=1.8\), partial eta squared = 0.09, or from baseline to follow-up, \(F(1, 18)=.25, p=0.65\), partial eta squared = 0.12, between the groups (Baby Triple P, \(m=9.49, CI=5.2-17.5\); TAU, \(m=7.77, CI= 3.9-15.5\)) (see Table 2).
Table 2. Adjusted means and confidence intervals for all outcome measures at all time points

<table>
<thead>
<tr>
<th>Measure and condition</th>
<th>Baseline&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Post-test</th>
<th>3 month follow-up</th>
<th>Baseline to post-test</th>
<th>Baseline to 3 month follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M (SD)</td>
<td>M (CI)</td>
<td></td>
<td>F(df)</td>
<td>p</td>
</tr>
<tr>
<td>Baby TP</td>
<td>31.50&lt;sup&gt;b&lt;/sup&gt;</td>
<td>9.39 (5.5-16.1)</td>
<td>9.49 (5.2-17.5)</td>
<td>1.9(1)</td>
<td>.18</td>
</tr>
<tr>
<td>TAU</td>
<td>30.56&lt;sup&gt;b&lt;/sup&gt;</td>
<td>11.23 (6.3-20.3)</td>
<td>7.77 (3.9-15.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OHI</td>
<td>68.23 (15.23)</td>
<td>117.80 (101.75-133.85)</td>
<td>118.30 (101.11-135.57)</td>
<td>2.89(1)</td>
<td>.11</td>
</tr>
<tr>
<td>TAU</td>
<td>83.99 (19.97)</td>
<td>98.20 (80.57-115.83)</td>
<td>102.70 (82.70-122.62)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WPL</td>
<td>155.52 (30.63)</td>
<td>171.73 (160.97-182.02)</td>
<td>176.30 (165.76-186.87)</td>
<td>0.28(1)</td>
<td>.60</td>
</tr>
<tr>
<td>TAU</td>
<td>175.15 (20.55)</td>
<td>175.00 (165.63-184.77)</td>
<td>172.70 (160.42-184.92)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PBS-b</td>
<td>54.71 (9.63)</td>
<td>65.09 (61.04-69.15)</td>
<td>62.32 (57.65-66.99)</td>
<td>1.19(1)</td>
<td>.29</td>
</tr>
<tr>
<td>TAU</td>
<td>56.25 (10.82)</td>
<td>61.88 (57.20-66.56)</td>
<td>60.90 (55.18-66.62)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PBQ&lt;sup&gt;d&lt;/sup&gt;</td>
<td>20.62 (8.65-75.96)</td>
<td>9.5 (0-67.0)</td>
<td>7.0 (0-48.0)</td>
<td>54.0</td>
<td>-0.40</td>
</tr>
<tr>
<td>TAU</td>
<td>18.9 (1.92-56.73)</td>
<td>9.75 (1.0-38.0)</td>
<td>16.0 (0-31.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Adjusted geometric mean (95% confidence intervals)<sup>b</sup> Geometric mean (range)<sup>c</sup> Raw data mean (SD)<sup>d</sup> Median (range), p value from Mann Whitney test.

BDI-II= Beck Depression Inventory-II; OHI= Oxford Happiness Inventory; PBQ= Postpartum Bonding Questionnaire; WPL= What Being the Parenting of a Baby is Like; PBS= Parenting Beliefs Scale
There was a significant effect of time across both groups on happiness (OHI scores) from baseline to post-treatment \(F(1, 19)= 8.19, p= 0.01\), and from baseline to three-month follow-up \(F(1, 18)= 5.89, p= 0.03\). Women receiving Baby Triple P obtained comparatively higher happiness (OHI scores) compared with women receiving TAU at post post-treatment \(\text{(Baby Triple P, } m=117.80, \text{ CI=101.75-133.85}; \text{ TAU, } m=98.20, \text{ CI=80.57-115.83})\) and at follow-up \(\text{(Baby Triple P, } m=118.30, \text{ CI=101.11-135.57}; \text{ TAU, } m=102.70, \text{ CI=82.70-122.62})\). However, these differences were not statistically significant when controlling for happiness (OHI scores) at baseline from baseline to post-treatment, \(F(1, 19)=2.89, p=0.11\), partial eta squared = 0.13 and from baseline to three-month follow-up, \(F(1, 18)=1.5, p=0.23\), partial eta squared = 0.08.

6.3.4 Self-regulation

There was a significant effect of time across both groups on self-regulation (BPBS-b) scores from baseline to post-treatment \(F(1,18)= 6.88, p= 0.02\). Although the Baby Triple P group \(m= 65.09, \text{ CI= 61.04-69.15})\) obtained higher scores at post-treatment compared with women allocated to TAU \(m= 61.88, \text{ CI= 57.20-66.56})\), this difference was not statistically significant \(F(1,18)= 1.19, p=0.29\). Again, there was a significant effect of time across both groups on self-regulation scores from baseline to three-month follow-up \(F(1, 17)= 5.32, p= 0.03\). Women receiving Baby Triple P \(m=62.32, \text{ CI= 57.65-66.99})\) obtained higher self-regulation scores compared with those receiving Tau \(m=60.90, \text{ CI= 55.18-66.62})\), although these differences were not significant \(F(1,17)= 0.16, p= 0.69\).

6.3.5 Parenting attitudes

With regard to experience of parenthood (WPL), there was a significant effect of time \(F(1, 19)=14.13, p=0.001\). However, no significant group differences were found (when controlling for baseline WPL scores) from baseline to post-treatment \(F(1, 19)=0.28, p=0.60\), partial eta squared = 0.02 \(\text{(Baby Triple P } m=171.73, \text{ CI= 160.97-182.02}; \text{ TAU, } m=175.00, \text{ CI=165.63-184.77})\). There was also a significant effect of time across both groups on experience of parenthood from baseline to three-month follow-up \(F(1, 18)= 6.45, p= 0.02\). However, the groups did not differ significantly (when controlling for baseline WPL scores) from baseline to follow-up \(F(1, 18)=0.22, p=0.65\), partial eta squared = 0.01 \(\text{(Baby Triple P } m=176.30, \text{ CI= 165.76-182.87}; \text{ TAU, } m=172.72, \text{ CI=160.42-184.92})\).
6.3.6 Subjective bonding
Since subjective bonding (PBQ) scores could not be transformed successfully, change scores were calculated from baseline to post-treatment and again from baseline to three-month follow-up; groups were then compared using Mann Whitney U. Although subjective bonding scores improved from baseline to post-treatment for women receiving Baby Triple P (mdn= 9.5, range= 0-67.0) compared with those receiving TAU (mdn= 9.75, range=1.0-38.0), the difference was not significant $u= 54.0$, $z= -0.40$, $p= 0.69$. A similar pattern of change was observed from baseline to three-month follow-up. Women allocated to Baby Triple P (mdn= 7.0, range= 0-48.0) reported greater improvements compared with women allocated to TAU (mdn= 16.0, range= 0-31.0); however, the difference was not statistically significant $u= 40.0$, $z= -1.00$, $p= 0.32$.

6.3.7 Dyad relationship
With respect to maternal sensitivity, although it increased from baseline to post-treatment in women receiving Baby Triple P compared with those receiving TAU, group differences were not significant, $U= 51.5$, $p=0.57$, $z=-0.57$ (see Table 3). Changes in maternal controlling behaviour decreased for women receiving Baby Triple P, and increased for the TAU group from baseline to post-treatment. However, these differences did not reach significance, $U= 39$, $p=0.16$, $z=-1.39$. Again, changes in maternal unresponsiveness were not significant between the two groups from baseline to post-treatment, $U= 39.5$, $p=0.17$, $z=-1.36$. The infants of mothers in both groups were observed to be more cooperative from baseline to post-treatment; however, these differences were non-significant $U= 51.5$, $p=0.57$, $z=-0.56$. Infants of mothers in both groups were observed to display more difficult behaviour from baseline to post-treatment but this change in difficult behaviour was non-significant $U= 53$, $p=0.64$, $z=-0.47$. Infant compulsivity also did not appear to non-significantly increase for infants of mothers receiving Baby Triple P compared with infants of TAU mothers from baseline to post-treatment $U= 53$, $p=0.64$, $z=-.47$. Non-significant decreases in infant passivity were also observed in both groups $U= 50$, $p=.51$, $z=-.67$.

The pattern of results was similar from baseline to three-month follow-up. Maternal sensitivity increased although the change from baseline to three-month follow-up was not statistically significant, $U= 43.5$, $p=0.45$, $z=-0.75$. Changes in maternal controlling did not reach significance, $U= 43$, $p=0.43$, $z=-0.79$. Again, changes in maternal unresponsiveness were not significant between the two groups from baseline to post-test, 43, $p=0.43$, $z=-0.79$. The infants of mothers in both groups were observed to be more cooperative from baseline to post-test, however these differences were non-significant, $U= 48.0$, $p=0.67$, $z=-
0.42. This non-significant pattern was the same for change in infant difficult behaviour, $U= 52.0$, $p=0.89$, $z=-0.14$ and infant compulsivity $U= 41.0$, $p=0.35$, $z=-0.93$. A non-significant decreases in infant passivity was found in both groups $U= 41.0$, $p=0.35$, $z=-0.94$. 
### Table 3. Medians and ranges for Care index variables for Baby TP group and TAU at Baseline (Time 1), post treatment (Time 2) and 3 month follow-up (Time 3)

<table>
<thead>
<tr>
<th>Care index variable</th>
<th>Baby TP Median (range)</th>
<th>TAU Median (range)</th>
<th>Baby TP Median (range)</th>
<th>TAU Median (range)</th>
<th>Baseline to post-treatment delta</th>
<th>a</th>
<th>z</th>
<th>p</th>
<th>Baseline to follow-up delta</th>
<th>TAU a</th>
<th>z</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mother</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensitive</td>
<td>4.0 (2-11)</td>
<td>5.0 (2-12)</td>
<td>4.5 (1-9)</td>
<td>6.0 (2-12)</td>
<td>5.0 (2-8)</td>
<td>6.0 (2-11)</td>
<td>0.5 (-4.0 to 4.0)</td>
<td>.5 (-6.0 to 5.0)</td>
<td>51.5</td>
<td>-0.57</td>
<td>0.57</td>
<td>1.0 (-5.0 to 4.0)</td>
</tr>
<tr>
<td>Controlling</td>
<td>6.0 (1-9)</td>
<td>5.0 (1-12)</td>
<td>5.0 (3-13)</td>
<td>7.0 (1-10)</td>
<td>6.0 (2-11)</td>
<td>7.0 (1-12)</td>
<td>-0.5 (-4.0 to 5.0)</td>
<td>2.0 (-2.0 to 7.0)</td>
<td>39.0</td>
<td>-1.39</td>
<td>0.16</td>
<td>1.5 (-4.0 to 6.0)</td>
</tr>
<tr>
<td>Unresponsiveness</td>
<td>2.0 (0-11)</td>
<td>3.0 (0-10)</td>
<td>2.0 (0-8)</td>
<td>0.5 (0-2)</td>
<td>2.0 (0-5)</td>
<td>2.0 (0-4)</td>
<td>-0.5 (-6.0 to 4.0)</td>
<td>-2.5 (-9.0 to 2.0)</td>
<td>39.5</td>
<td>-1.36</td>
<td>0.17</td>
<td>-1.0 (-8.0 to 3)</td>
</tr>
<tr>
<td><strong>Infant</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cooperativeness</td>
<td>4.5 (1-10)</td>
<td>4.0 (0-12)</td>
<td>5.0 (1-9)</td>
<td>7.0 (1-12)</td>
<td>5.0 (2-9)</td>
<td>7.0 (3-12)</td>
<td>0.5 (-3.0 to 4.0)</td>
<td>1.0 (-5.0 to 6.0)</td>
<td>51.5</td>
<td>-0.56</td>
<td>0.57</td>
<td>0.5 (-5.0 to 5.0)</td>
</tr>
<tr>
<td>Difficult behaviour</td>
<td>2.0 (0-7)</td>
<td>2.0 (0-7)</td>
<td>3.5 (0-12)</td>
<td>4.0 (0-13)</td>
<td>3.5 (0-11)</td>
<td>3.0 (0-8)</td>
<td>0.5 (-10.0 to 12)</td>
<td>0.0 (-5.0 to 7.0)</td>
<td>53.0</td>
<td>-0.47</td>
<td>0.64</td>
<td>1.0 (-9.0 to 11.0)</td>
</tr>
<tr>
<td>Compulsivity</td>
<td>1.0 (0-10)</td>
<td>1.0 (0-12)</td>
<td>1.5 (0-12)</td>
<td>0.0 (0-9)</td>
<td>3.0 (0-7)</td>
<td>4.0 (1-7)</td>
<td>0 (-6.0 to 12.0)</td>
<td>1.5 (-2.0 to 8)</td>
<td>53.0</td>
<td>-0.47</td>
<td>0.64</td>
<td>1.5 (-6.0 to 5.0)</td>
</tr>
<tr>
<td>Passivity</td>
<td>1.0 (0-11)</td>
<td>1.0 (0-9)</td>
<td>0.5 (0-5)</td>
<td>0.5 (0-5)</td>
<td>0.0 (0-5)</td>
<td>0.0 (0-3)</td>
<td>-1.0 (-11.0 to 4.0)</td>
<td>-1.0 (-7.0 to 2.0)</td>
<td>50.0</td>
<td>-0.67</td>
<td>0.51</td>
<td>0.0 (-11.0 to 2.0)</td>
</tr>
</tbody>
</table>
6.3.8 Reliable change index

At post-treatment women allocated to the Baby Triple P group had lower BDI-II scores. Although the ANCOVA analysis indicated that the difference between the groups was not significant, there was a significant effect of time. Therefore, individual scores were assessed using Jacobson and Truax’s (1991) reliable change index (RCI). From baseline to post-treatment 75% of women in Baby Triple P had a clinically significant improvement to depressed mood compared with 70% of women allocated to TAU. From baseline to three-month follow-up 75% of women in Baby Triple P had clinically significant improvements compared with 80% of the TAU group (Appendix, p. 265).

6.3.9 Baby Triple P acceptability

Women receiving Baby Triple P rated Baby Triple P as highly acceptable. Table 4 shows means and standard deviations for each of the 13 items on the CSQ. Scores ranged from 1 (least satisfied) to 7 (most satisfied). The mean total score was 85.83 (sd=4.47), from a maximum score of 91.

Table 4. Client satisfaction ratings for women allocated to Baby Triple P

<table>
<thead>
<tr>
<th>Item</th>
<th>Client satisfaction questionnaire (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of service</td>
<td>M</td>
</tr>
<tr>
<td>Baby Triple P provided the help sought</td>
<td>6.75</td>
</tr>
<tr>
<td>Baby Triple P met child’s needs</td>
<td>6.67</td>
</tr>
<tr>
<td>Baby Triple P met parental needs</td>
<td>6.83</td>
</tr>
<tr>
<td>Satisfied with amount of help</td>
<td>7.00</td>
</tr>
<tr>
<td>Programme has helped with child behaviour</td>
<td>6.75</td>
</tr>
<tr>
<td>Programme has helped deal with family problems</td>
<td>6.58</td>
</tr>
<tr>
<td>Programme has helped with partner relationship</td>
<td>5.64</td>
</tr>
<tr>
<td>Overall satisfaction with programme</td>
<td>7.00</td>
</tr>
<tr>
<td>Would do Triple P again if needed</td>
<td>6.92</td>
</tr>
<tr>
<td>Programme skills can be applied to other family members</td>
<td>6.42</td>
</tr>
<tr>
<td>Child’s development at this point</td>
<td>6.25</td>
</tr>
<tr>
<td>Satisfaction with child progress</td>
<td>6.67</td>
</tr>
</tbody>
</table>
6.4 Discussion

The primary aim of this study was to investigate the efficacy and acceptability of the newly developed Baby Positive Parenting Programme (Baby Triple P) compared with TAU in women with PND. The primary hypothesis that Baby Triple P would be associated with greater decreases in depressed maternal mood compared with TAU was not supported. The hypothesis that women receiving Baby Triple P would be observed to be more sensitive in their interaction with their infants was also not supported, as demonstrated by the non-significant findings across the sensitivity scale and all other CARE-Index subscales. There were no significant group differences on any of the other secondary outcome measures including happiness, subjective bonding, the parenting experience and self-regulation.

Our hypothesis that any significant changes would be maintained at three-month follow-up was also not supported. Despite the non-significant findings reported here, Baby Triple P was rated highly acceptable by the women receiving it. This is comparable to CSQ scores obtained in other Triple P trials (i.e., Hoath & Sanders, 2002).

Whilst a possible explanation for the non-significant findings may be due to low power, there are also some additional alternative explanations. One possibility is related to the level of depressive symptoms in the present study. The intended sample was women with mild to moderate PND. However, the present sample was more severely depressed compared with previous studies which reported total BDI-II scores between 14.4 and 28.9 at baseline. The level of depression in the present study may have elicited added support to the participants, including more careful monitoring by health visitors and stronger medication prescription by GP. Indeed, 11 participants across both groups had been referred to the study following an eight-session support group. Although when assessed they were still elevated in terms of their depression symptoms, they described that the group had helped normalise their experiences and reduce feelings of isolation. Furthermore, the health visitors who referred women to this study represent a minority of health visitors who were especially interested in PND and the objectives of the research. Their level of motivation may have had an impact on recovery rates in the TAU group compared with the quality of health visiting services in other areas.

The fact that the majority of the women (21/27) in the present study were also taking anti-depressants may have further contributed to improvement in symptoms. Previous studies which compared anti-depressant medication with Interpersonal Psychotherapy (IPT; Pearlstein et al., 2006) and another with Cognitive Behaviour Therapy (CBT; Misri, Reebye, Corral, & Mills, 2004) reported a similar pattern of results to the present study. It is also possible that there may have been improvements in the
intervention group, which our measures were not sensitive to; for example, marital relationship and parenting stress.

Women receiving Baby Triple P had greater improvements in their self-regulation scores compared with TAU. Although this was not significant, it supports the theorised relationship between depression and dysfunctional self-regulation posed by Bandura (1991). Indeed the effect of time on self-regulation was significant across both groups. Specifically, self-regulation increased for both groups. This may be related to decreases in depression, or that women became more confident in their parenting skills over time.

6.4.1 Implementation issues
High scores on the Client Satisfaction Questionnaire (CSQ) suggest that Baby Triple P was highly acceptable to women with PND. Although the sample size was modest (N=27), the drop out was very low (N=2/14), which further demonstrates the acceptability of the intervention and engagement from the research team.

With regard to implementation, future studies may consider building in time to the first session to debrief about the birth experience if relevant since it may promote engagement. Furthermore, with a more severely depressed sample the practitioner may also need to build in time to manage and contain participant distress, because this sometimes affected the ability to focus on the session. However, this aspect can be challenging when the practitioner is constrained to cover the content of a manualised intervention that must be delivered within a particular time frame.

Another consideration is whether to have the baby present during sessions. In this study, all assessments and sessions (for women of the intervention condition) were conducted in participants’ homes. This decision was taken to increase participation and reduce drop out, as well as facilitate attendance at sessions when parents could not afford or arrange child-care. Clinical observations suggest that, for the most part, having the baby present during sessions was generally not obstructive and allowed for practising of skills in situ. However, there was no measurement of whether having baby present significantly distracted or facilitated women from focusing on the content.

6.4.2 Limitations
Despite some encouraging findings, some limitations need to be considered. Firstly, the sample size was small. According to the power analysis, the study was under-powered to detect significant group differences. This is a common limitation of pilot studies, but one that does not necessarily imply a negative result (Altman & Bland, 1995). A further limitation was that all assessments and the delivery of Baby Triple P sessions were
undertaken by the same person (ZT). Although this decision potentially introduced a response bias, it promoted a rapport with participants. Indeed, at the referral stage, several participants had expressed concerns over having to deal with multiple researchers; therefore, contact with only one researcher may have contributed to low attrition.

6.4.3 Recommendations for future research

Although this was a small pilot trial, it provides a foundation for informing the methodological decisions of future (larger scale) trials. Lancaster and colleagues (2004) have highlighted that pilot studies can lead to higher quality RCTs. The present study has provided information to enable calculation of future sample sizes. Based on the findings from the present study a retrospective power calculation was completed and it was determined that future studies would need 237 participants per group, to detect an effect size of 0.258 between the groups (Whiteside, 2012). Although this is a large figure, with more participants in each group the number needed to detect an effect is likely to decrease.

The study protocols have been developed and have also undergone further refinement. These include an intake interview schedule designed to assess initial eligibility criteria and provide further information about randomisation and Baby Triple P session content.

In relation to data collection, in the present study it took approximately 30-45 minutes to complete all questionnaires. Some participants reported that this was too long. Alternatively, assessment batteries could be completed by participants on-line, which may be more convenient. Whilst this approach could reduce response biases, it may result in reduced response rates. All measures in the present study were validated, reliable measures. The primary outcome measure, (the BDI-II) is a very robust indicator of depression severity. The inclusion of the BDI-II in future studies would allow comparisons between studies with respect to changes in depression symptoms.

Responses on the CSQ indicated that Baby Triple P had a positive effect on the marital relationship. Although the marital relationship and paternal wellbeing were not formally assessed, future studies could include indexes of marital adjustment and paternal wellbeing since these may be affected by PND. The variables could be potential mediators in recovery from PND and infant wellbeing. Future studies should also collect detailed information on participants’ psychiatric histories (including: chronicity and severity of symptoms) their socio-economic status, age of infant, factors around their pregnancy and the nature of the experience since these variables may play an important part in their engagement as well as their recovery.
Regarding recruitment of the sample, there are further considerations for future research. Women with PND have historically been a very difficult population to recruit successfully to research trials (Appleby & Whitton, 1993). Literature on help-seeking behaviour has elucidated several factors, which influence whether women disclose their experiences and seek support. For example, women with PND are often reluctant to disclose their experiences, particularly women from Black and Ethnic Minority (BME) populations (Dennis & Chung-Lee, 2006; Shakespeare, Blake, & Garcia, 2006).

The experience in the present study was comparable to the literature despite assertive and varied methods of recruitment. This involved contacting all general practitioners (GP), community pharmacists, health visitors, community midwives, charitable organisations in the local area and public advertising. Following contact, individual visits were made to teams to present what the research involved, what the potential benefits to clients might be and how it might help support the service. Brief information leaflets were provided to all teams. Social media was also used to promote the research, including Twitter and Facebook. Despite prevalence rates in the geographical area, referral rates were by comparison extremely low. The teams that did refer clients had a great deal of interest in parenting and reported a need for continued support of their clients.

Given these difficulties with recruitment, there are important implications concerning the process by which people are recruited and consent to research. With respect to participants who were referred by health visitors, the researcher was only able to make contact with participants once they had agreed. Therefore, the task of answering questions about the research is left to the referrer. Unless the referrer has detailed knowledge and understanding of the research, this is likely to result in a lower referral rate. Future studies could overcome this by having a research nurse or health visitor who has detailed knowledge of the study integrated within the service in order to recruit women. Not all participants will enter the study via referral systems. In the present study, it was noted that the individuals who self-referred (i.e., saw the study advertised in the public domain), although still met inclusion criteria, had fewer difficulties and symptoms were less severe compared with clients who were referred via a primary care healthcare professional.

6.5 Conclusion
This pilot RCT represents one of the first applications of parenting interventions in the context of PND and is the first to examine the efficacy and acceptability of Baby Triple P to PND. Several important observations related to implementation could inform future
research. Although the present study failed to demonstrate an additive effect of Baby Triple P, the pattern of results was in the predicted direction with regard to level of happiness, self-regulation, subjective bonding, and depression (at post-treatment only). The lack of power suggests that these results should be taken as preliminary. It also suggests that an intervention with a parenting focus is highly acceptable to women with PND. On the basis of establishing feasibility and high acceptability in the present study, a larger scale RCT is warranted.
References


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Chapter 7

General Discussion
7.0 Overview of general discussion

The quality of parenting has implications for the course of child development. Despite the difficulties with parenting in the context of PND, this area has received little attention in the literature. Therefore, the primary aim of this thesis was to investigate whether the Baby Positive Parenting Programme (Baby Triple P), a newly adapted variant of the Positive Parenting Programme for parents with babies, could be efficacious in the treatment of women with Postnatal Depression (PND). A secondary aim was to develop and validate a measure of parental self-regulation for use in the present study and future investigations of parenting interventions.

After summarising the introductory chapters (Chapters 1, 2, 3, & 4), the Factor Analysis of the brief Parenting Beliefs Scale-baby version (BPBS-b) is discussed (FA; Chapter 5). Following this, Chapter 6, i.e., the pilot RCT of Baby Triple P is reviewed along with an exploration of the findings. Methodological limitations and recruitment difficulties and barriers to access are then considered. The strengths of the study are reviewed, followed by implementation issues and clinical implications. Finally, recommendations for future research are made.

7.1 Thesis summary

In Chapter 1, a broad overview was presented to provide a conceptual understanding of PND and to summarise the treatment literature. A number of literature reviews on the subject have been completed (Boath & Henshaw, 2001; Cuijpers, Brannmark, & van Straten, 2008; Field, 1997; Leahy-Warren & McCarthy, 2007; Leis, Mendelson, Tandon, & Perry, 2009; Morrell, 2006); therefore, the present aim was to provide an overview only. Whilst publicizing the study, the authors were approached by the National Childbirth Trust (NCT) to publish an overview of treatments for PND. The content of Chapter 1 was therefore shortened and published in the NCT midwifery practice journal, Perspectives. For the purposes of this thesis Chapter 1 served as an introductory chapter. The literature overview highlighted the absence of treatments targeting parenting and the limited number of child developmental outcomes despite the widely present evidence impact of the on parenting and child development. The efficacy of treatments for PND on child development and the dyad relationship were therefore not clear and warranted further investigation.

Although narrative reviews use more “idiosyncratic, informal and subject methods to collect and interpret information” (p.81; Jadad, 1998), the search method was
appropriate for the aim of the overview, which was to gain an understanding of the
literature and provide a context for the present study.

Although there have been a large number of reviews of PND treatments, many of
the reviews focus on maternal outcomes. The insights from Chapter 1 provided the basis
and rationale for Chapter 2, a systematic review of treatments, in which child related
outcomes and/or the mother-infant relationship in addition to maternal mood were assessed.

Given the implications for infant development and the relational aspect of PND
outlined in Chapter 1, the treatment literature on these issues were assessed using a
systematic method in Chapter 2. After an extensive literature search, a total of 15 studies
were identified and were systematically evaluated using Tarrier and Wykes’ (2004)
Clinical Tool for Assessment of Methodology (CTAM). This was the first study of its kind
to calculate effect sizes (where possible) across maternal and child developmental
outcomes.

In Chapter 2 it was highlighted that whilst some interventions have demonstrated
efficacy in reducing maternal depression, their effects were not sufficient to translate into
comparable outcomes in the mother-infant relationship and child development. This
observation was supported by the magnitude of effect sizes across different measures.

One of the key strengths of the systematic review was the precision with which the
quality of the studies was assessed. The CTAM is a rigorous method for assessing quality.
The aspects of a methodology that it assesses (sample, allocation, assessment, control
group, analysis & treatment) have been defined by the authors of the Delphi list as
important items in quality assessment (Verhagen et al., 1998).

A key limitation was that it was not possible to calculate effect sizes for all
outcomes on each of the studies due to missing information needed to perform effect size
calculations. A further limitation was that the literature search was not extended to
unpublished studies; therefore, some studies may have been missed. However, since
unpublished studies are not subjected to peer-review, the quality of these studies may be
lower. It is possible that some interventions had big effects, but these were not identified
due to the missing information. A final limitation was the assessment method with which a
PND diagnosis was confirmed. For example, some studies used less rigorous methods of
identifying women with PND, including screening methods (i.e., the Edinburgh Postnatal
Depression Scale, EPDS).

The findings from the systematic review of Chapter 2 are comparable with the
findings reported by Poobalan and colleagues (2007), as well as reviews of intervention
literature in that there was no superior intervention for PND. Although interventions
focused on relationship between mother and infant, none of the studies had focused on parenting, despite evidence for the difficulties women with PND experience in this domain. The poverty of parenting focused interventions within the context of PND provided the basis for Chapter 3 and the subject of this thesis.

The purpose of Chapter 3 was to provide an introduction to the Triple P system, to describe the evidence base and to outline the session content of Baby Triple P. A rationale for the application of a parenting approach to PND was also provided with particular emphasis on the role of self-regulation in adaptive parenting. Chapter 4 detailed the methodology for Chapters 5 and 6 respectively.

7.2 Review of Chapter 5
The theoretical framework of Triple P proposes that improvements and maintenance following Triple P are a result of more functional parental self-regulation. Bandura (1991) also theorised that self-regulation is dysfunctional in the context of depression. Therefore, given the hypothesized importance of self-regulation, the purpose of Chapter 5 was to investigate the validity and reliability of a new measure of parental self-regulation, the brief Parenting Beliefs Scale- baby version (BPBS-b, Tsivos & Sanders, 2012) for use in the present and future studies.

The Factor Analysis (FA) resulted in a three-factor-solution, including: personal agency, self-management and self-efficacy (Tsivos, Wittkowski, Calam, & Sanders, submitted). Items designed to reflect self-sufficiency and self-efficacy did not form separate factors as indicated by self-regulatory theory. This could be explained by the proposed overlap between self-efficacy and self-sufficiency. Indeed it is noted within the literature that the two terms are difficult to distinguish (Reck, Noe, Gerstenlauer, & Stehle, 2012). Based on the outcome of the FA, the scale was revised and initially reduced from 22-to-19-items. However, the internal consistency of the resultant scale was affected by the combination of positively and negatively phrased items within the personal agency subscale. Consequently, these problematic items were deleted, which resulted in improved internal consistency and the final 16-item scale of parental self-regulation.

The FA resulted in a reliable measure of self-regulation following the deletion of items that did not load or those that affected the internal consistency of the scale. Given the proposed role of dysfunctional self-regulation in depression (Bandura, 1991), and in parenting interventions (Sanders, Mazzucchelli, & Ralph, in press), the BPBS-b would allow for investigation of this relationship within the main study. Although there have been
studies investigating self-efficacy, until now there has been no investigation of self-regulation as a whole construct within this area of the literature.

The main limitation of the FA was the homogeneity of the participant sample. Firstly, the sample was predominantly white British, and therefore the generalizability to other ethnic groups is limited. Secondly, the participant sample was new mothers, which limits our understanding of parental self-regulation in fathers. However, the intention was to validate the measure in a non-clinical sample of women for use in the pilot study. Furthermore, infant gender was not included. Although these limitations reduce the generalizability, they are limitations which could be explored in future investigations.

The result of Chapter 5 was a reliable brief measure of self-regulation which was appropriate for use in the pilot study. The BPBS-b could also be used in future research of parenting interventions to measure change in self-regulation.

7.3 Review of Chapter 6

The objective of Chapter 6 was to conduct a pilot trial in order to investigate the efficacy and acceptability of Baby Triple P compared with treatment as usual (TAU). The primary hypothesis that compared with TAU, Baby Triple P would be associated with greater decreases in symptoms of depression, as measured by the Beck Depression Inventory-Second Edition (BDI-II), was not supported. The hypothesis that Baby Triple P would be associated with greater improvements in the dyad relationship, as measured by the CARE-Index, was also not supported. While both groups appeared to significantly improve across time, there were no significant group differences.

Non-significant findings were also reported across all secondary measures including happiness, as measured by the Oxford Happiness Inventory (OHI); subjective bonding, as measured by the Postpartum Bonding Questionnaire (PBQ); the parenting experience, as measured by the What Being the Parenting of a baby is Like (WPL); and self-regulation, measured by the Brief Parenting Beliefs Scale-baby version (BPBS-b). The hypothesis that there would be a maintenance effect at three-month follow-up was also not supported. Despite these non-significant findings for differences between groups, both groups improved significantly. Furthermore, Baby Triple P was rated highly acceptable (measured by the Client Satisfaction Questionnaire, CSQ) by the women receiving it.

7.4 Exploration of the findings

Although it was reported that the women receiving Baby Triple P had improvements in depressed mood relative to the TAU group, these differences were not clinically significant.
Although low power might partly account for the non-significant findings, a number of other alternative explanations exist.

The findings from this study replicate others who reported improvements to maternal mood in both groups (i.e., treatment vs. control/TAU) but found no significant group differences. These include studies where the TAU group was mostly receiving antidepressant medication. For example, Misri and colleagues (2004) found no group differences in their RCT (N=35) comparing paroxetine with Cognitive Behavioural Therapy (CBT) combined with paroxetine. Similarly, Pearlstein and colleagues (2006) reported significant improvements in maternal mood when they compared sertraline with Interpersonal Psychotherapy (IPT) and a third group combining sertraline with IPT (N=23). The findings reported in the present study and those by Misri et al. (2004) and Pearlstein et al. (2006) could also be explained by their similarly small sample sizes, which prevented detection of significant group differences.

Findings from the present and aforementioned studies suggest that the intervention did not have an additive effect. It is possible that anti-depressants (taken by TAU and Baby Triple P) added additional support, which may explain the absence of significant group differences. It is also possible that participants in TAU may have benefited from assessment sessions; particularly the initial assessment during which the SCID was used as a clinical interview, and involved a thorough assessment of their experiences.

With respect to the reliable change index (RCI; Jacobson & Truax, 1991), 75% and 70% of participants in Baby Triple P and TAU respectively, had a clinically significant and reliable change. However, a small sample of women from both groups did not improve. With respect to the women who did not improve, this could be explained in light of the dose-effect relationship in psychotherapy which details that the level of intensity of the intervention was not sufficient to produce significant improvements (Howard, Kopta, Krause, & Orlinsky, 1986). For these women the time-limited intervention may not have been sufficient to significantly reduce symptoms of depression.

Despite both groups improving in their depression scores, the infant characteristics observed on the CARE-Index remained the same. This finding does fit with previous literature (see Tsivos et al., submitted), which found improvements in maternal mood, but not improvements in the dyadic relationship. Two explanations exist for this finding. Firstly, it may simply be the case that the intervention was not sufficient to produce a change in the relationship.

An alternative explanation may be that the infant did not habituate to the mother’s new, non-depressed interactive style (and might still be adjusting) and, therefore, was
observed to be interacting in a way that was consistent with the mother’s previous, depressed interaction style. This notion could be explained by Tronick’s (1989) dyadic consciousness hypothesis which is based on his mutual regulation model (MRM) (for a detailed description, see Tronick et al., 1998). The hypothesis details the parameters of adaptive mother-infant interaction, which involves how mothers and infants repair normal breaks or dis-synchrony during their interactions. With regard to dyadic interaction the non-significant findings in the present study could be, as Tronick and Weiberg (2007; 1997), describe, the result of prolonged miscommunication in the (mother-infant) dyadic interaction. Miscommunication is a normal aspect of the dyadic interaction (Tronick, 1989). However, in depressed dyads these miscommunications crucially go un-repaired (Tronick, 2007; Tronick & Beeghly, 2011). This hypothesis could explain atypical interactive style observed between depressed dyads and the consequence if this was prolonged. This theory could also account for the similar non-significant findings in the interactive style in other studies (Clark, Tluczek, & Brown, 2008; Clark, Tluczek, & Wenzel, 2003; Logsdon, Wisner, & Hanusa, 2009; Van Doesum, Riksen-Walraven, Hosman, & Hoefnagels, 2008).

In keeping with Tronick’s hypothesis, it is possible that the three-month follow-up period was not long enough to capture the change in interactive style either. A follow-up period of six months was originally planned; however, due to difficulties with recruitment it was shortened to three months so that the recruitment period could be extended.

A further explanation for the non-significant findings relates to the possible level of support in the TAU condition, which could not have been anticipated at the beginning of the study. Almost half of the participants (TAU=5; Baby Triple P=6) were referred by a specialist health visitor following the completion of an eight-session PND-psychoeducation group (PEG). Although they met inclusion criteria (elevated EPDS, BDI-II, & SCID diagnosis), participants who were seen for Baby Triple P sessions described that the PEG helped reduce their feelings of isolation, having met women also experiencing PND and it also normalised their experiences. This was also a focus of Baby Triple P; as such, there may have been some overlap between the two interventions.

Further support reported by women in both TAU and Baby Triple P conditions included anti-depressants (n= 21) and some form of CBT or counselling. This finding is not unique to the present study, a meta-analysis by Cuijpers and colleagues (2008) found that studies using usual care (TAU in the case of the present study), demonstrated more non-significant findings and lower effect sizes than studies that had used a control group.

The health visitors who referred the women to the present study represent a group of very dedicated people with special interest in the subject of this research. They were
motivated by the fact that at least half of their participants would receive additional support. This group of health visitors may not have been representative of all services. Although it is encouraging that this group of women were well supported, it may indicate a selection bias.

Based on the findings from this pilot trial it is tempting to conclude that Baby Triple P is an ineffective intervention for PND and label it “negative” evidence. However, Altman and Bland (1995) strongly advocated that the “absence of evidence is not evidence of absence”. They highlighted that pilot trials are often underpowered and are at greater risk of missing clinically significant effects (i.e., Type II error) rather than concluding significant findings in the absence of any (Altman & Bland, 1995). According to this view, the current findings should not necessarily be considered evidence either for or against the efficacy of the Baby Triple P treatment. Instead, the findings indicate further investigation is required to fully the efficacy of Baby Triple P.

7.5 Methodological limitations
Owing to the small sample size of the present pilot study, there are limitations that must be considered in light of the findings. Firstly, the greatest limitation was that the present study had limited power to detect significant group differences; as such these findings are regarded as preliminary and must be interpreted with caution. Kazdin and Bass (1989) advised a sample of greater than 27 in each arm of an RCT. Despite strenuous efforts, the present study was not able to recruit a sufficient number of mothers to meet this criterion. Thus, it was not possible to conduct the analyses as originally planned. Additionally, as this was the first study to apply Baby Triple P to women with PND, there were no available data with which to calculate power analysis. The power calculation was based on BDI-II scores from treatments mainly focusing on reducing PND symptoms, as these were the most similar available studies at the time.

Secondly, with respect to treatment allocation, although randomisation lists were generated by an individual external to the research team, and the assessor was blind until after baseline, the process of randomisation (informing participants which group they were allocated), was conducted by ZT. Ideally, the process of randomisation should be independent of assessment and treatment. However, in the present study this was an acknowledged limitation since the researcher was acting as Baby Triple P therapist and project manager.

An additional point relates to stratification of depression severity. The BDI-II values (informed by average BDI-II scores as cited in O’Hara, Stuart, Gorma & Wenzel,
2000; Milgrom, Negri, Gemmill, McNeil & Martin, 2005; Van Doesum, Riksen-Walvern, Hosman & Hoefnagels, 2008), which determined stratification, may not have been appropriate for the severity obtained in the present sample. Based on the baseline (Time 1) BDI-II scores of the participants in the present study (M= 32.4, SD = 9.5), they were more severely depressed than those in the studies used to determine the stratification cut off points (M= 23.6, SD=7.2; M= 22.8, SD= na and M=24.5, SD= 10.4 respectively). As a result, there were uneven numbers between low and severe depression groups. This is unlikely to have had an impact on the findings because participants were still randomised, it may, however, affect the generalizability of the findings to women experiencing milder symptoms of depression, in that they were not represented.

Thirdly, all assessments (with the exception of baseline assessments and the CARE-Index which were conducted blind and double blind rated, respectively) were not conducted independently, by an assessor blind to treatment allocation. Consequently, this may have introduced a response bias. Specifically, the assessor, ZT, had prolonged contact with women in the treatment arm. The rapport could have influenced responses on the self-report outcomes. For example, participants knew that the researcher was undertaking the research to obtain a PhD; therefore, they may have felt that they needed to report favourable outcomes, thereby creating a response bias. However, all women were advised to answer questionnaires honestly, and that there were no correct answers.

A fourth point relates to the handling of missing data. Initially, it was planned that missing data would be addressed by multiple imputations (using multiple predictors to build a model for estimating drop out data). However, it was determined that due to the small sample size, the multiple imputations method was inappropriate and, therefore, unreliable for handling the missing data. Since it was not possible to use the multiple imputations method, analyses were conducted using treatment completers as well as last observation carried forward (LOCF) to account for missing data in a sensitivity analysis. Although, LOCF is not an accepted method for addressing drop outs, since there is no statistical and theoretical rationale (Tarrier & Wykes, 2004, http://www.missingdata.org.uk/). Last observation carried forward assumes that participants stay the same. However, in the present sample, session data from non-completers from the Baby Triple P arm suggested an improvement. Indeed, literature suggests that natural remission is common in PND (Campbell, Cohn, Flanagan, Popper, & Meyes, 1992).

The generalizability of these findings may be affected given that the sample of women who entered this study received a great deal of support from services. Therefore,
the sample of participants who entered the study following the PEG group may not be an accurate representation of the services and input in other areas. Despite randomisation, women allocated to the Baby Triple P arm were all white British, which limits the generalisability of the findings to ethnic minority populations and whether or not Baby Triple P is an acceptable intervention to them.

7.6 Recruitment difficulties and barriers to access
It is frequently reported that women experiencing PND are a difficult population to recruit to treatment trials (Appleby & Whitton, 1993). Indeed, individuals with mental health difficulties are generally more difficult to recruit to RCTs than analogue samples. Generally speaking, the randomisation aspect of RCT designs is associated with recruitment difficulties (Ashery & McAuliffe, 1992; Hetherton, Matheson, & Robson, 2004). The experience of recruitment in this trial is comparable to those in the PND literature and RCTs evaluating programmes for other difficulties (Daley et al., 2008; Hetherton, et al., 2004).

A common obstacle to recruitment in RCT designs is the strictness of the inclusion criteria (Prescott et al., 1999; S. Ross et al., 1999). At the start of the present study, an initial inclusion criterion was that women needed to be primiparous. The rationale for this criterion was based on literature concerning the differences in the experience of parenthood between multiparous and primiparous mothers (Gameiro, Moura-Ramos, & Canavarro, 2009). However, during initial stages of recruitment it was noted that a number of potential participants were being excluded due to multiparity. Furthermore, a review of the literature (Tsivos et al., submitted) found that studies employed different approaches with respect to parity as an inclusion criterion. For example, studies within the literature are usually mixed (multiparous and primiparous) with regard to parity. As the majority of studies were mixed, the parity inclusion criterion was amended to include multiparous women experiencing PND. An additional benefit of amending the inclusion criterion was the potential for increased generalisability of the findings. For example, if the intervention were to eventually be disseminated, it could be delivered to both first and second time (plus) parents. In terms of the present study, it maximised the sample size and in turn the power to detect significant differences between the two groups.

Another important factor in maximising recruitment was to gain support from the local health services. Despite assertive and active recruitment efforts in the present study, it was a challenge to gain the support of local health services. This challenge could be explained by systemic blockages. Statistics obtained from the Improving Outcomes and
Ensuring Quality report (Sheppard, 2011) indicate that 3,953 of the 39,527 registered births in Greater Manchester (2009/2010) were affected by PND. The target number of cases for the present study was 60, approximately 1.5% of the total number of estimated cases in Greater Manchester. However, the final sample size was 27, approximately 0.7% of the total number of estimated cases in Greater Manchester. Although when given the option to participate in a research trial, a percentage of participants would naturally decline, failure to obtain support from services may have greatly impacted on the final sample size. Four of the ten Primary Care Trusts (PCT) in Greater Manchester participated in recruitment by referring eligible participants. The other six PCTs refused to participate in recruitment due to capacity issues, because they believed their service to be sufficient, or because they did not respond despite assertive and multiple attempts to contact them. Despite multiple contacts and onsite visits to the service with an aim to promote engagement with the professionals, and to provide resources and materials, of the four trusts that made referrals, two of the trusts referred only one client each. The other two services referred between seven and 15 women. All general practitioners (GPs) in the Greater Manchester area were also informed of the study through GP consortiums, as well as a letter, leaflets and participant information sheets to each GP detailing the study. An understanding of why authorities declined participation is an important consideration for future research.

The limited support from the local health authorities undoubtedly had a major impact on the final sample size obtained in this study. The health visitors who did support the research therefore, represent a minority of those working in Greater Manchester. Given the acceptability of the study in the geographical areas that did recruit successfully, there was potential to recruit many more participants in the remaining areas had there not been systemic blockage.

These observations regarding recruitment may reflect capacity issues within the health care trusts. For example, limited time within which to conduct consultations has been established as an issue within the GP literature (Say & Thomson, 2003). They could also be explained by the RCT design, such that potential participants or their healthcare professionals may have been discouraged by the randomisation element of the trial and not being guaranteed allocation to the treatment arm. Indeed, Howard and Thornicroft (2006) explained that the strength of patient preference could lead them to refuse participation in RCTs altogether. Similar findings were reported in a pilot group CBT trial for women with depression, where some organisations felt the process of randomisation was unethical and
therefore, did not assist with randomisation (Cramer, Salisbury, Conrad, Eldred, & Araya, 2011).

The difficulties with recruitment may also indicate a more complex interplay between participants’ perceived benefits of treatment and their relationships with health care professionals as well as healthcare professional beliefs about PND and views on effective treatment (Dennis & Chung-Lee, 2006; Di Mascio, Kent, Fiander, & Lawrence, 2008). Indeed, these issues have also been experienced in other depression studies utilising GP settings to identify, recruit and randomise participants (Hetherton, et al., 2004; King, Broster, Lloyd, & Horder, 1994; Tognini et al., 1991). Hetherton and colleagues (2004) outlined difficulties with randomisation, time constraints, GP views on needs of patients and perceived equality of treatment options as some of the main reasons for poor recruitment in their RCT comparing computerised psychology therapy and CBT. In order to maximise recruitment they recommended that study designs were done in collaboration with GPs, highlighting potential benefits of participation in trials, detailing research on treatment options, maintaining regular contact with GPs and providing financial incentives to staff (Hetherton, et al., 2004). The approaches outlined by Hetherton and colleagues were adopted in the present study, with the exception of the study design being constructed with input from GPs (or health visitors) and providing financial incentives to staff.

Despite the recruitment difficulties, the attrition rate of the present study was low (n=2, 17%) which compares favourably with other studies in this area. However, four studies (Cooper, Murray, Wilson, & Romaniuk, 2003; Horowitz et al., 2001; Mulcahy, Reay, Wilkinson, & Owen, 2010; Murray, Cooper, Wilson, & Romaniuk, 2003) compared more favourably with the present study in that their attrition rates were less than 15%. This low attrition rate in the present study may reflect the assertive efforts made to recruit and retain participants. For example, this may involve conducting sessions (for the treatment arm) at a convenient time and location (usually the home) for the participant. Alternatively, it may be due to having therapy and assessments conducted by the same person. It may also be related to the high acceptability of the intervention.

A final point relates to the timing of referral. In Chapter 1, it was highlighted that many women with PND feel a sense of shame and reluctance to disclose their experiences of motherhood which contrast with the joyous image of motherhood projected by society. This leads women to delay reporting their depressed feelings (Patel, Wittkowski, Fox, & Wieck, 2012). The delay in disclosure may spell more adverse outcomes for the mother and her relationship with her infant since women have reported feeling they were at the point of crisis before they reported this (Patel, et al., 2012). The age of the infant, around
six months, at onset in many trials reflects this delay. The stigma associated with the experience of PND is likely to continue to act as a major barrier to help-seeking and the recruitment to intervention trials. However, through normalising the experience, women may feel empowered to report their feelings.

**7.7 Strengths of the study methodology**

Pilot trials provide important methodological information and promote the development and inform the design of high quality full scale RCTs (Lancaster, Dodd, & Williamson, 2004). Lancaster and colleagues (2004) defined a list of objectives that contribute to high quality pilot studies, relating to estimating sample sizes, study protocol development, data collection procedures, randomisation procedures, recruitment and consent, acceptability of intervention and measurement selection. Despite being limited by a small sample size, the present study has a number of methodological strengths. In this next section, the strengths of the present study are outlined in relation to Lancaster and colleagues objectives listed above. Future recommendations reflecting these objectives are then detailed in a subsequent section.

**7.7.1 Sample size**

The present study has contributed to the development of Baby Triple P in terms of informing future sample sizes. Based on the collected data in the pilot trial of Baby Triple P, a retrospective power calculation was completed and suggested that future trials would need 237 participants in each arm in order to detect significant group differences (Whiteside, 2012). Despite the seemingly large number, it should be noted that estimates of power vary depending on the sample size.

**7.7.2 Randomisation procedures**

Lancaster et al. (2004) described that pilot studies would allow for testing randomisation and for testing the acceptability of randomisation to participants. In terms of the randomisation procedure used in the present study, the sealed opaque envelopes method was utilised and is a viable option for future studies. In terms of informing participants of their treatment allocation, all participants were informed via telephone and were given the opportunity to ask questions about their allocation. Particular attention was given to informing participants about the randomisation process, highlighting that they were not guaranteed to be allocated to the treatment condition. This transparency in the randomisation process may have helped to reduce attrition by managing expectations of participants.
With respect to the description of allocation, the present study is comparable with other studies (Cooper, et al., 2003; Horowitz, et al., 2001; Logsdon, et al., 2009; Mulcahy, et al., 2010; Murray, et al., 2003; O’Higgins, Roberts, & Glover, 2008; Van Doesum, et al., 2008), in the literature which described the process of randomisation; however, the present study is limited in that the process of randomisation was not carried out fully independently of the research team. Despite this, having only one person conducting therapy and assessments may have reduced dropout.

The present study also addressed issues of severity of depression using stratification. It was only possible to stratify randomisation on severity of depression. Although there were no significant differences between groups in terms of other important participant characteristics, including the age of infant, history of depression, etc., future studies with appropriately sample sizes, should consider stratification of some these variables as well as features of depression including severity, chronicity and history of depression. Stratification of depression features is important given the heterogeneity of PND. Indeed these features have been identified as important within the literature (Phillips, Sharpe, Matthey, & Charles, 2010).

7.7.3 Study protocol development
Lancaster and colleagues (p. 308, 2004) described the pilot trial as a “dummy run” in terms of testing out procedures, defining relevant exclusion/inclusion criteria; screening procedures, number of research assistants, etc. For the purposes of the present study, a screening protocol was developed and implemented successfully; it helped to engage interested potential participants and explained the randomisation process. The present study also established relevant inclusion and exclusion criteria. In terms of assessing for participant eligibility and conducting the baseline assessment, the present study has established that it is feasible to do this in one visit. The SCID was especially helpful in engaging the participant. Since it collects information on the timeline of the participants presenting problems, it gives them an opportunity to debrief. Many of the participants reported that their birth experience played a significant part in the onset of their symptoms and that being able to debrief about it was helpful. The present study described in detail the session content of the intervention as well as session checklists to maintain fidelity. This is comparable with other studies in the literature (Clark, et al., 2008; Clark, et al., 2003; Cooper, et al., 2003; Kersten-Alvarez, Hosman, Riksen-Walraven, van Doesum, & Hoefnagels, 2010; Mulcahy, et al., 2010; Van Doesum, et al., 2008).
7.7.4 Recruitment and consent

Information on rates of recruitment and consent from pilot studies can also help inform feasibility and predict the likely timeframe of recruitment in full scale RCTs (Lancaster et al., 2004). A number of issues relating to recruitment and consent were outlined in the previous section. Since it was not possible to directly obtain consent from women in a health setting (due to ethical reasons) rates of consent (the ratio of individuals approached to participate who actually consented) in the context of this study are unknown. However, information on recruitment timescale and a realistic appraisal of length of recruitment could be informed by the recruitment figures from this study. During the early stages of recruitment few referrals were made, however, after investing a significant amount of time liaising with potential referrals the numbers increased exponentially. In the present study contact was maintained with referrers to motivate them and provide them with regular updates with study progress. This is important given the significant demands on the services of individuals.

The present study identified that it was possible for one person to manage the study, including recruit, assess, randomise and conduct Baby Triple P sessions. However, full scale RCTs would benefit from a dedicated health visitor or research nurse being embedded within a perinatal service, since they routinely screen for PND, are likely to identify potential participants, and provide support to women through their PND experience. A health visitor or research nurse could also liaise with other health visitors who identified women experiencing PND. Given the role of health visitors in the perinatal period, this could help maximise and increase referrals to the research.

With regard to engaging potential participants, all interested women were followed up with a telephone screen in which they were provided with further information about the study. When providing women with further details, little emphasis was placed on PND and difficulties with parenting. Instead, when describing the programme to parents, the content was described in a way that could potentially benefit all parents who are in the transition to parenthood in order to normalise their experiences. Prospective participants seemed to engage and be accepting of this approach. This approach could be particularly important in reducing stigma and could be used in future studies.

7.7.5 Acceptability of Baby Triple P

Pilot studies also help to determine whether interventions are likely to be accepted by participants (Lancaster et al., 2004). The acceptability of Baby Triple P was evaluated using the CSQ. The findings from this study suggest that women found the intervention
highly acceptable. One participant said… “I found the programme easy to follow, very practical, easy to implement.” Another stated “It is brilliant! It has really helped me find ways to cope with difficult situations.” Other participants reported that they would recommend the programme “Think it should be given to all parents by hospital” and “This programme should be more known as it is a brilliant programme and really helps” (for all reports, see Appendix, 264).

Although it was not directly assessed, through clinical observation many parents seemed to be accepting of the self-evaluative framework of first acknowledging the positives (what they did well in implementing the skills or solving a parenting problem) and then addressing what they might do differently in future. Consistent with the notion that Baby Triple P is an acceptable intervention, participants reported that they utilised aspects of the programme outside of their interaction with their baby, for example, praising their partner for carrying out household tasks. The high acceptability ratings and low drop out reported in the present study suggest that the intervention is favourable and provides support for conducting a larger scale trial.

7.7.6 Measurement selection
Measurement selection is crucial in exploring proposed outcomes (Lancaster et al., 2004). In the present study, the primary outcome measure, the BDI-II, is a standardised scale, commonly used in this area of research, and is a very good indicator of severity of depressive symptoms, enabling comparison with other treatment studies. With respect to confirmation of PND diagnosis, the present study used the SCID, which is a robust research tool for establishing a diagnosis in line with the DSM-IV. This present pilot confirms that it is feasible to use the SCID to confirm major depression. The SCID is a more precise form of measurement compared with other methods used in the literature. For example, some studies confirmed PND based on elevated EPDS scores, which only indicates probable PND.

Secondly, within the intervention literature of PND, there are few studies, which measure dyadic and/or child developmental outcomes (Poobalan, et al., 2007; Tsivos, Wittkowski, Calam & Sanders, submitted). These measures are important since they help shed light on whether the intervention has benefits beyond maternal mood. The CARE-Index, an observational measure of the quality of the dyadic relationship, was included in the present study for that reason. Some women were initially uncomfortable about being filmed; however, women were given reassurance and advised that they had the option not to be filmed. None of the participants declined being filmed.
7.7.7 Data collection procedures
Pilot studies help to establish whether assessment batteries are comprehensible to participants and give information about administration (Lancaster et al., 2004). In the present study assessment booklets were designed for each time point (Baseline, post-test and three-month follow-up) and took approximately 30-45 minutes to complete. Some participants reported that this was too long. A system for managing and storing the data was devised for this trial and could be used in future studies. This includes a method for storing observational data in an encrypted form so that it could be securely transported and viewed by a rater. With respect to assessment, in the present study it was not possible to have data collected by a blind assessor; however, future studies could benefit from this as a blind rater may potentially reduce response biases.

7.7.8 Study design
In the present study a randomised controlled design was employed, commonly accepted as the gold standard for evaluating treatment efficacy and building an evidence base for psychological therapies (Jadad, 1998; Kang, Ragan, & Park, 2008; Pocock, 1983; Roberts & Torgerson, 1998). The TAU arm helped to control for non-specific effects and selection bias. The inclusion of a control group will strengthen the rigour of future studies. Whilst single group designs may be more appealing to prospective participants and healthcare professionals alike (since they are guaranteed to receive the intervention) they may provide a false sense of efficacy. Many women may spontaneously recover (Campbell, et al., 1992); therefore, the use of a TAU group may help to address this, but also to investigate effects of the mother-infant relationship and/or child development.

7.8 Implementation issues and observations
Participants were often busy with family commitments; this required a significant degree of flexibility when arranging assessments and therapy sessions. This approach meant substantial commuting for the researcher in the community. Furthermore, despite telephone and/or email reminders about sessions and assessments, there were instances where the participant missed the appointment, which meant that a significant amount of time was lost in travel.

Although it was more convenient to conduct the therapy session in the home of the participant, having the infant in the sessions proved both advantageous and challenging. The presence of the infant during sessions provided opportunities for the mother to practice what she learnt in the session and then self-evaluate and gain feedback immediately.
However, if the infant was unsettled or needed attention or care, this proved distracting for
the mother and led to longer sessions as it was difficult to rearrange sessions due to
geographical location and cost of travel for the researcher.

Further observations relate to the in-session experience. With respect to
implementing a self-evaluative framework (Chapter 3, p. 109), some women reported that
they found it especially challenging in initial sessions to think of positive things, or
examples of where they had done something well. When discussing how the parent coped
with a problem or issue when implementing Baby Triple P parenting skills, many parents
found it difficult to focus on the positives (i.e., what they were doing well). Examples
include using descriptive praise, implementing a routine, having a casual conversation with
their partner. However, through later sessions, parents reported that the positives (i.e., their
use of a strategy, or ability to cope with a stressful situation) came much more easily to
them. The challenging aspect of identifying what the parent was doing well may reflect
negative thinking patterns about competence in the parenting role (Teti & Gelfand, 1997).

7.9 Clinical implications
A primary goal of clinical research is to produce effective interventions with the aim of
relieving psychological distress and improving quality of life. To retain participants in
therapy, the intervention needs to be regarded as acceptable. Literature on psychological
interventions for other mental health difficulties supports this, as higher retention rates are
positively correlated with acceptability (Ehlers, Clark, Hackmann, McManus, & Fennell,
2005; Milosevic & Radomsky, 2008; Rachman, Radomsky, & Shafran, 2008). It is clear
that women with PND experience difficulties with parenting, and the present study found
that Baby Triple P is an acceptable parenting intervention for women with PND. However,
on the basis of the pattern of results presented here, Baby Triple P is not superior but may
be more acceptable than usual services. Tentatively, it is possible that targeting parent
using Baby Triple P alone is not sufficient to treat PND. As discussed earlier, it is possible
that the effects of the intervention were masked by the level of support received in the
TAU intervention. Equally, the benefits of Baby Triple P may not be beyond those of other
treatments. On the face of the present findings a great degree of caution should be observed
when using Baby Triple P in postnatal populations.

More generally, the findings from the systematic review (Chapter 2) suggest a
number of treatments which may be helpful for PND. However, the evidence to date does
not indicate a gold standard treatment. A further point relates to the impact of PND on
child developmental outcomes. Specifically, in earlier chapters evidence of PND on child
outcomes was summarised. Therefore, this should be considered within the context of intervening in this population.

7.10 Recommendations for future research

The present study has provided foundational research on Baby Triple P and its initial feasibility and acceptability to women with PND. There is scope to conduct a larger RCT, reflecting on the limitations and building on the methodological strengths of this pilot trial. Indeed, the present study demonstrates that with limited funding and resources, this study was still feasible.

In order to maximise recruitment, future studies should give special consideration to the recruitment difficulties encountered in the present study. Firstly, with regard to getting the support of healthcare professionals for a study of this kind, it may be advantageous to involve health visitors in the design of the study, since they are likely to have contact with eligible women during health visits. Although referrals via health visitors are likely to result in the greatest number of referrals, additional routes should also be considered, including GPs and community midwives. It is recommended that regular contact is maintained with referral sources and where possible, financial incentive should be considered. Additional methods of recruitment could utilise non-NHS pathways. These include groups available to new mothers through Sure Start services, community groups, NCT, online parenting forums, public advertising and/or charitable organisations. However, it should be noted that in the present study, individuals who self-referred tended to present with less severe depressive symptoms compared with participants who had been referred to the study by a health visitor.

An additional method of increasing recruitment and ascertaining intervention preference would be to conduct a patient-preference trial (Hotopf, 2002). This approach may be more appealing and acceptable to healthcare professionals and boost recruitment figures; however, this type of design can result in uneven group sizes. In disseminating study information to potential participants highlighting the benefits of participation in this trial may also make a difference to recruitment figures. Providing a balanced view of treatment options for women with PND may also aid recruitment. Furthermore, although there is no formal evidence on the effectiveness of testimonial reports, clinical observations from the present study suggest these seemed to have a positive effect on recruitment. This may have a destigmatising and normalising effect. With respect to client inclusion criteria it is recommended that future studies do not exclude on the basis of parity.
Although expectant parents and women with infants were consulted during the development of the Baby Triple P programme, there has not been a detailed analysis of the acceptability of the programme to women with PND. However, the low dropout rate suggests a high degree of acceptability of the intervention. It would be interesting to conduct more in-depth interviews with participants to gain a more comprehensive understanding of their experiences with Baby Triple P (this was not possible within the time limits of the present study). For example, future studies could explore specifically which of the intervention skills and strategies were found to be useful. This could contribute to the ongoing development of the programme.

Furthermore, regarding outcome measurement, future research may consider measuring symptoms of anxiety in addition to those of depression. It was noted during baseline assessment that a number of participants were experiencing sub-clinical levels of anxiety. Indeed, within this population, it is not uncommon for depression and anxiety to present comorbidly (Bevan, Wittkowski, & Wells, in press; Ross, Gilbert-Evans, Sellers, & Romach, 2003). Lifetime comorbidity between generalised anxiety and depression is high (80%; Judd et al., 1998) and the average number of diagnosable disorders per person is 2.1 disorders (Kessler, 1994).

Another consideration relates to comorbid personality disorders (Axis II disorders). This is especially relevant due to the rates of comorbidity (approx 30-40%; Shea, Widiger & Klein, 1992) between personality disorders and depression. A review on the subject suggested an association between the presence of a personality disorder and poorer outcomes for treatment of depression (Shea, et al., 1992). This review also summarised evidence suggesting that depressed individuals with a comorbid personality disorder displayed slower responses to treatment compared with depressed individuals without a comorbid personality disorder. Recent research by Conroy and colleagues (2012), found that PND with comorbid personality disorder was associated with increased levels of dysregulated infant behaviour compared with PND without a comorbid personality disorder. Future studies may consider assessing for Axis II disorders (by utilising the relevant sections of the SCID or screening measures) given their implication for treatment of depression.

With respect to the dyadic and child developmental outcomes it would be advantageous to continue to use the CARE-Index (or similar observer rated interaction) and also to measure child developmental outcomes. It was not possible to measure child outcomes in the present study as reliable child development batteries (i.e., Bayley scales of infant development) were outwith the budget of the present study. Furthermore, they would
have added significant time on to already lengthy assessment sessions. The triangulation of methods increases the rigour of the study. This will enable researchers to understand whether interventions are effective in reducing symptoms of depression and promoting adaptive development in the infant.

In the present study the follow-up period (Time 3) was limited to three months due to time constraints. Given the possible time delay where infants become accustomed to their mother’s new non-depressed interaction style, it may be especially important to implement longer-follow-up periods. For example, future studies could implement a longer-term follow up to investigate maintenance effects and child related outcomes.

Postnatal depression (PND) is also experienced by an estimated 10% fathers (Paulson & Bazemore, 2010), although this area is still undeveloped and is beyond the scope of this thesis (Goodman, 2004; Letourneau et al., 2012). Postnatal depression also has implications for the marital relationship (Boath, Pryce, & Cox, 1998). However, in the present study, many women described difficulties in their relationship with their partner. Marital adjustment was not measured in the present study; therefore, it was not possible to explore whether there were any changes to the quality of the marital relationship. Previous Triple P research has reported reductions in couple conflict following intervention (Ireland, Sanders, & Markie-Dadds, 2003; Sanders & McFarland, 2000). Future research could investigate this aim as well as whether the quality of the marital relationship predicts treatment outcome in women with PND, and whether the intervention indirectly improves wellbeing in the father.

Future studies may also consider using a wait-list-control group, to increase recruitment rates. This may help the reluctance of potential participants to enter into RCT trials due to the randomisation aspect, since they would eventually receive the intervention. Due to the fact that the present study was limited by time and resources, it was not possible to offer a wait-list group. However, participants in the TAU arm were offered a Triple P self-help resource (The Every Parents Self-help Workbook; Markie-Dadds, Sanders, & Turner, 1999) at the conclusion of the study. An additional strategy to optimise sample size in this population could include visiting participants in their homes (this is an issue for parents who cannot afford child care or crèche facilities in particular).

Few studies in the PND literature have demonstrated significant improvements to child developmental outcomes. Perhaps an alternative way to measure projected improvements would be to include a healthy comparison group. Forman et al. (2007) and O’Higgins et al. (2008) reported using a no treatment or waitlist control (WLC) group, as well as a non-depressed comparison group that controlled for non-specific effects of the
interventions. Although this would increase the number of participants needed to detect significant differences it would control for effects of normal development and adjustment to parenthood.

7.11 Conclusion
The impact of PND on the mother, her infant and family more generally is clear. This thesis has attempted to investigate parenting, a pertinent issue within the context of PND. It is the first to examine the efficacy and acceptability of the Baby Triple P Positive Parenting Programme in a sample of women experiencing PND. It has also sought to develop a reliable measure to investigate parental self-regulation. The target sample size was not achieved; therefore, the study was not appropriately powered to detect clinically significant group differences. As such, the efficacy of Baby Triple P for women with PND cannot be confirmed or disconfirmed. Nevertheless, the findings from this pilot RCT have important implications with regard to design and implementation of a full scale, powered trial of Baby Triple P.
References


Whiteside, S. (2012). Retrospective power calculation for Baby Triple P pilot. *University Hospital of South Manchester.*
Glossary of terms

**Baby Positive Parenting Programme (Baby Triple P)** A newly developed variant of the multi-level Triple P Positive Parenting Programme. Baby Triple P focuses on providing new parents with the knowledge and skills to promote adaptive development in their infants.

**Baby Massage** A therapeutic approach involving massage techniques specifically designed to soothe and settle infants.

**Beck Depression Inventory (BDI)** Is a 21-item self-report measure of depression severity. Items are rated on a four point scale. Scores range from 0 to 63. High scores indicated increasing severity of symptoms.

**CARE Index** An observer-rated measure of a mother-infant dyad synchrony for infants of between 0-15 months. Three to five minutes of video interaction are recorded and rated on seven subscales, including maternal sensitivity, control, unresponsiveness and infant cooperation, compulsive and difficult responses and passivity. Each individual subscale is scored on a scale of between 0 and 14. High scores indicate high dyadic synchrony.

**Clinical Tool for Assessment of Methodology (CTAM)** A method of assessment for determining the methodological quality of psychological treatment trials. Trials are rated for quality against 15 items across six domains, including sample size and recruitment method, allocation to treatment, assessment of outcomes, control groups, description of interventions and analysis of data. Scores are between 0 and 100, where scores over 65 indicate good quality.

**Dyad** A term used to describe a mother-infant pair.

**Edinburgh Postnatal Depression Scale (EPDS)** A commonly used 10-item self-report measure to establish probable depression in women during the postnatal period. Scores range from 0-30 and scores of 12 indicate probable depression.

**Multiparous** A term used commonly in the perinatal literature to indicate that a parent has more than one infant or child.
**Primiparous** A term used commonly in the perinatal literature to indicate that a parent has only one infant or child (see also multiparous).

**Postnatal Depression (PND)** Is an episode of depression occurring within the first 12 months of the postnatal period. Differentiated from transient “baby blues” and puerperal psychosis, a less prevalent psychotic episode within the postnatal period.

**Positive Parenting Programme (Triple P)** A system of parenting training programmes used to prevent psychopathology and promote sensitive adaptive parenting based largely social learning theory.

**Reliable Change Index (RCI)** An equation used to determine whether changes (on some measure of behaviour) is clinically significant from pre to post intervention. For example, how much the functioning of the clinical population in question moves to that of the normative population. The RCI can be calculated by subtracting the post-intervention score (of the measure in question) from the pre-intervention score and dividing the difference by the standard error of measurement. The difference from pre-intervention to post-intervention is clinically significant when RCI is $\geq 1.96$. Where the RCI is a negative number $\leq -1.96$ this suggests a clinical deterioration.

**Treatment as Usual (TAU)** Terminology used to describe a control condition whereby participants allocated to this arm/group are in receipt of usual services offered by their health services.
8.0 APPENDICES
Baby Triple P- Manchester
Telephone Screening Form

Mother’ Name: ________________________ Date:
__________________

It’s Zoe Tsivos here, from the University of Manchester. I am calling with regards to your
enquiry about the Baby Triple P project.

Is this a good time to talk? Ok, let me ask you a couple of initial questions-

Is this your first Baby? □ YES □ NO

When was your baby born? Date ________________

Are you between the ages of 18-45? □ YES □ NO

Are you currently in a committed relationship? □ YES □ NO

## FAMILY DETAILS (to be filled in last)

Ok, great! Now, in order to register you for the project, I need to get some details from
you.

Caller: ________________________

Address: Street__________________________

Suburb___________________Postcode_______

Ph: (home) ________________

Ph: (mobile) ________________

Email address:________________________________________________________

*** Ok, that sounds great! Now, what I thought we could do is that I start off by telling you a
little bit more about Baby Triple P and about this particular project and then if you are
interested, I will ask you a few questions to ensure that the programme is suitable for your
needs, and also that you are eligible to take part in the research. At the end, of course, you
might still have some questions, if I have missed something or something wasn’t clear so you
will get an opportunity to ask those questions at the end. How does that sound?
Programme Information

Ok, so Baby Triple P is a new addition of the Triple P Positive Parenting Programme. Have you heard of Triple P before? Triple P is a parenting programme for children of all ages that has been used successfully for a long time. Until now there was no version of the programme specially designed for parenting in the first twelve months of a baby’s life.

So Baby Triple P was designed to help prepare parents for the challenges to do with becoming a parent. Baby Triple P helps parents learn strategies for developing a positive relationship with their baby, promoting their baby’s development, as well as responding to their baby and teaching their baby new skills and behaviours. The programme also helps parents with survival skills for those first 12 months and teaches strategies to “baby proof” your relationship with your partner as well.

The programme runs for a total of ten sessions and is conducted in two parts. These sessions are conducted by the researcher who is a trained and accredited Baby Triple P Practitioner. The sessions will be run in your home once a week at a time convenient for you.

After the first four sessions you are encouraged to put all the parenting and relationship strategies into practice. That’s why you will get the opportunity to practice those strategies in four weekly practise sessions.

Now that you know a bit more about the programme- does this sound like something you would be interested in? □ YES □ NO  
DISCONTINUE IF NO

Reason  
if No ________________________________________________________

Ok, good! So I will just need to ask you a couple more questions to determine if you are eligible to participate. Is that ok?

Do you expect to live in Manchester for the next 6 months? □ YES □ NO

EXCLUDE IF no

Is everything okay with your baby?

____________________________________________________________________
____________________________________________________________________
____________________________________________________________________

EXCLUDE IF ANY KNOWN GENETIC DISORDERS OR DISABILITIES
Research

Ok, thanks for that. Now I would like to tell you a little bit more about the research.

Random Allocation

Firstly, you need to be aware that this is a research project being undertaken for a doctoral award (supervised by experienced clinical psychologists) and we are trying to evaluate how useful the programme is for new parents experiencing postnatal depression. As I mentioned before the programme has been shown to be effective for parents of older children but it hasn't been evaluated for parents of babies. In order to evaluate the programme, all women that are accepted into the programme will be randomly assigned to one of two groups. One group will receive the full Baby Triple Programme the way I described it to you before. The other group is the Monitoring group and will not receive the full Baby Triple P Programme, but they will receive a copy of the Every Parent’s Self Help Workbook when the study is finished and will be visited by the researcher the same number of times as the Baby TP group to do the questionnaires. You won’t be able to choose which group you’re assigned to – a computer randomly chooses this. This structure gives us a chance to compare outcomes, and achieve an accurate understanding of the programme’s benefits.

Do you understand this part of the project? Is that ok with you? □ YES □ NO DISCONTINUE IF NO

If concerns-
Of course it might be a little frustrating if by chance to land in the group that doesn’t get the full programme, but all participants will still be visited and asked questions about how you are getting on at certain intervals and will receive a free workbook containing lots of useful information. We need to run the research because we don’t know yet whether Baby Triple P will work better than the care families receive through usual services at the moment.

Questionnaires

Secondly, as part of our assessment of how well the programme works for parents we ask all mothers to answer some assessment questionnaires and 5 minute video tapping with baby that take about 30-60 minutes to complete. These will be completed at monthly intervals: now, before you start the programme, again when you have finished the programme (about 2 months for treatment as usual) and final questionnaires 3 months after finishing the programme. Of course all information you provide will be kept strictly confidential.

Would you be happy to complete the questionnaires? □ YES □ NO DISCONTINUE IF NO

Would you be happy to complete the 5 minute video of you and your baby interacting with eachother ? □ YES □ NO DISCONTINUE IF NO

If concerns-
The questionnaires are an essential part of the project for us.
The programme and all the materials are completely free of charge. The reason we can offer it free is because it is a research project. The only cost is your time in completing the questionnaires.

Because this programme uses a number of written resources, I just need to check whether you have any trouble with reading or understanding English.

☐ YES ☐ NO

EXCLUDE IF PARENT HAS DIFFICULTY READING ENGLISH

Do you have any questions about anything I have explained so far? Go To ##

How did you learn about this project?
Baby Clinic  Health visitor  GP  Radio  Newspaper

Other ___________________________

In general, when are good or bad times to contact you?

______________________________

Ok, Thank you for answering those questions, what I will do now is send you some information in the post which summarises a lot of what we have spoken about today. I will also include a consent form which you need to sign. Please complete the questionnaires and the consent form as soon as you can and return them in the reply paid envelope. Once I receive your paperwork, I will give you a call to arrange an appointment to ask you some questions about how you have been feeling. The next from there is to let you know which group you have been allocated to. Do you have any questions?

Date questionnaires mailed/link sent ___________________________
Date questionnaires returned: ___________________________
Follow-up phone call (if applicable): ___________________________
8.2 Edinburgh Postnatal Depression Scale (EPDS)

Please mark the answer that comes closest to how you have felt overall during the past seven days, not just how you feel today.

Here is an example, already completed:
I have felt happy:

Yes, all the time
**Yes, most of the time** This would mean: “I have felt happy most of the time” during the past week
No, not very often
No, not at all

Please complete the other questions in the same way.

**In the past 7 days:**

1. I have been able to laugh and see the funny side of things:
   - As much as I always could 0
   - Not quite so much now 1
   - Definitely less than I used to 2
   - Hardly at all 3

2. I have looked forward with enjoyment to things:
   - As much as I always could 0
   - Not quite so much now 1
   - Definitely less than I used to 2
   - Hardly at all 3

3. I have blamed myself unnecessarily when things went wrong:
   - Yes most of the time 3
   - Yes, some of the time 2
   - No, not very often 1
   - No, never 0

4. I have been anxious or worried for no good reason:
   - No, not at all 0
   - Hardly ever 1
   - Yes, sometimes 2
   - Yes, very often 3

5. I have felt scared or panicky for no very good reason:
   - Yes, quite a lot 3
   - Yes, sometimes 2
   - No, not much 1
   - No, not at all 0
6. Things have been getting on top of me:
   - Yes most of the time I haven’t been able to cope at all: 3
   - Yes, sometimes I haven’t been coping as well as usual: 2
   - No, most of the time I have coped quite well: 1
   - No, I have been coping as well as ever: 0

7. I have been so unhappy that I have had difficulty sleeping:
   - Yes most of the time: 3
   - Yes, sometimes: 2
   - Not very often: 1
   - No not at all: 0

8. I have felt sad or miserable:
   - Yes most of the time: 3
   - Yes, sometimes: 2
   - Not very often: 1
   - No not at all: 0

9. I have been so unhappy that I have been crying:
   - Yes most of the time: 3
   - Yes, quite often: 2
   - Only occasionally: 1
   - No, never: 0

10. The thought of harming myself has occurred to me:
    - Yes, quite often: 3
    - Sometimes: 2
    - Hardly ever: 1
    - Never: 0
8.3 Postpartum Bonding Questionnaire (PBQ)

Instructions: Please indicate how often the following are true for you. There are no “right” or “wrong” answers: Choose the answer which seems right in your recent experience.

<table>
<thead>
<tr>
<th></th>
<th>Always</th>
<th>Very often</th>
<th>Quite often</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel close to my baby</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>I wish the old days when I had no baby would come back</td>
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<tr>
<td>I feel distant from my baby</td>
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<tr>
<td>I love to cuddle my baby</td>
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<tr>
<td>I regret having this baby</td>
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<tr>
<td>The baby does not seem to be mine</td>
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<tr>
<td>My baby winds me up</td>
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<td>My baby irritates me</td>
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<tr>
<td>I love my baby to bits</td>
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<tr>
<td>I feel happy when my baby smiles or laughs</td>
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<tr>
<td>I enjoy playing with my baby</td>
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<tr>
<td>My baby cries too much</td>
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<tr>
<td>I feel trapped as a mother</td>
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<tr>
<td>I feel angry with my baby</td>
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<tr>
<td>I resent my baby</td>
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<tr>
<td>My baby is the most beautiful baby in the world</td>
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<tr>
<td>I wish my baby would somehow go away</td>
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<tr>
<td>I have done harmful things to my baby</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>My baby makes me anxious</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>I am afraid of my baby</td>
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<tr>
<td>My baby annoys me</td>
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<tr>
<td>I feel confident when changing my baby</td>
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<tr>
<td>I feel the only solution is for someone else to look after my baby</td>
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<tr>
<td>I feel like hurting my baby</td>
<td></td>
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<td></td>
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<tr>
<td>My baby is easily comforted</td>
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</tbody>
</table>
8.4 Family Background Questionnaire (FBQ)

This information collects information about your family. Please read and answer every question in this booklet. All information provided will be treated in strict confidence and will not be made available to any other source without your written approval.

Today’s date: ………../……………/……………

(day) (month) (year)

Mother’s Age……………

Father’s Age……………

1. **Current Relationship Status**

Married ☐ If so, how long have you been married?..............

Living together ☐ If so, how long have you been living together?............... 

Separated or divorced ☐

Other ☐ please describe ………………………………..

At present, does anyone else live at home with you and your partner (e.g., grandparents, lodger)?

Yes ☐ If so, who? …………………………………

No ☐

2. **Country of Birth**

If not born in UK, where were you born (country)? ………………………………………………….
Which ethnic group do you most identify with?

- British
- Irish
- Other white background
- Indian
- Pakistani
- Bangladeshi
- Other Asian Background
- Other Ethnic Group

(please specify) __________

3. Mother’s Education

What is your highest level of education?

- No qualifications
- GCSEs, CSEs, or O-levels
- A levels/ BTEC
- Trade/apprenticeship
- University degree
- Other (please specify) ________________
4. **Partner’s Education**

What is your partner’s highest level of education?

- No qualifications [ ]
- GCSEs, CSEs, or O-levels [ ] To end of year ___
- A levels/ BTEC [ ]
- Trade/apprenticeship [ ]
- University degree [ ]
- Other (please specify) [ ]

5. **Mother’s Employment Status**

- Full time [ ]
- Part time [ ] If so, how many hours per week? …… hours
- Home duties [ ]
- On Maternity Leave [ ] If so, please also indicate your employment status prior to your leave………….
- Unemployed [ ]

6. **Partner’s Employment Status**

- Full time [ ]
- Part time [ ] If so, how many hours per week? …… Hours
- Home duties [ ]
- On Paternity Leave [ ] If so, please also indicate his status before you went on leave.
- Unemployed [ ]

During the past 12 months, has there been a time when your household could not meet its essential expenses? By essential expenses, we mean things like food, the mortgage or rent payment, utility bills, child care, or important medical care.

[ ] Yes [ ] No [ ] I don’t know
After you have paid for your essential expenses like food, housing, utilities, child care, and medical care, how much money is left over?

☐ enough that we can comfortably purchase most of the things we really want
☐ enough that we can purchase only some of the things we really want
☐ not enough to purchase much of anything we really want

7. Health

In the last six months have either you or your partner sought professional help for any psychological or relationship problems you may have experienced? Please tick all that apply:

Mother
Psychologist ☐ Yes ☐ No
Psychiatrist ☐ Yes ☐ No
Counsellor ☐ Yes ☐ No
Social Worker ☐ Yes ☐ No
Other Professional ☐ Yes ☐ No  If yes, please indicate what type of professional …………………

Have you been diagnosed with a psychological or psychiatric disorder?
☐ Yes ☐ No
If YES, please specify………………………………

Note. This information is treated confidentially. Your response to this question is optional.

Father
Psychologist ☐ Yes ☐ No
Psychiatrist ☐ Yes ☐ No
Counsellor ☐ Yes ☐ No
Social Worker ☐ Yes ☐ No
Other Professional ☐ Yes ☐ No

Have you been diagnosed with a psychological or psychiatric disorder?
☐ Yes ☐ No
If YES, please specify………………………………

Note. This information is treated confidentially. Your response to this question is optional.
8. Pregnancy

Was this pregnancy planned?

Yes ☐  If so, did you make use of IVF to help you get pregnant? Yes ☐  No ☐

No ☐

How long have you been trying before you got pregnant?

______________________________________________

When was your baby born? ………./…………../……………..

(day)  (month)  (year)

How did you give birth?

Vaginal Delivery ☐

Assisted Delivery (forceps) ☐

Emergency caesarean ☐

Planned caesarean ☐

Other (e.g., privately run birth centre) ☐ Please describe……………..

Did you experience any complications during this pregnancy?

Yes ☐  Please describe……………………………………………………………………………….

No ☐

9. Other children

Do you have other children?

Yes ☐

No ☐

If yes, How many …………. Boy/s, Ages:………….. ……….. Girl/s. Ages:…………..
Overall, do you think that your child has difficulties in one or more of the following areas: emotions, concentration, behaviour or being able to get on with other people?

<table>
<thead>
<tr>
<th>No</th>
<th>Yes- Minor difficulties</th>
<th>Yes-definite difficulties</th>
<th>Yes- severe difficulties</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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</tbody>
</table>

Do the difficulties put a burden on you or the family as a whole?

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Only a little</th>
<th>Quite a lot</th>
<th>A great deal</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
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<td>☐</td>
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</tbody>
</table>
### 8.5 Parenting Beliefs Scale (PBS)

Version 1 04/08/2011

Listed below are a number of statements. Please read and think about each statement and respond to each item by indicating your agreement or disagreement with the statement.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>Mildly Agree</th>
<th>Mildly Disagree</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is no such thing as good or bad babies - just good or bad parents</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>When my baby is content, it is because he/she is responding to my efforts</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Parents who can’t get their baby to settle don’t understand how to get along with their baby</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>The difficulties I have with my baby are no one’s fault but my own.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Capable people who fail to become good parents have not followed through on their opportunities</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Difficulties people have with their babies are often due to mistakes their parents made</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Parents whose babies make them feel helpless just aren’t using the best parenting techniques</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Most difficulties people experience with their baby would not have developed if their parents had had better parenting skills</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>I am responsible for my baby’s behaviour</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>The misfortunes and successes I have had as a parent are the direct result of my own behaviour</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>I know what I need to do differently to get on better with my baby</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>I can set parenting goals</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Statement</td>
<td>1</td>
<td>2</td>
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<td>4</td>
<td>5</td>
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<tr>
<td>For myself to improve my relationship with my baby</td>
<td></td>
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</tr>
<tr>
<td>I have the skills to develop a practical parenting plan to solve most of</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>the difficulties I experience with my baby’s behaviour</td>
<td></td>
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</tr>
<tr>
<td>I am able to monitor or keep track of my own parenting behaviours</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
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<tr>
<td>that affect my relationship with my baby</td>
<td></td>
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<tr>
<td>I know when I have achieved the parenting goals I have set myself</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>I know how to congratulate myself when I have achieved one of my parenting</td>
<td>1</td>
<td>2</td>
<td>3</td>
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<td>6</td>
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<tr>
<td>goals</td>
<td></td>
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<tr>
<td>I am confident in the parenting choices I make</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<td>6</td>
</tr>
<tr>
<td>I seek the advice of experts regarding my parenting problems</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>I prefer to solve baby behaviour problems by myself</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<td>6</td>
</tr>
<tr>
<td>I feel I have the skills to accomplish my everyday parenting responsibilities</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>When it comes to a difficult parenting issues I seek advice from others</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<tr>
<td>rather than attempt to deal with the problem myself</td>
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<tr>
<td>I have the knowledge I need to complete most of my parenting responsibilities</td>
<td>1</td>
<td>2</td>
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<td>6</td>
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</table>
8.6 What being the parent of a baby is like (WPL)

Instructions: for each question, please circle the number that best show your answer.

1. How satisfying has being the parent of a new baby been for you?
   
   1  2  3  4  5  6  7  8  9
   Not at all satisfying  Completely satisfying

2. How much has your life changed since you had the baby?
   
   1  2  3  4  5  6  7  8  9
   Hardly at all  A great deal

3. How much is the baby on your mind when you are at home with him/her?
   
   1  2  3  4  5  6  7  8  9
   Very little  All of the time

4. Overall, how easy is it for you to be distracted from thinking about the baby?
   
   1  2  3  4  5  6  7  8  9
   Not easy at all  Very easy

5. How much do you think that you positively affect your baby’s development?
   
   1  2  3  4  5  6  7  8  9
   Not at all  A great deal

6. How much is the baby or the baby’s care on your mind?
   
   1  2  3  4  5  6  7  8  9
   Very little of  All of time

7. How much have the tasks of taking care of a new baby been satisfying to you?
   
   1  2  3  4  5  6  7  8  9
   Not at all satisfying  Completely satisfying
8. How much do you think your baby enjoys his/ her interactions with you?

Not at all 1 2 3 4 5 6 7 8 9 A great deal

9. How much do you relate to family members in a different way since you have had the baby?

Not at all 1 2 3 4 5 6 7 8 9 A great deal

10. On the whole, how stressful is your life, being the parent of a young baby and perhaps having other things to deal with?

Not at all stressful 1 2 3 4 5 6 7 8 9 Very stressful

11. How much do you look at yourself differently since you have had the baby?

Not at all 1 2 3 4 5 6 7 8 9 A great deal

12. When you go out and leave the baby with someone else, how much do you have the baby on your mind during the time that you are away?

Very little of the time 1 2 3 4 5 6 7 8 9 All of the time

13. How much of the time can you tell what your baby needs?

Hardly ever 1 2 3 4 5 6 7 8 9 All of the time

14. How much does the baby see like a person with his/ her own personality to you?

Very little of the time 1 2 3 4 5 6 7 8 9 All of the time
15. How much is the baby’s physical health on your mind?

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<tr>
<td></td>
<td>Very little</td>
<td>All of the time</td>
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16. How easy would it be for you to leave the baby with your spouse/partner when you go out?

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<tr>
<td></td>
<td>Not easy at all</td>
<td>Very easy</td>
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___ Not applicable

17. How well do you think that you know your baby?

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<tbody>
<tr>
<td></td>
<td>Hardly at all</td>
<td>Very well</td>
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18. How well are you meeting your expectations for yourself as a parent of a new baby?

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<tr>
<td></td>
<td>Not at all</td>
<td>Completely</td>
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19. How much has the baby’s growth and development been a source of satisfaction for you?

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<tbody>
<tr>
<td></td>
<td>Not at all</td>
<td>A great deal</td>
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</table>

20. How in tune with your baby do you feel? (How much do you feel like you and your baby are in harmony with each other?)

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<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not at all in tune</td>
<td>Completely in tune</td>
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</table>

21. How much has your life with members of your family changed?

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<tr>
<th></th>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hardly at all</td>
<td>A great deal</td>
<td></td>
<td></td>
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</table>
22. How easy would it be for you to leave the baby with someone other than your spouse/partner when you go out?

<table>
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<tr>
<th>1</th>
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<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not easy at all</td>
<td>Very easy</td>
<td></td>
<td></td>
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</tbody>
</table>

23. How satisfied are you with the way you relate to your baby and your baby’s needs?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all satisfied</td>
<td>Completely satisfied</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

24. How much do you feel that having a baby affects what you do and when?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
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<th>5</th>
<th>6</th>
<th>7</th>
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<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>A great deal</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

25. How much does the baby or the baby’s care come first in your thoughts, taking precedence over things you would otherwise spend time thinking about?

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
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<th>7</th>
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<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>A great deal</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

26. Please use this space to write anything that you think is important to help us understand what being the parent of a baby is like for you?
8.7 Care Index scoring sheet
Maternal Sensitivity: 
Maternal Control: 
Maternal unresponsiveness: 

Infant Co-operation: 
Infant Compulsiveness: 
Infant difficult behaviour: 
Infant passivity: 

Overall Synchrony Score: 

### Instructions

This questionnaire will help us to evaluate and continually improve the programme we offer. We are interested in your *honest opinions* about the services you have received, whether they are positive or negative. Please answer all the questions.

*Please circle the response that best describes how you honestly feel.*

| 1. How would you rate the quality of the service you and your child received? |
|---|---|---|---|---|---|
| Excellent | Good | Fair | Poor |
| 7 | 5 | 3 | 2 | 1 |

| 2. Did you receive the type of help you wanted from the programme? |
|---|---|---|---|---|
| No definitely not | No not really | Yes generally | Yes definitely |
| 1 | 3 | 5 | 7 |

| 3. To what extent has the programme met your child’s needs? |
|---|---|---|---|---|
| Almost all needs have been met | Most needs have been met | Only a few needs have been met | No needs have been met |
| 7 | 5 | 3 | 1 |

| 4. To what extent has the programme met your needs? |
|---|---|---|---|---|
| Almost all needs have been met | Most needs have been met | Only a few needs have been met | No needs have been met |
| 7 | 5 | 3 | 1 |

| 5. How satisfied were you with the amount of help you and your child received? |
|---|---|---|---|---|
| Quite dissatisfied | Dissatisfied | Satisfied | Very satisfied |
| 1 | 3 | 5 | 7 |

| 6. Has the programme helped you to deal more effectively with your child’s behaviour? |
|---|---|---|---|---|
| Yes, it has helped a great deal | Yes, it has helped somewhat | No, it hasn’t helped very much | No, it has made things worse |
| 7 | 5 | 3 | 1 |
| 7. Has the programme, helped you to deal more effectively with problems that arise in your family? |
|---|---|---|---|---|---|---|
| Yes, it has helped a great deal | 6 | Yes, it has helped somewhat | 5 | No, it hasn’t helped very much | 4 | No, it has made things worse | 2 | 1 |

| 8. Do you think your relationship with your partner has been improved by the programme? |
|---|---|---|---|---|---|---|---|
| No definitely not | 1 | 2 | 3 | No not really | 4 | 5 | Yes generally | 6 | 7 |

| 9. In an overall sense, how satisfied are you with the programme you and your child received? |
|---|---|---|---|---|---|---|
| Very satisfied | 7 | Satisfied | 6 | Dissatisfied | 4 | 2 | 1 |

| 10. If you were to seek help again, would you come back to Triple P? |
|---|---|---|---|---|---|---|---|
| No, definitely not | 1 | 2 | 3 | No, I don’t think so | 4 | 5 | Yes, I think so | 6 | 7 |

| 11. Has the programme helped you to develop skills that can be applied to other family members? |
|---|---|---|---|---|---|---|---|
| No, definitely not | 1 | 2 | 3 | No, I don’t think so | 4 | 5 | Yes, I think so | 6 | 7 |

| 12. In your opinion, how is your child’s development at this point? |
|---|---|---|---|---|---|---|---|
| Considerably worse | 1 | 2 | 3 | Slightly worse | 4 | The same | 5 | Improved |

| 13. How would you describe your feelings at this point about your child’s progress? |
|---|---|---|---|---|---|---|
| Very satisfied | 7 | Satisfied | 6 | Slightly satisfied | 5 | Neutral | 4 | Slightly dissatisfied | 3 | Dissatisfied | 2 | Very dissatisfied | 1 |
14. Since beginning this programme, have you sought further assistance for your child’s behaviour or for your family from any other source? If so, please describe?

________________________________________________________________________

________________________________________________________________________


15. Have you had any other problems with your child which you feel may be related to the original difficulty?

________________________________________________________________________

________________________________________________________________________


16. Do you have any other comments about this programme?

________________________________________________________________________

________________________________________________________________________


8.9 Participant Information Sheet (BPBS-b)

Version 4- 21/10/2011

Understanding Parenting Beliefs of Parents with Babies

We would like to invite you to take part in our research study. This study is being undertaken for a doctoral award. Before you decide we would like you to understand why the research is being done and what it would involve for you. You are very welcome to talk to others about the study if you wish. Please ask if there is anything that is not clear or you would like more information.

Who will conduct the research
This research will be conducted by Zoe Tsivos.

What is the study about?
This is a research study looking at attitudes new mothers have about parenting.

Why have I been asked to take part?
You have been asked to take part because you have had a baby in the past 12 months.

If I decide to take part, what will I have to do?
If you choose to take part in this study, we will ask you to complete a consent form. You will then be given three questionnaires to complete. Ten weeks later, you will complete one of these questionnaires again. The questionnaires will take between five to ten minutes to complete.

What will happen if I do not take part?
Participation in this research is completely voluntary. You do not have to take part. If you wish to withdraw from the study at any point just tell the researcher that you do not wish to continue. We will destroy identifiable information but we will continue to use the data collected up to your withdrawal. Your decision to withdraw from the study will not affect the care that you or your baby receives.

Will I be paid for participating in the research?
Unfortunately, we will not be able to pay you for your participation. You will be entered into a draw to win a high street voucher worth £25.

How will the results be used?
We will use the results from this study to develop a tool for looking at mothers’ beliefs about parenting when they have had a baby. We will also compare the results from this study with another study involving women who experience low mood after they have had a baby.
What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact the research practice coordinator, Lynne Macrae, Faculty of Medical and Human Sciences, University of Manchester, Room 3.53, Simon Building, Brunswick Street, Manchester, M13 9PL, tel: 0161 275 5436, email: lynne.macrae@manchester.ac.uk.

Harm
In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against The University of Manchester but you may have to pay your legal costs. Any payment would be without legal commitment. (Please ask if you wish more information on this). The University would not be bound to pay the compensation where the injury resulted from a drug or procedure outside the trial protocol or the protocol was not followed.

What will happen to the information I supply?
The answers you give will be anonymous. All data will be stored in a locked filing cabinet or secure servers, accessed only by the researcher, and authorised persons to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a participant. Your personal contact details will be retained so we can contact you to complete the questionnaire at the second time point, ten weeks later and if you decide you want to see the findings from the study. Your personal contact details will be stored separately from your other answers, also in locked storage or secure server.

What will happen when the study is complete?
You will be involved in the study at two time points with nine weeks in between. The study will take up to 2 years to complete. Once all the data has been collected and analysed, the results will be written up in a report, which will be sent to academic journals to be published, and the findings will be presented at conferences. A summary report of the findings will also be written for the participants of the study. If you decide you would like a copy of this summary, you will receive it when the study has finished.

Who is funding this research?
The research is being funded by the Medical and Human Sciences Faculty at the University of Manchester and the Medical Research Council (MRC).

Who has reviewed the study?
This study has been reviewed by an independent group of people known as an ethics committee. The ethics committee that reviewed this study was the University of Manchester Research Ethics Committee. The Committee gave this study favourable opinion on 29/09/2011, the reference is 11185.

What do I do now?
Once you have had time to read this information, the researcher will ask you whether you wish to take part or not. If you have decided not to take part, then we would like to thank you for taking the time to read this information. If you have decided that you would like to take part, the researcher will give you an opportunity to ask any questions that you may have. You will be asked to sign a form confirming that you consent for your questionnaire responses to be used in the study. You will then be given three questionnaires to complete, please return these together with the reply slip in the envelope provided.
Thank you for taking the time to read this information sheet. Please contact us if you are interested in participating or would like further information.

Miss Zoe Tsivos  
PhD Clinical Psychology Candidate  
(Principal Investigator)  
The University of Manchester  
Division of Clinical Psychology  
2nd Floor Zochonis Building  
Brunswick Street  
Manchester M13 9PL  
Email: Zoe-lydia.tsivos@postgrad.manchester.ac.uk  
Tel. 0161 306 0419  
Mobile 0790 213 2964  
Fax. 0161 306 0406

Dr Anja Wittkowski  
Lecturer in Clinical Psychology  
The University of Manchester  
Division of Clinical Psychology  
2nd Floor Zochonis Building  
Brunswick Street  
Manchester M13 9PL  
Tel. 0161 306 0400  
Fax. 0161 306 0406
We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. You are very welcome to talk to others about the study if you wish.

**What is the study about?**

While usual treatment has been found to be helpful for women experiencing postnatal depression, there has been little focus on parenting for women coping with postnatal depression. This is a research study looking at whether a new type of parental support, *Baby Triple P Positive Parenting Programme (Baby TP)*, in addition to usual treatment can help new mothers who experience mild to moderate depression after they have given birth to their baby. We are interested to see if taking part in this new programme helps mothers feel better and improves the relationship between mums and their babies. We are also interested to see if improvements carry on over time.

**Why have I been asked to take part?**

You have been asked to take part because you have had a baby in the past 12 months and you have described that you may have been feeling low recently.

**What will happen if I do not take part?**

Participation in this research is completely voluntary. You do not have to take part. If you wish to withdraw from the study at any point just tell the researcher that you do not wish to continue. We will destroy identifiable information but we will continue to use the data collected up to your withdrawal. Your decision to withdraw from the study will not affect the care that you or your baby receives.

**If I decide to take part, what will I have to do?**

If you choose to take part in this study, we will ask you to complete a consent form. We will then arrange a telephone and follow-up appointment with you to ask some questions about how you have been feeling and further details about yourself. This is to find out whether *Baby TP* may be useful for you. We will also ask you for your contact details to arrange the next appointment.
You will then be given some questionnaires to complete. We will also ask you to interact with your baby for 3 to 5 minutes (which we wish to videotape). You will be randomly allocated to either the Baby TP group or the Monitoring group. Due to the nature of the design of the study you will not be able to decide which group you will join. If you are allocated to the Baby TP group you will receive 8 individual therapy sessions (once a week, about 1 hour each) in your home by a trained and accredited Triple P practitioner. Some of these sessions may be audiotaped to make sure the practitioner is covering the same content with all the mothers in the study. You will also receive a Baby TP workbook which will be used alongside the sessions. You may also decide to continue to receive any other treatment normally offered by your service.

If you are allocated to the Monitoring group you will not receive the Baby TP sessions but may continue to receive the same treatment that would normally be offered by your service. You will also be visited by the researcher to complete some questionnaires and if you feel comfortable to do so, you may also talk about your experiences. At the end of the study you will receive the Triple P Every Parent’s self help work book, which offers suggestions and ideas on positive parenting to help you promote your child’s development and feel better prepared to face the challenges associated with being a parent.

After about 8 weeks after entering the study (when the Baby TP sessions have finished) we will ask you to complete some questionnaires and to videotape another five-minute-session with you and your baby. Finally, we will ask you to complete the same questionnaires and videotaping again three months later.

How will the results be used?

We hope to find that Baby TP is helpful in treating mothers with mild to moderate levels of postnatal depression and care for their baby. We hope that the results from this study will lead to better postnatal care for women, their babies and families.

What if there is a problem?

Complaints
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 2757583 or 0161 2758093 or by email to research-governance@manchester.ac.uk.

Harm
In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against The University of Manchester but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you. Any payment would be without legal commitment. (Please ask if you wish more information on this). The University would not be bound to pay this compensation where the injury resulted from a drug or procedure outside the trial protocol or the protocol was not followed.
What will happen to the information I supply?

The answers you give will be anonymous. However, in the event of risk of harm to yourself or your baby it will be necessary to breach confidentiality and inform your GP. All data will be stored in a locked filing cabinet accessed only by the researcher and authorised persons to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a participant. Your personal contact details will be stored separately from your other answers, also in locked storage.

The video footage taken during the assessments of you and your baby will also be securely stored in locked filing cabinets and will only be viewed by members of the research team. An external examiner will only look at the video footage to make sure that we are analyzing the video footage correctly. At the end of the study all the video tapes will be destroyed.

Involvement of the General Practitioner/Family Doctor (GP)

We will ask for your permission to notify your GP that you are participating in the research and ask if there is any reason why you should not participate.

What will happen when the study is complete?

You will be involved in the study for approximately 6 months and the study will take up to 2 years to complete. Once all the data has been collected and analysed, the results will be written up in a report which will be sent to academic journals to be published and the findings will be presented at conferences. A summary report of the findings will also be written for the participants of the study. If you decide you would like a copy of this summary, you will receive it when the study has finished.

Who is funding this research?

This research is being conducted for the purposes of obtaining a doctoral award and is being supervised by two experienced clinical psychologists. The research is being funded by the Medical and Human Sciences Faculty at the University of Manchester and the Medical Research Council (MRC).

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC), to protect your interests. This study has been reviewed by Northwest 6 Research Ethics Committee and was given a favourable opinion on 10/09/2010. The REC reference number is 10/H1003/73.

What do I do now?

Once you have had time to read this information, the researcher will ask you whether you wish to take part or not. If you have decided not to take part, then we would like to thank you for taking the time to read this information. If you have decided that you would like to take part, the researcher will give you an opportunity to ask any questions that you may have. You will be asked to sign a form confirming that you consent for your questionnaire
responses and video and audio tape to be used in the study. You will then be given the initial questionnaires to complete.

Thank you for taking the time to read this information sheet. Please contact us if you are interested in participating or would like further information.

Miss Zoe Tsivos  
PhD Clinical Psychology Candidate  
(Principal Investigator)  
The University of Manchester  
Division of Clinical Psychology  
2nd Floor Zochonis Building  
Brunswick Street  
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Tel. 0161 306 0419  
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Fax. 0161 306 0406

Dr Anja Wittkowski  
Lecturer in Clinical Psychology  
The University of Manchester  
Division of Clinical Psychology  
2nd Floor Zochonis Building  
Brunswick Street  
Manchester M13 9PL  
Tel. 0161 306 0400  
Fax. 0161 306 0406
Dear Dr [insert name]

I am writing to advise you that your patient, Ms [insert participant name] is participating in a doctoral research study. Baby Triple P Positive Parenting Programme (Baby TP) is being trialed for efficacy in the treatment of women with mild to moderate Postnatal Depression (PND) as part of a research project at The University of Manchester in the Division of Clinical and Health Psychology.

Baby TP is an 8-session individual parenting programme for new parents adapted from the Triple P Positive Parenting Programme, which is now widely evidenced and successfully used in 19 countries around the world. It was developed at the Parenting and Family Support Centre (PFSC) at the University of Queensland, Australia and draws on relevant and expert knowledge in parenting, child development and clinical psychology. Baby TP offers practical ideas and ongoing support to help new parents learn how to settle their baby, help their baby sleep, how to develop a positive relationship with their baby and how to look after themselves as well as after the relationship with their partner. Please visit http://www.psych-sci.manchester.ac.uk/pfrg/ for more details.

It is anticipated that women who receive this intervention will report improvements in mood, increases in happiness and confidence in caregiving as well as an improved relationship with their baby. This project has received ethical clearance from the University of Manchester and an NHS Research Ethics Committee.

Ms [insert participant name] has been invited to participate because she has reported mild to moderate PND symptoms and has expressed an interest in taking part. A SCID and clinical risk assessment have been completed and Ms [insert participant name] is eligible to take part in the research study and poses low risk of harm to self and others. Ms [insert participant name] has given consent for me to contact you in the unlikely event of increased risk to either herself or her baby.

Text will read as the following if client is randomized to Baby TP group [Ms [insert participant name] has been randomized to receive the Baby TP intervention]. Text will read as the following if client is randomized to TAU [Ms [insert participant name] has been randomized to the Treatment as Usual (TAU) group, she will participate in three assessment periods]. Ms [insert participant name] participation in this study should not affect any of the usual treatment she receives.

If there is any reason why Ms [insert participant name] should not participate in this study, please do not hesitate to contact me.

Yours Sincerely,

_________________________________________________________________

Zoe Tsivos
PhD Clinical Psychology Candidate
MSc Developmental Psychopathology
BSc (Hons) Psychology

Tel. 01613060419
Email. Zoe-lydia.tsivos@postgrad.manchester.ac.uk
Participant Identification Number for this trial:

8.12 Consent Form (BPBS-b)

Consent form (Version 2) 29/09/2011

Title of Project: Parenting Beliefs of Parents with Babies

Please Initial Box

1. I confirm that I have read and understood the information sheet dated 21/10/2011 (version 4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I give my permission for my data to be retained by the researcher and used confidentially in connection with the study if I withdraw.

4. I understand the reasons for disclosing my contact details, so that I can be contacted to complete a questionnaire 10 weeks after the first questionnaires and agree to this.

5. I would like to receive a summary of the findings from the study.

6. I agree to take part in the above study.

7. I understand that data collected during the study may be looked at by individuals from the University of Manchester, from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

Name of Participant  Date  Signature

Name of Person taking consent  Date  Signature
8.13 Consent Form (Baby Triple P)

Consent form (Version 1) 08/07/2010

Title of Project: An Evaluation of Baby Triple P Positive Parenting Programme

Please Initial Box

1. I confirm that I have read and understood the information sheet dated 24/08/2010 (version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I give my permission for my data to be retained by the researcher and used confidentially in connection with the study if I withdraw.

4. I give my permission for my GP to be informed of my participation in this study.

5. I understand the reasons for disclosing my contact details and agree to this.

6. I would like to receive a summary of the findings from the study.

7. I give my permission for my sessions to be recorded on audio tape.

8. I give my permission for three five-minute audiovisual recordings of my baby and me at home during a 3 minute play activity.

9. I give permission to be contacted about future studies

10. I agree to take part in the above study.

11. I understand that data collected during the study may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

Name of Participant Date Signature

Name of Person taking consent Date Signature
8.14 Baby Triple P Session Checklists 1-8
Standard Baby Triple P Session 1 Checklist

Use this as a guide and as a record of what you covered in the session. Indicate with a tick (✓) if the item was covered. Leave a blank if the item was omitted.

Client Number:……………. Date:…………..
Start time:………… Finish time:…………

Content Checklist
1. Positive Parenting
   - Welcome and self-introduction
   - Provide an overview of Baby Triple P
     o Explain research objectives

Baby Development and Behaviour
- Discuss general concerns about their baby’s development and/or behaviour (nature, context, intensity, onset, course, frequency, duration)
- Factors around birth?

Parent/s’ Expectations
- Discuss each parent’s expectations for the intervention process- additional topics they want to cover?
- Generic Feedback of Assessment Results

2. Agenda (outline proposed session goals and gain consent from the group)
   - What is positive parenting?
   - Creating a safe environment for babies
   - Promoting your baby’s development
   - Developing a positive relationship with your baby
   - Teaching infants new skills and behaviours
   - Session close

3. What is Positive Parenting?
   - Introduce 5 key aspects of positive parenting
   - Exercise 3: What is positive parenting

4. Creating a safe environment for babies
   - Introduced major causes of injury during infancy
   - Discussed what parents can do to create a safe environment for baby around the home

5. What influences babies’ development and behaviour?
   - Outline the purpose of discussing influences of babies’ development and behaviour
   - Introduce influences
   - Ask parent/s for any additional factors not listed

6. Goal setting
   - Exercise 4: Looking forward- reflecting back
   - setting goals for change (note the parent/s goals)
7. Developing a positive relationship with your baby
   • Introduce quality time
   • Introduce ways to communicate with your baby
   • Exercise 5: Things to talk about
   • Introduce baby’s signals (content, distressed, hungry, tired)
   • Exercise 6: Ways to show affection

8. Session close
   • Review main points covered in the session
   • Explain why the homework tasks are important
   • Explain homework tasks (review reading on infant development and how this
     knowledge may impact on parenting)
   • Outline the content of the next session and give a reminder of the day and time of
     the next group session

Session Notes

Additional Agenda Items (note any additional content or major deviation from the
set program)

Signed

Date completed:
Standard Baby Triple P Session 2 Checklist

Use this as a guide and as a record of what you covered in the session. Indicate with a tick (✓) if the item was covered. Leave a blank if the item was omitted.

Client Number:……………. Date:…………..
Start time:…………Finish time:…………

Content Checklist

1. Agenda (outline proposed session goals and gain consent from the parent/s)
   - Review of Session 3(1)
   - Review of homework
   - Responding to your baby
   - Applying strategies with a crying infant
   - Applying strategies to promote positive sleeping patterns
   - Homework tasks

2. Previous Session Review
   - Positive parenting (ensuring safe, engaging, loving environment; creating a positive learning environment; having realistic expectations; creating a predictable environment; taking care of yourself)
   - Promoting your baby’s development
   - Goal setting
   - Developing a positive relationship with your baby

3. Homework Review
   - Get feedback from couples about infant development reading and how this may impact on parenting
   - Promoting baby’s development exercise

4. Responding to your baby
   - Explain strategies for how to encourage contentment
   - Introduce settling techniques
   - Exercise 3: Settling techniques
   - Introduce diversion
   - Introduce establishing limits

5. Applying parenting strategies with a crying infant
   - About crying
   - why babies cry
   - how much babies cry
   - what to do if crying persists

6. Applying parenting strategies to promote positive sleeping habits
   - Introduce baby sleep and patterns
   - Introduce how much and where babies should sleep
   - Introduce safe sleeping tips
• Introduce strategies to promote good sleep patterns
• Introduce strategies for dealing with persistent sleep problems
• How to look after yourself

7. Session close
   • Review main points covered in the session
   • Explain homework tasks (developing a routine; fun activities in your area; sleep and settling checklist)
   • Outline the content of the next session and give a reminder of the day and time

Session Notes

Additional Agenda Items (note any additional content or major deviation from the set program)

Signed

Date completed:
Standard Baby Triple P Session 3 Checklist

Use this as a guide and as a record of what you covered in the session. Indicate with a tick (√) if the item was covered. Leave a blank if the item was omitted.

Client Number:……………. Date:…………..
Start time:…………..Finish time:…………

Content Checklist

1. Agenda (outline proposed session goals and gain consent from the parent/s)
   • Review of Session 4(2)
   • Review of homework
   • Challenges in transition to parenthood
   • Expectations about becoming a parent
   • Understanding unpleasant emotions
   • The effect of emotions on parenting
   • Coping strategies
   • Homework tasks

2. Previous Session Review
   • Teaching infants new skills and behaviours
   • Responding to your baby
   • Applying strategies with a crying infant
   • Applying strategies to promote positive sleeping patterns

3. Homework Review
   • Check how parent/s went with developing a routine; locating fun activities in their area; and using the sleep and settling checklist

4. Challenges
   • Introduce 6 common parent traps

5. Expectations about becoming a parent
   • Exercise 1: How is your life changing?
   • Acceptance
   • Common experiences of new parents

6. Understanding unpleasant emotions
   • Introduce basic emotions; stress, depression, anxiety and anger
   • Exercise 2: Recognising unpleasant emotions
7. How emotions affect parenting
   - Introduce how emotions work
   - Introduce how emotions affect parenting

8. Coping skills
   - Introduce coping skills
   - Catching unhelpful thoughts
   - Coping statements
   - Exercise 3: Developing your own coping statements
   - Introduce looking after yourself
   - Exercise 4: Ways to look after yourself
   - Introduce pleasant activities list
   - Abdominal breathing
   - Exercise 5: Practice abdominal breathing
   - Social support
   - Exercise 6: Developing a personal support list
   - Introduce personal coping plans and coping plan worksheet

9. Session Close
   - Review the main points covered in the session
   - Explain homework tasks (develop a personal coping plan for a stressful situation expected in the next few weeks)

Session Notes

Additional Agenda Items (note any additional content or major deviation from the set program)

Signed
Date completed
Standard Baby Triple P Session 4 Checklist

Use this as a guide and as a record of what you covered in the session. Indicate with a tick (✓) if the item was covered. Leave a blank if the item was omitted.

Client Number:…………….Date:…………..  
Start time:…………Finish time:…………

Content Checklist

1. Agenda (outline proposed session goals and gain consent from the group)  
   • Review of Session 5(3)  
   • Review of homework  
   • Relationship changes during transition to parenthood  
   • Communication skills  
   • Casual conversations  
   • Communicating about parenthood  
   • Maintaining relationship happiness  
   • Sharing tasks and chores  
   • Organizing telephone consultations  
   • Homework tasks

2. Previous Session Review  
   • Challenges in transition to parenthood  
   • Expectations about becoming a parent  
   • Understanding unpleasant emotions  
   • The effect of emotions on parenting  
   • Coping strategies

3. Homework Review  
   • Check how parents went with developing a personal coping plan for a stressful situation

4. Relationship changes during transition to parenthood  
   • Introduce 3 common partner traps  
   • Exercise 1: what changes for a couple when they have a baby?

5. Communication skills  
   • Introduce communication between partners  
   • Exercise 2: Identifying positive and negative communication habits  
   • Exercise 3: Setting goals for change in communication habits

6. Casual conversations  
   • Introduce casual conversations and guidelines  
   • Exercise 4: Practicing casual conversations

7. Communicating about parenthood  
   • Introduce communication rules for speaking to partner
8. Maintaining relationship happiness
   - Introduce positive actions for relationships
   - Exercise 5: Setting goals for relationship happiness

9. Deciding who does what
   - Introduce division of tasks and chores
   - Steps for planning division of tasks and chores
   - Family jobs list
   - Baby task list
   - Common problems

10. Organizing telephone consultations
    - Introduce telephone consultations
    - Exercise 7: Choosing a time for telephone consultation

11. Session Close
    - Review the main points covered in the session
    - Explain homework tasks (practice communication habits; decide how to share tasks and responsibilities using Family Jobs List)
    - Discuss parents’ reactions to the group sessions and remind them to be available and prepared for the first telephone session

Session Notes

Additional Agenda Items (note any additional content or major deviation from the set program)

Signed:                      Date completed:
Standard Baby Triple P Session 5 Checklist (PRACTICE SESSION)

Use this as a guide and as a record of what you covered in the session. Indicate with a tick (√) if the item was covered. Leave a blank if the item was omitted.

Client Number: ……………………………… Date:…………………….

Start time:……………………….Finish time:…………………………

Content Checklist

1. Agenda
   - Setting the agenda (Negotiate the session goals with the parent/s)
   - Previous session review
   - Practice task
   - Self-evaluation, feedback and goal setting
   - Review of homework
   - Additional agenda items

2. Previous Session Review
   - Prompt the parent to recall the topic areas discussed in the previous sessions (Parenting strategies, coping skills and partner support skills)

3. Practice Task
   - Review the parent/s goals for the practice task as listed in Exercise 1: setting the agenda
   - Check how the parent/s feel
   - Prompt the parent/s to complete Exercise 2: Keeping track of what you do, as part of the practice task
   - Begin the practice task (on a Practice Session Observation Form, keep a tally and note examples of descriptive and general praise comments)

4. Feedback
   - Set up to conduct a self-evaluation and feedback
   - Exercise 2: reviewing your use of positive parenting strategies (use minimal amount of prompting to help the parent/s identify their strengths and weaknesses, shape the parent/s skills as appropriate)

5. Goal Setting
   - Set goals for change (prompt the parent/s to set specific goals for practice before and during the next session)

6. Set Homework
   - Discuss homework tasks (write down practice tasks for coming week)

7. Additional Agenda Items
   - Discuss any additional agenda items
• Use minimal prompts to help the parent/s to solve problems
• Note any additional content or major deviation from the set program

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

8. Session Close

• Review the session
• Check homework tasks
  o Practice skills as per goals set in this session
  o Reading
  o Monitor the target baby behaviour/s
  o Prepare for the next practice session (set goals for the practice task and record them in set homework section pg 95 of parent workbook)

• Schedule the next appointment
• Close the session (thank the parent/s for participating)

Session Notes

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

Homework Tasks

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

_________________________________________________________________________

Signed ___________________________ Date completed ___________________________
Standard Baby Triple P Session 6 Checklist (PRACTICE SESSION)

Use this as a guide and as a record of what you covered in the session. Indicate with a tick (√) if the item was covered. Leave a blank if the item was omitted.

Family’s Name: ………………………………

Date:……………………. Start time:……………………….Finish time:……………………………

**Content Checklist**

1. **Exercise 1: Setting the agenda**
   - √ (ask the parent what issues they would like to discuss)

   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________

2. **Exercise 2: Update on Progress**
   - √ Ask the parent to list their practice tasks:

   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________

   - Ask what worked (at least two positive points):

   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________

   - Ask what they could have done differently:
3. Other Issues
   - Discuss any other issues that the parent wants to cover (use minimal prompts to help the parent solve any problems):

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

4. Session Close
   - Prompt the parent to review the main points covered in the session which they are to follow up on:

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

   - Prompt the parent to set and note down their practice tasks for the week:

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

   - Prompt the parent to list any material they feel they need to review:

   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

Signed                                      Date completed
Standard Baby Triple P Session 7 Checklist (PRACTICE SESSION)

Use this as a guide and as a record of what you covered in the session. Indicate with a tick (✓) if the item was covered. Leave a blank if the item was omitted.

Family’s Name: ………………………………

Date:……………………. Start time:……………………….Finish time:…………………………

Content Checklist

1. Exercise 1: Setting the agenda
   □
   (ask the parent what issues they would like to discuss)

   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________

2. Exercise 2: Update on Progress
   □
   • Ask the parent to list their practice tasks:

   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________

   • Ask what worked (at least two positive points):

   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________
   ___________________________________________________________________________

   • Ask what they could have done differently:
3. Other Issues
   - Discuss any other issues that the parent wants to cover (use minimal prompts to help the parent solve any problems):

   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________

4. Session Close
   - Prompt the parent to review the main points covered in the session which they are to follow up on:

   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________

   - Prompt the parent to set and note down their practice tasks for the week:

   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________

   - Prompt the parent to list any material they feel they need to review:

   __________________________________________________________________________
   __________________________________________________________________________
   __________________________________________________________________________

Signed                        Date completed
Standard Baby Triple P Session 8 Checklist (PRACTICE AND ASSESSMENT SESSION)

Use this as a guide and as a record of what you covered in the session. Indicate with a tick (✓) if the item was covered. Leave a blank if the item was omitted.

Client Number: ……………………………… Date:…………………………

Start time:……………………….Finish time:…………………………

Content Checklist

1. Exercise 1: Setting the agenda

   (ask the parent what issues they would like to discuss)

   ________________________________________________________________
   ________________________________________________________________
   ________________________________________________________________
   ________________________________________________________________
   ________________________________________________________________

2. Exercise 2: Update on Progress

   • Ask the parent to list their practice tasks:

     ________________________________________________________________
     ________________________________________________________________
     ________________________________________________________________
     ________________________________________________________________
     ________________________________________________________________

   • Ask what worked (at least two positive points):  

     ________________________________________________________________
     ________________________________________________________________
     ________________________________________________________________
     ________________________________________________________________
     ________________________________________________________________

   • Ask what they could have done differently:

     ________________________________________________________________
     ________________________________________________________________
     ________________________________________________________________
3. Other Issues
   - Discuss any other issues that the parent wants to cover (use minimal prompts to help the parent solve any problems):

4. Phasing Out the Program
   - Review suggestions for phasing out the program

5. Progress Review
   - Exercise 3: Reviewing progress
     Prompt parents to refer to goals they set in exercise 4, Session 1 on page 13 of the workbook.

     Prompt parents to identify aspects that are going well:

     Prompt parents to identify aspects they would like to work on:

6. Keeping up the good changes
   - Discuss obstacles to maintaining changes
   - Review ideas for keeping up the good changes
   - Exercise 4: Identifying high-risk times

7. Session Close
Exercise 5: Discuss completing assessment two (advise parents they will receive assessment booklet two in the mail or they can do it online)
• Congratulate and thank the parents for participating in Group Baby Triple P

Signed

Date completed
8.15 Ethics approval Baby Triple P Pilot

Dear Miss Tsivos

Study Title: An evaluation of the Baby Triple P Positive Parenting Programme in women with Postnatal Depression (PND)

REC reference number: 10H1003/73

Thank you for your letter of 06 September 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study:

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

This Research Ethics Committee is an advisory committee to North West Strategic Health Authority.

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England.
For NHS research sites only, management permission for research (“R&D approval”) should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator CV</td>
<td>1</td>
<td>08 July 2010</td>
</tr>
<tr>
<td>Protocol</td>
<td>1</td>
<td>08 July 2010</td>
</tr>
<tr>
<td>Telephone Screening Form</td>
<td>1</td>
<td>26 August 2010</td>
</tr>
<tr>
<td>REC application</td>
<td>3.0</td>
<td>08 July 2010</td>
</tr>
<tr>
<td>Questionnaire: Edinburgh Postnatal Depression Scale (EPDS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Questionnaire: Baby Behaviour Inventory (BBI)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advertisement</td>
<td>Poster -1</td>
<td>06 July 2010</td>
</tr>
<tr>
<td>Advertisement</td>
<td>2</td>
<td>31 August 2010</td>
</tr>
<tr>
<td>GP/Consultant Information Sheets</td>
<td>2</td>
<td>24 August 2010</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>2</td>
<td>24 August 2010</td>
</tr>
<tr>
<td>Response to Request for Further Information</td>
<td></td>
<td>06 September 2010</td>
</tr>
<tr>
<td>Participant Consent Form</td>
<td>1</td>
<td>08 July 2010</td>
</tr>
<tr>
<td>Questionnaire: Family Background Questionnaire (FBQ)</td>
<td>1</td>
<td>26 August 2010</td>
</tr>
<tr>
<td>Questionnaire: What being the parent of a baby is like (WPL)</td>
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<td></td>
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<tr>
<td>Questionnaire: Beck Depression Inventory II (BDI)</td>
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<tr>
<td>Questionnaire: Parent Beliefs Scale (PBS)</td>
<td>1</td>
<td>26 August 2010</td>
</tr>
<tr>
<td>Questionnaire: Oxford Happiness Inventory (OHI)</td>
<td></td>
<td></td>
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<tr>
<td>Questionnaire: Client Satisfaction Questionnaire (CSQ)</td>
<td></td>
<td></td>
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<tr>
<td>Questionnaire: Post Bonding Questionnaire (PBQ)</td>
<td></td>
<td></td>
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<tr>
<td>Questionnaire: Outcome Questionnaire (OQ-30)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information leaflet</td>
<td>1</td>
<td>08 July 2010</td>
</tr>
<tr>
<td>Recording Form Postnatal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Newsletter Article</td>
<td>1</td>
<td>31 August 2010</td>
</tr>
<tr>
<td>Website Advert</td>
<td>1</td>
<td>31 August 2010</td>
</tr>
<tr>
<td>Evidence of insurance or indemnity</td>
<td></td>
<td>09 July 2010</td>
</tr>
<tr>
<td>Letter from Statistician</td>
<td>1</td>
<td>14 January 2009</td>
</tr>
<tr>
<td>Referees or other scientific critique report</td>
<td>1</td>
<td>14 May 2010</td>
</tr>
</tbody>
</table>
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2000) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H1063/73 Please quote this number on all correspondence

Yours sincerely

Dr Ann Wakefield
Chair
Email: elaine.hutchings@northwest.nhs.uk

Enclosures: “After ethical review – guidance for researchers”

Copy to: Mr Mohammed Zubair, R&D University of Manchester
8.16 Ethics approval brief Parenting Beliefs Scale- baby version (BPBS-b)

Miss Zoe-Lydia Tsivos  
Clinical Psychology  
School of Psychological Sciences  
Faculty of Medical and Human Sciences  
Zoe-lydia.tsivos@postgrad.manchester.ac.uk

ref: ethics/11185

29 September 2011

Dear Miss Tsivos  

Research Ethics Committee 1  
Tsivos, Wittkowski: Validation of the Parenting beliefs Scale for Parents with Babies (PBS-B) in a sample of Non-Depressed Mothers. (Ref 11185)

I write to confirm that, at its meeting on 15th September 2011, the Committee reviewed the above research project, and gave it a provisional favourable ethical opinion. Before ethical approval can be granted, the Committee requires that your application is revised to address / clarify the following points:

Participant Information Sheet (PIS)

There needs to be clarification in the PIS as to why participants’ addresses need to be retained.

The PIS needs to have the same information as the consent form that the data will be measured over 2 time points.

A section needs to be added to the PIS for the participant to fill in their address / contact details; maybe create a reply slip.
Please revise the documents based on the above points, highlighting any changes from the original version, and send the revised documents to me by e-mail (katy.boyle@manchester.ac.uk) for consideration by the Chair outside of a Committee meeting.

This provisional approval is effective for a period of five years and, if the project continues beyond that period, it must be submitted for review. It is the Committee’s practice to warn investigators that they should not depart from the agreed protocol without seeking the approval of the Committee, as any significant deviation could invalidate the insurance arrangements and constitute research misconduct. We also ask that any information sheet should carry a University logo or other indication of where it came from, and that, in accordance with University policy, any data carrying personal identifiers must be encrypted when not held on a university computer or kept as a hard copy in a location which is accessible only to those involved with the research.

Yours sincerely,
Katy Boyle
Secretary to University Research Ethics Committee
8.17 Post-hoc power calculation


The study was completed by 27 participants in total, 13 in group TAU and 14 in group Baby TP. The BDI data were analysed using an ANCOVA model of Log(n) BDI at Time 2 with factor group and covariate Log(n) BDI at Time 1. The observed adjusted means for Log(n) BDI at Time 2 were 2.703 for TAU and 2.453 for Baby TP (geometric means 14.92 and 11.62 respectively). The common Log(n) standard deviation was estimated as 0.968 from descriptive summary statistics.

The following power calculations are based on comparing two groups using a simple Student’s t-test at the conventional two-sided 5% significance level. The observed Log(n) adjusted means (2.703 and 2.453) and estimated common standard deviation (0.968) were used in the post-hoc power calculations.

<table>
<thead>
<tr>
<th>n per group</th>
<th>237</th>
<th>13</th>
<th>14</th>
<th>13</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power ( % )</td>
<td>80</td>
<td>9</td>
<td>10</td>
<td>80</td>
<td>80</td>
</tr>
<tr>
<td>Effect size, ( d = \frac{</td>
<td>m_1 - m_2</td>
<td>}{s} )</td>
<td>0.258</td>
<td>0.258</td>
<td>0.258</td>
</tr>
<tr>
<td>Difference in Log(n) means, ( m_1 - m_2 )</td>
<td>0.250</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common Log(n) standard deviation, ( s )</td>
<td>0.968</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1 Log(n) mean, ( m_1 )</td>
<td>2.703</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 2 Log(n) mean, ( m_2 )</td>
<td>2.453</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The observed results of effect size 0.258 with 13 participants in each group have 9% power to detect a difference between the groups.

With 237 participants in each intervention group, the study would have 80% power to detect an effect size of 0.258 between the groups.

With 13 participants in each group, the study has 80% power to detect an effect size of 1.145 between groups.

---

*The power calculation was completed by Whiteside, S. (2012). Retrospective power calculation for Baby Triple P pilot. University Hospital of South Manchester.*
8.18 Information on Postnatal Depression

Postnatal Depression affects between 10 and 13% of new mums. Not all women have the same experience. Some mums have described low mood, lack of motivation, irritability, uneasiness, confusion, forgetfulness, fatigue, insomnia, anxiety and/or guilt. Depression can make parenting difficult and affect your relationships with others. If you are concerned about your mood you should contact your General Practitioner, health visitor or midwife. There are also a range of useful support and information services:

- CALM (5pm – 3am every day) 0800 585858
- Samaritans (24 hours every day) 0845 7909090
- MIND Information Line 0161 272 8205
- Crisisline (8pm – 12 midnight every day) 0808 8082007
- 42nd Street 0161 832 0170
- Hearing Voices Network Helpline 0616 8343033
- NHS Direct (24 hours every day) 0845 4647

For a range of self help groups and services, contact Self Help Services, The Big Life Company on 0161 226 5412

Useful information on Postnatal Depression:

National Women’s Health Information Centre: [www.4women.gov](http://www.4women.gov)

http://www.nhs.uk/conditions/Postnataldepression/Pages/Introduction.aspx

Support groups:

Depression after Delivery: [www.depressionafterdelivery.com](http://www.depressionafterdelivery.com)
### 8.19 Open CSQ responses (Baby Triple P)

<table>
<thead>
<tr>
<th>PP</th>
<th>CSQ_14</th>
<th>CSQ_15</th>
<th>CSQ_16</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>No</td>
<td>No</td>
<td>I found the programme easy to follow, very practical, easy to implement</td>
</tr>
<tr>
<td>b</td>
<td>Lost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c</td>
<td>No</td>
<td>DNA</td>
<td>DNA</td>
</tr>
<tr>
<td>d</td>
<td>DNA</td>
<td>DNA</td>
<td>This programme should be more known as it is a brilliant programme and really helps</td>
</tr>
<tr>
<td>e</td>
<td>DNA</td>
<td>DNA</td>
<td>This programme is very helpful</td>
</tr>
<tr>
<td>f</td>
<td>No</td>
<td>No</td>
<td>Great help</td>
</tr>
<tr>
<td>g</td>
<td>No just GP and mental health services</td>
<td>No</td>
<td>Think it should be given to all parents by hospital</td>
</tr>
<tr>
<td>h</td>
<td>Yes- I have started to accept help from family members</td>
<td>No</td>
<td>I found it very helpful in helping me realise that some of the issues I have are actually very common and its not just me</td>
</tr>
<tr>
<td>i</td>
<td>1 CBT session</td>
<td>No</td>
<td>I am so pleased with the results! I have been given the guidance I needed.</td>
</tr>
<tr>
<td>j</td>
<td>No</td>
<td>No</td>
<td>Brilliant, learnt a lot</td>
</tr>
<tr>
<td>k</td>
<td>No</td>
<td>Colic</td>
<td>It’s brilliant! It has really helped me find ways to cope with difficult situations</td>
</tr>
<tr>
<td>l</td>
<td>Lost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>m</td>
<td>Lost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>CAPS</td>
<td>No</td>
<td>I really felt it dealt with issues that were relevant to me and also could be tailored to my needs. It really helped me to be a better parent and be more confident in my abilities. I am really happy I received this support and not sure if I would have coped without it.</td>
</tr>
</tbody>
</table>

PP= participant, CSQ= Client Satisfaction Questionnaire
8.20 Individual (BDI-II) scores and Reliable Change Index (RCI)
(Jacobson & Truax, 1991)

<table>
<thead>
<tr>
<th>Participant</th>
<th>BDI-II Scores</th>
<th>Statistically and clinically significant change (RCI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Post-intervention</td>
</tr>
<tr>
<td>Baby TP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>18</td>
<td>16</td>
</tr>
<tr>
<td>2</td>
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<td>21</td>
<td>36</td>
<td>3</td>
</tr>
<tr>
<td>22</td>
<td>36</td>
<td>11</td>
</tr>
</tbody>
</table>

*RCI is clinically significant when RCI > 1.96